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The Committee’s Report drawing on this oral and written evidence is published as a separate volume, HL Paper 166-I.
Memorandum by the Department of Health

INTRODUCTION

1. The Government welcomes this opportunity to set out its position on allergy and allergic conditions.

2. This memorandum is structured in accordance with the particular questions asked in the Committee’s Call for Evidence. Although this inquiry will not focus primarily on allergy service provision, many of its questions were addressed in the recently completed review of services for allergy (“the DH review”) that was undertaken by the Department of Health (DH) following an inquiry (Report, November 2004) by the House of Commons Health Committee.

3. This memorandum therefore refers to—but does not repeat at length—the evidence presented in the report of the DH review, *A review of services for allergy—the epidemiology, demand for and provision of treatment and effectiveness of clinical interventions*, published in July 2006. Members of the Committee have had printed copies of this report. It is available on the DH website, along with supporting information on the epidemiology and on clinical interventions, at:


4. The memorandum includes contributions from:
   
   — the Health and Safety Executive (HSE) and the Department for Work and Pensions (DWP), covering work-related allergy and Industrial Injuries Disablement Benefit, attached as Annex A;
   
   — the Department for Education and Skills (DfES) on allergic diseases and schools—including a summary of medicines guidance to schools, attached as Annex B; and
   
   — the Department for Communities and Local Government (DCLG) on housing policy and regulations, attached as Annex C.

5. The key points made in Annex A are that:
   
   — work-related allergies have declined over the last 10 years;
   
   — HSE is working in partnership with key stakeholders to ensure this downward trend continues; and
   
   — there is a robust regulatory framework in place to tackle work-related allergies.

DEFINING THE PROBLEM

What is allergy?

6. Allergy can be defined as a hypersensitivity, a heightened or exaggerated immune response to some external stimulus or stimuli. Allergic processes contribute to a range of conditions—including asthma, rhinitis and eczema—many of which also occur in the absence of a specific allergy. Various allergic conditions often co-exist in the same individual. Also, some individual allergic disorders may cause symptoms in several organ systems simultaneously.
Allergy is very common. Around a third of the population have some form of allergy at some point in their lives. In England, about three million people each year are seen in primary care with conditions that may be allergic in origin.

What is the difference between allergy and intolerance?

Unlike allergy, intolerance (for example, food intolerance) does not involve the immune system. It is generally not life threatening. Around 20 per cent of adults have perceived food intolerance. The correct diagnosis of food intolerance generates a substantial workload for services.

What is and what is not known about the origins and progression of allergic disease?

Whilst a good deal is known about the mechanisms of allergic processes, the underlying causes of allergic conditions in individuals and populations are more difficult to understand. A variety of factors have been identified as possible causes or modifiers of allergic illness. These include genetic factors, early allergen exposure, maternal and infant feeding practices, viral infections, environmental tobacco smoke and other pollutants, pet contact, family size and rural living.

Allergies, once established, tend to be lifelong despite treatment, although some forms—such as egg and milk allergy in infants—do frequently resolve.

Why is the incidence of allergy and allergic diseases rising? Why does the UK in particular have such a high prevalence of allergy?

The DH review found good evidence that allergy has increased in the population in the last 30 years. However, for the last 10 years the picture is less clear—some studies suggest that it has not increased, and may even have fallen (for example, the latest ISAAC study data from the UK), whilst others show a continued rise in allergy symptoms.

The apparent changes in the prevalence of allergy over the last three decades cannot be reliably explained, and nor can the particularly high prevalence of allergic conditions in the UK and certain other developed countries. A number of theories have been considered, to do with changes in our environment as a consequence of increasing affluence and modern lifestyles. Possible influences include increased exposure to allergens or pollutants, dietary changes and a change in infectious triggers.

In 1995, DH’s Committee on the Medical Effects of Air Pollutants (COMEAP) published a major report on Asthma and Outdoor Air Pollution. It concluded that, with regard to the initiation of asthma (ie causing the disease in the first place), most of the available evidence did not support a causative role for outdoor air pollution. While it was accepted that exposure to air pollutants could produce a worsening of symptoms in those suffering from asthma, factors other than air pollution (diet and the role of infections, for instance) were more likely to have had more of an impact on the number of people suffering from asthma.

COMEAP is working on a new report, Does Air Pollution Cause Asthma?, to be published in 2008.

What gaps exist in establishing the overall disease burden for all types of allergy and what are the barriers to filling these gaps?

From secondary analyses of national databases, the direct cost to the NHS of managing allergic diseases has recently been estimated at over £1 billion per annum in the UK. Primary care prescribing costs are around £0.9 billion per annum, or 11 per cent of the total drugs budget.

There is a considerable body of data on the occurrence of allergic conditions in the population, although the distribution of research studies is heavily weighted towards asthma. There is much less information about the extent to which these conditions are caused by untreated allergy in the community, or about the distribution of severity and unmet need for specific services.

Furthermore, as the DH review concluded, the absence of baseline data on the profile of services and the cost makes it difficult to develop a strategic national view of how and where services could be developed. DH will consider what actions may need to be taken to support the NHS and others in developing baseline data on NHS services, capacity and costs, and workforce—including cost modelling, using evidence from a range of services in different settings.
In addition to the impact on the health service, what is the overall socio-economic impact of allergic diseases (for example, absence from work and schools)?

18. The DH review highlighted that the indirect and intangible costs of allergic diseases, such as school or workdays lost, lower productivity or diminished quality of life, are potentially huge. A survey in the late 1990s found that 38 per cent of children and 16 per cent of adults in the UK had lost school/work days due to their asthma in the past year. In 1994–95, it was estimated that 17 million work days were lost due to asthma, costing an estimated £1.1 billion. Studies have also reported the economic burden due to reduced productivity at work caused by allergic rhinitis to be greater than that resulting from the treatment of the condition and its symptoms.

19. Evidence on the socio-economic impact of work-related illness is given in the corresponding section of Annex A.

20. In general, it is not possible to say how many pupils do not attend school or miss exams because they are affected by allergies, because data on pupil absence is not routinely collected in this level of detail. From September 2006, schools will be asked to inform the Department for Education and Skills (DfES) of the reasons for pupil absence from school. Illness will be one category—but it would overburden schools to have to record for each absent pupil their individual type of illness.

21. Pupils who suffer from allergies may need to have medication whilst at school: a summary of the current guidance is at Annex B.

Treatment and Management

What is the effect of current treatments on the natural history of allergic disease?

22. The DH review report sets out what is known about the nature and the effectiveness of clinical interventions for allergy, drawing on professional input, including clinical guidelines which have been informed by research.

23. Making an allergy diagnosis is a key step in allergy management. An accurate diagnosis targets the appropriate clinical intervention and allows avoidance of the allergic trigger and amelioration or resolution of symptoms.

24. Allergy treatments in widespread use can be classified in four broad categories—symptom control, allergen avoidance, rescue medication and immunotherapy. Examples are given in the DH review report. New therapies are also in development.

What is the evidence-base for pharmacological and non-pharmacological management strategies?

25. A number of Royal Colleges and professional bodies have drawn up good practice guidelines for specific allergic conditions. However, there are no nationally agreed, evidence based clinical guidelines which address allergic conditions as a whole—nor nationally agreed clinical guidelines or protocols addressing how patients with less serious allergies can be treated in primary care.

26. As early steps to follow its review, DH will consider the options for commissioning the development by the National Institute for Health and Clinical Excellence (NICE) of guidelines for the diagnosis and management of allergic conditions, and work with the Royal Colleges and others on guidance for referral and care pathways.

27. To inform its review, DH commissioned an overview of systematic reviews of the research evidence on clinical interventions for allergy, focusing particularly on service delivery and organisation. This “review of reviews” also identified significant gaps in research knowledge. The full report was published on the DH website with the DH review report itself.

Is the level of UK research into allergy and allergic disease adequate?

28. There is no absolute way of determining whether a level of research spend is adequate. Ultimately, it is a value judgement by a range of research funders with differing remits. Such judgements will include consideration of disease burden, likely success of scientific endeavour, likely impact on health of affected population, capacity to address issues relevant to the UK and assessment against other competing priorities.
29. In May 2006, the UK Clinical Research Collaboration (UKCRC) published the first ever national analysis of spending on health research in the UK (UK Health Research Analysis). This analysis included most government and charity funding on all types of health research across all areas of health and disease during the year 2004–05.

30. Analysis was done by “high level” categories such as respiratory disease and cardiovascular disease. The UKCRC analysis shows that there appears to be an imbalance in research funding for respiratory disease against burden of disease. The majority of research on allergies has focused on asthma, and therefore probably falls within the respiratory disease category. However, it is not clear that the imbalance in spend against disease burden reflects the position for allergy-related respiratory disease (since much of respiratory disease burden is not allergic in origin); and it obviously provides no indicators about non-respiratory allergic research.

31. The main agency through which the government supports medical and clinical research is the Medical Research Council (MRC). Other research councils—the Biotechnology and Biological Sciences Research Council and the Economic and Social Research Council, for example—also support research of relevance to health and healthcare. The Councils’ umbrella body, Research Councils UK, is submitting a separate memorandum of evidence to the Committee.

32. DH funds research to support policy and the delivery of effective practice in the NHS through a number of national programmes. It also meets the service costs to the NHS of research funded by the research councils and charities and undertaken in research-active NHS organisations.

33. The new health research strategy, Best Research for Best Health, was launched in January 2006. It set out the Government’s goals for research and development in the NHS and demonstrated DH’s commitment to creating a vibrant research environment that will contribute to the health and wealth of our nation.

34. The key planks of the strategy are to:
   — establish the NHS as an internationally recognised centre of research excellence;
   — attract, develop and retain the best research professionals to conduct people-based research;
   — commission research focused on improving health and care;
   — strengthen and streamline systems for research management and governance; and
   — act as sound custodians of public money for public good.

35. Best Research for Best Health has a range of related objectives that require different approaches. We have developed implementation plans for sixteen of the major components for the new National Institute of Health Research (NIHR), through which we shall deliver many of the components of the strategy. Further details are available on the NIHR website (www.nihr.ac.uk), together with details of calls for proposals.

36. Some of the programmes of research being carried out by NHS organisations and that have allergy and allergic disease as a major component are shown in the following table.

<table>
<thead>
<tr>
<th>NHS organisation</th>
<th>Programme</th>
<th>R&amp;D allocation 2005–06 (£m)</th>
<th>External funding 2005–06 (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guy’s and St Thomas’ NHS Foundation Trust</td>
<td>Allergy and obstructive lung disease</td>
<td>0.6</td>
<td>2.6</td>
</tr>
<tr>
<td>King’s Consortium</td>
<td>Allergy and obstructive lung disease</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Royal Brompton and Harefield Hospitals NHS Trust</td>
<td>Management of severe respiratory disease: atopy, allergy and asthma</td>
<td>3.5</td>
<td>3.0</td>
</tr>
<tr>
<td>Southampton University Hospitals NHS Trust</td>
<td>Allergy and inflammation</td>
<td>1.2</td>
<td>1.8</td>
</tr>
<tr>
<td>South Manchester University Hospitals NHS Trust</td>
<td>Obstructive and parenchymal lung disease</td>
<td>0.6</td>
<td>1.2</td>
</tr>
</tbody>
</table>

37. The DH Policy Research Programme funds a programme of research at the Social Medicine and Health Services Research Unit, now based at Imperial College. Part of this programme focuses on the role of allergy in asthma. In addition, it has funded a £1 million initiative on the impact of air pollution on health, which is now drawing to a close.
38. Other national programmes (principally the Health Technology Assessment programme) have, over the last five years, allocated some £2.2 million to primary research and systematic reviews concerned with allergy.

39. The Food Standards Agency supports a programme of research on food allergy and intolerance. It is submitting a separate memorandum to the Committee.

40. Research on allergy is also supported through EC Research Framework Programmes. Proposals for the 7th Framework Programme (2007–13) make provision for research relating to allergy and allergic diseases in several areas of the Programme—including under “chronic diseases” within the Health theme, “food, health and wellbeing” within the Food, Agriculture and Biotechnology theme, and “environment and health” within the Environment theme.

41. Funding for research in allergy and allergic disease under the 6th Framework Programme (2002–06) includes 14.4 million euros (£9.7 million) for a Global Allergy and Asthma European Network and 14.1 million euros (£9.5 million) for a UK-led integrated project on the prevalence, cost and basis of food allergy across Europe.

42. The review of systematic reviews commissioned by DH for its review of services for allergy found that much current research deals with specific interventions, but fails to address questions around models and methods of service delivery. It suggested that more work might be required to investigate the role of specialists, and the linkage between specialist and generalist services. Such studies would need to collect basic demographic information. The review also highlighted the need for consistency in the standardisation of key measures in trials.

43. In all, the DH review highlighted a range of gaps in the research evidence—relating to epidemiology, diagnostics and interventions, service models and also basic science. The Department proposes to invite key research funders to note these gaps.

What are the most promising areas of research into preventing or treating allergy?

44. The Government is aware that new therapies are being developed that are aimed at modifying the underlying immunological processes that either cause or mediate clinical allergy. Examples include:

- anti-IgE therapy, which is presently licensed in the UK only for severe asthma, but could potentially be used in the management of other severe IgE (immunoglobulin E) mediated allergic problems;
- new types of immunotherapy, for example with recombinant allergens or peptides, are in development and clinical trials: for example, peptides have been used in a randomised controlled trial in cat allergy and recombinant allergens are being developed for use in peanut allergy;
- sublingual immunotherapy (SLIT) is a safe treatment significantly reducing symptoms and medication requirements in allergic rhinitis; further research is required concentrating on optimising allergen dosage and patient selection;
- vaccines are in development for a number of different allergic conditions; and
- other research on prevention is in progress, although this approach is not yet clinically validated or adopted in current allergy practice.

45. Extensive research on the mechanisms of allergy and therapeutics to combat allergic disease will provide an opportunity to find new strategies for establishing effective treatments. Continued research on the molecular mechanisms of allergic disease can be expected to generate new forms of therapy.

Government Policies

How effective have existing Government policy and advice been in addressing the rise in allergies?

46. The DH review identified good practice in the NHS, across the wide range of services available for people with allergies, and the spectrum of skills and competences of clinicians involved in their care. However, it has also revealed some gaps in the knowledge and skills of clinical staff dealing with allergy (especially in diagnosis), in systematic planning and commissioning of services for allergy, in baseline data on NHS services for allergy, relevant service capacity and costs, and workforce, and in research.
47. The DH review report acknowledges that, although incomplete, the evidence is sufficient for recommendations to be made for action over the next few years in order to improve services for allergy. It identifies three areas in which initial action will be of key importance:

— local commissioners to establish levels of need for services for allergy in their health community;
— SHA workforce planners to work with Deans and providers to explore the scope for creating additional training places for allergists; and
— DH to consider the options for commissioning the development of NICE guidelines for allergy, and work with the Royal Colleges on guidance for referral and care pathways.

48. The key levers for change for NHS services for allergy in the future will, essentially, continue to be for local rather than national level action. In the light of local priorities, local health commissioners will need to consider—for allergy as for other services—how to include patient choice, high quality information for the public, increased investment in the Expert Patient Programme, practice based commissioning for services, joint commissioning between Primary Care Trusts and local authorities, introducing a wider range of providers, workforce modernisation, better clinical and management information and a focus on self care, in line with the White Paper Our health, our care, our say: a new direction for community services (January 2006).

49. Nevertheless, at national level, the DH review has been a catalyst in energising and bringing together a wide range of national and local interests in constructive debate on the future of services for allergy. The Government is committed to sustaining and building on that momentum.

50. The DH review report stresses that, in the context of current constraints in the NHS and the Department, any initiatives to support the NHS and others to generate and lever change in services for allergy will need to be incremental, phased in steps over a number of years. It will be essential for stakeholders—including patients, the NHS, Royal Colleges, the independent sector and voluntary organisations—to work together if this is to be achieved.

How is current knowledge about the causes and management of allergic disease shared within Government?

For example:

— Do housing policy and regulations governing the indoor environment pay enough attention to allergy?

51. A contribution from the Department for Communities and Local Government (DCLG) addressing this question is attached at Annex C.

— How effectively are food policy and food labelling regulations responding to the rise in food allergies?

52. The separate memorandum to the Committee from the Food Standards Agency will cover food policy and labelling.

53. The Committee may also wish to know that the Government has an air pollution information service, the “Air Quality Bulletin”, which provides free up-to-date information and forecasts on air quality in areas throughout the UK. It informs the public when pollution levels are high and advises accordingly.

54. The Department for Environment, Food and Rural Affairs (Defra) has published a leaflet, in partnership with DH, the Scottish Executive and the Department of Environment in Northern Ireland, entitled Air Pollution: what it means for your health; the public information service. It explains where to get up-to-date information on current levels of air pollution, what air pollution can mean for your health, and what you can do about it.

Patient and Consumer Issues

What impact do allergies have on the quality of life of those experiencing allergic disease and their families?

55. The DH review was informed by people with—and parents of children with—allergic conditions, both through individuals as members of the National Allergy Advisory Group or attending the stakeholder workshops, and through evidence submitted by patient representative organisations.
56. As the Parliamentary Under Secretary of State acknowledges in his foreword to the DH review report, “those living with severe allergy can face a huge battle every day, and their quality of life and that of their extended family may be greatly affected. In surveys, many people express feelings of constant stress and anxiety. Everyday areas of life may be affected, such as eating out as a family, school trips, schools meals and packed lunches, children’s parties and other social situations.”

57. The evidence is that people with allergies often feel let down by a poor and frequently unobtainable service. For those living with allergy severe enough to require specialist care, the lack of allergy services is a problem which can greatly affect their quality of life.

What can be done to better educate the public and to improve the quality of information that is available to patients and undiagnosed sufferers?

58. With high quality information and guidance, those affected by allergy can be empowered to manage the condition and protect themselves from harm, generally by learning to self-administer appropriate medication or to avoid those allergens which cause an allergic reaction. The DH review recognises the help that not-for-profit organisations give, through helplines and other information services, to fulfil an important need that is yet to be addressed by the NHS. DH has helped support these efforts through grants made under Section 64 of the Health and Public Services Act 1968.

59. The DH review highlighted the importance of general practitioners and others in primary care having sufficient clinical knowledge and support systems in order to spot allergy in the early stages, so that an effective management plan can be offered from the start, and patients are not referred unnecessarily to specialists for care of less severe allergic disease.

Are current regulatory arrangements, for example, those governing private clinics offering diagnostic and therapeutic services and the sale of over the counter allergy tests, satisfactory?

60. Private and voluntary healthcare providers are subject to regulation by the Healthcare Commission if they provide services set out in current legislation. Those services do not include over the counter allergy tests. However, providers registered with the Commission might offer allergy tests as part of a wider range of services.

61. DH will be consulting later in the year on the range of services, including diagnostic techniques, to be subject to regulation by the Healthcare Commission. There are no plans to extend the scope of regulation specifically to include over the counter allergy tests.

62. Allergy test kits can be regulated as either medicines or medical devices, depending on how they work. Those that place something on or under the skin to provoke a reaction act immunologically, and are regulated as medicinal products. There are currently no such test kits available over the counter in the UK. There are, however, products available on prescription and these tests are usually carried out in specialist clinics.

63. The safety, quality and performance of those tests which detect antibodies from blood or other human fluid samples in vitro are regulated under the Medical Devices Regulations 2002. Those in vitro diagnostic devices (IVD) intended to be supplied direct to the public have the self test element assessed by a third party certification organisation, known as a notified body, which has been designated by an EC member state on the basis of strict expertise criteria. Moreover, the instructions for use that the manufacturer is required to supply would be expected to warn of possible false results, and provide guidance on interpretation and that, if symptoms persist, the user should seek medical advice.

64. UK manufacturers of IVDs have to register with the Medicines and Healthcare products Regulatory Agency (MHRA). The Agency believes the current regulatory regime is appropriate to control those over the counter allergy test kits that are devices.

65. Other over the counter allergy tests, employing such techniques as hair analysis and electromagnetic field detection, which are not for a medical diagnostic purpose do not come within the scope of the Medical Devices Regulations. They would, however, be regulated as consumer products under the General Product Safety Regulations, which are enforced by local authority Trading Standards Departments.
Annex A

Work-related aspects—contribution from the Health and Safety Executive and the Department for Work and Pensions

INTRODUCTION

1. The tripartite Health and Safety Commission (HSC) has overall responsibility for policy on health and safety, and advises Ministers on relevant standards and regulations. The Chair and members of the Commission are appointed by the Secretary of State for Work and Pensions following consultation, advertisement and open competition. The Health and Safety Executive (HSE) advises and assists HSC and has a statutory responsibility to make adequate arrangements for the enforcement of the Health and Safety at Work Etc Act 1974 and other relevant statutory provisions in Great Britain.

DEFINING THE PROBLEM

What is allergy? What is the difference between allergy and intolerance?

2. Chemicals and biological agents used in or arising from work activities can cause the same allergic diseases, and by the same mechanisms, as those in the more general environment. The most commonly reported work-related allergic respiratory disease is occupational asthma, though rhinitis and extrinsic allergic alveolitis (EAA) are also important. By far the most common type of work-related skin allergy is allergic contact dermatitis. Anaphylaxis is a rare consequence of some workplace exposures.

3. High levels of substances irritant to the lung can cause persisting asthma and exposures to low levels of irritants at work can exacerbate pre-existing asthma, but these are not allergic reactions. Exposure to beryllium arising from work activities may cause a rare, specific and atypical allergic disease of the lungs called berylliosis.

What is and what is not known about the origins and progression of allergic disease?

4. Occupational asthma, rhinitis, EAA and occupational skin allergy arise because of abnormal sensitivity of the human immune system to specific substances. High molecular weight substances, such as laboratory animal proteins, enzymes in detergents or mouldy hay, may provoke the response directly. Low molecular weight substances, such as isocyanates probably combine with proteins in the body, and provoke the allergic reaction by altering human protein structure. Little is known about the relative contributions of different routes of exposure (ingestion, inhalation and/or penetration through the skin) to the development of allergy.

5. The main causes of occupational asthma are reviewed in HSE’s publication Asthmagens? Critical Assessments of the evidence for agents implicated in occupational asthma (http://www.hse.gov.uk/asthma/asthmagen.pdf). Lists of substances that commonly cause occupational asthma and rhinitis are included in the Regulations of the Industrial Injuries Scheme (http://www.iiac.org.uk/prescribed_diseases/index.asp).

6. Within groups of people exposed to respiratory allergens:
   — some will show no evidence of an allergic reaction;
   — some will show evidence in immunological tests of some immune reaction—they will be “sensitised”—but not have any symptoms;
   — some will be sensitised and have symptoms; and
   — some may have symptoms without objective evidence of sensitisation in immunological tests.

7. It is easier to demonstrate sensitisation to high molecular weight substances by laboratory tests than to those of low molecular weight.

8. Three general determinants have been identified for an increased risk of occupational asthma, and are likely to be relevant to rhinitis too. They are: atopy (in the case of high molecular weight allergens); smoking (low molecular weight allergens); and a particular genotype. There is good evidence that the risk of developing occupational asthma is directly related to the levels of exposure in the workplace, although there is insufficient data to define a level at which there is no risk. It is generally thought that clinical allergic reactions can be induced in sensitised individuals by much lower exposures than are required to initiate disease.
9. EAA is most often due to a work exposure. It is not associated with atopy, and less readily associated with specific genotypes. Smoking appears to reduce the risk.

10. Little is known about individual susceptibility to the development of skin allergy, except that allergic skin conditions (along with other allergic conditions such as asthma and hay fever) may run in families. A family history of asthma, hay fever or eczema (skin allergy) may predispose to childhood eczema—this is known as atopic dermatitis. An individual with atopic dermatitis may be more prone to skin allergy and skin irritation in later life.

11. Specific respiratory allergies persist once they have become established. There is evidence that longer exposure to occupational respiratory allergens, and the presence of more severe disease, before diagnosis is associated with a poorer prognosis (eg persisting symptoms after cessation of further exposure to the allergen in the case of asthma, development of irreversible fibrosis—scarring—of the lung in the case of EAA). Complete prevention of exposure to the causative agent does not necessarily lead to complete remission of symptoms, but improvement can continue over years afterwards. Where affected individuals reduce, but do not eliminate, further exposure they are more likely to have persisting symptoms, and worsening asthma over the longer term.

12. There is very little published information on clinical outcome in cases of workers who develop skin allergy related to exposures at work. HSE is jointly funding, with the British Occupational Health Research Foundation (BOHRF), a research project to identify prognostic factors for people diagnosed with work-related contact dermatitis. However, in general, once work-related skin allergy has developed, avoidance of exposure is necessary to control progression of the disease and prevent the reoccurrence of symptoms.

13. HSE’s approach, through the appropriate regulatory framework, is to prevent individuals from developing occupational allergic diseases by ensuring that employers use, where possible, a safer alternative or, if this is not possible, that workplace exposures are adequately controlled. Health surveillance in the workplace is also important so that early signs of allergic diseases can be identified and exposures controlled.

Why is the incidence of allergy and allergic diseases rising? Why does the UK in particular have such high prevalence of allergy?

14. Although the overall burden of occupational asthma and work-related allergic contact dermatitis in the UK is not known, a number of sources provide information on the possible scale and probable trends in the diseases.

15. The latest Survey of Self-reported Work-related Illness estimated that:
   — 137,000 people who had ever worked in 2004–05 had “breathing or lung problems” caused or made worse by work; and
   — 29,000 people who had ever worked in 2004–05 had “skin problems” caused or made worse by work.

16. Although these figures give an indication of the number of people currently suffering from occupational lung and skin problems (the disease prevalence), it is difficult to estimate what proportion are suffering from asthma or allergic contact dermatitis. Estimates of the proportion of asthma cases that are work-related from other studies (the challenge is to identify cases that are primarily due to work activities in any common disease having both work and non-work-related causes) vary between 2 per cent and 15 per cent.

17. An indication of the number of new cases of occupational asthma and contact dermatitis (including allergic contact dermatitis) occurring each year (the disease incidence) can be obtained from the reports of cases from physicians who participate in the respective voluntary surveillance schemes forming part of The Health and Occupation Reporting network (THOR). According to these figures, over the last three years (2003–05):
   — there were around 570 new cases of occupational asthma per year, compared with about 1,000 new cases per year during the mid 1990s; and
   — there were around 2,400 new cases of work-related contact dermatitis per year, compared with 3,000–4,000 new cases per year during the late 1990s.

18. These figures tend to underestimate the true incidence, since many cases will not be referred to a consultant physician, and not all workers have access to occupational physicians. Whilst trends can also be misleading, because of year-by-year variability caused by changes in the numbers of participating
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doctors and alterations in their caseloads, more detailed analyses suggest that there is likely to have been a real reduction in the incidence of both diseases. Further statistical information is available at:

19. Prevalence and incidence statistics are available from other countries but the comparison of national rates is problematic, because of differences in the data collection procedures and systems of notification. No firm conclusions can, therefore, be drawn from international comparisons about whether or not the prevalence of work-related allergy in the UK is higher than that in other countries.

What gaps exist in establishing the overall disease burden for all types of allergy and what are the barriers to filling these gaps?

20. There is currently no simple test for objectively confirming cases of work-related allergic respiratory disease. Diagnosis depends on expert clinical judgement in the great majority of cases. Standardised criteria for diagnosis and for accepting an occupational origin would significantly assist with measuring the trends in the incidence of these diseases.

21. An HSE funded investigation of patient referrals from primary to secondary care found that there were some significant delays before patients were being referred to secondary care and subsequently diagnosed. A baseline audit of hospital medical care provision for diagnosis of occupational lung disease, undertaken for HSE and the British Thoracic Society, illustrated a wide variation in the facilities available in respiratory departments and clinical approaches employed by general respiratory consultants for treatment of occupational asthma. It found that it was usual for patients to be diagnosed in-house, as opposed to being referred to a specialist occupational respiratory centre, but that respiratory departments often lacked the necessary resources to arrive at a definitive diagnosis.

22. A Group of Occupational Respiratory Disease Specialists (GORDS), convened regularly by HSE, aims to develop a standard of care document for the diagnosis of occupational asthma, that will be ratified by the relevant medical bodies. This will reiterate key messages from other work, highlighting diagnosis and management issues and will be promulgated throughout the medical community, including general respiratory consultants, general practitioners, occupational health consultants and other occupational health professionals.

23. The wide variation in disease severity is likely to be a key issue –particularly for skin disease—since many less serious cases may not be recognised by individuals or by physicians. Thus, the THOR schemes are subject to under-reporting since specialist physicians only tend to see the more serious cases, and those with more minor symptoms may not seek medical attention anyway. In addition, many workers do not have access to occupational physicians. The Self Reported Work Related Illness Surveys rely on individuals’ own perceptions of the problem and there may be a tendency for people to misinterpret the relevance of their work exposures to their symptoms.

24. Difficulties in attribution of cases to workplace causes are likely to affect both these sources. Comprehensive epidemiological assessment of work-related allergic disease is impractical because of, for example, the wide range of occupational allergens and the circumstances in which they are used.

In addition to the impact on the health service, what is the overall socio-economic impact of allergic diseases (for example, absence from work and schools)?

25. In the 2004–05 Survey of Self-reported Work-related Illness (SWI), an estimated 791,000 full time equivalent working days were lost due to breathing or lung problems in 2004–05 (95 per cent CI: 387,000–1,194,000), a substantial proportion of which may be due to occupational asthma, with an average of 18.6 days lost per case (95 per cent CI: 9.9–27.3). This compares with 28.4 million days lost due to all self-reported work-related disease in the same year, with an average of 23.1 days lost per case.

26. In the 2001–02 SWI (the most recent year in which there were sufficient sample cases to produce a reliable estimate of the number of working days lost due to skin problems), it was estimated that 230,000 (95 per cent CI: 96,000–370,000) working days were lost due to skin problems, with an average of 8.2 days lost per case (95 per cent CI: 3.9–12.5). The total number of days lost due to all self-reported work-related disease in 2001–02 was about 32 million days with an average of 23 days lost per case.

27. Research recently published by HSE on The True Costs of Occupational Asthma in Great Britain (http://www.hse.gov.uk/research/rrhtm/rr474.htm found that the cost burden of new cases falls most heavily on the individual worker and society (taxpayers or Government). The report estimates total lifetime costs
to society of new cases diagnosed in 2003 ranging from £71.7 to £100.1 million. If comparable numbers of new cases were diagnosed in future years, this would give rise to additional streams of lifetime costs of similar magnitude.

**TREATMENT AND MANAGEMENT**

*What is the effect of current treatments on the natural history of allergic disease?*

28. Treatments for occupational allergic disease are identical to those for non-occupational allergic disease. HSE is not involved in the treatment of individual sufferers. Our focus is on preventing ill health by ensuring that the legislative framework means that employers prevent or, if this is not possible, adequately control exposures to substances known to cause work-related allergic disease, and that health surveillance is in place to identify signs of disease as soon as possible.

*What is the evidence-base for pharmacological and non-pharmacological management strategies?*

29. Within the occupational setting, the most effective strategy is removal of the allergic individual from exposure to the substance causing the allergy.

*Is the level of UK research into allergy and allergic disease adequate, and what are the most promising areas of research into preventing or treating allergy?*

30. Much valuable research has already been conducted by HSE on substances causing asthma in the workplace. There are areas that could be explored in further detail (primary causes, individual susceptibility, prognosis and mechanisms). HSE is now aware of the main causes of allergic disease and how exposures can be controlled. Therefore, our emphasis is now on achieving the behaviour change in the workplace so that employers and employees understand the need for, and use, suitable control measures.

**GOVERNMENT POLICIES**

*How effective have existing Government policy and advice been in addressing the rise in allergies?*

31. Evidence suggests that there is a downward trend in the incidence of work-related allergies. We do not have information at this stage on how HSE policy and advice has contributed to this trend, although a planned programme of evaluation will address this over the next two years.

32. Nevertheless, occupational asthma and allergic contact dermatitis continue to be priorities for HSE within its Disease Reduction Programme; the aim is a 10 per cent reduction in the incidence of these diseases by 2008 from a 2004 baseline. HSE also has a target to reduce the incidence of occupational asthma by 30 per cent by 2010 compared with the 2000 baseline.

*How is current knowledge about the causes and management of allergic disease shared within Government?*

33. In 2001, the Health and Safety Commission agreed a package of measures aimed at achieving the 2010 target. An Asthma Project Board was set up, because partnerships with stakeholders are vital if this target is to be reached. Its members include representatives from unions, industry, an asthma charity and health professionals. The board provides mechanisms to ensure that information is shared with organisations who have an interest in occupational asthma.

34. As a result of partnership working, Asthma UK has developed a Workplace Charter that sets out 10 steps to reduce the impact of asthma in the workplace (http://www.asthma.org.uk/all_about_asthma/asthma_at_work/workplace.html), and the British Occupational Health Research Foundation has published an evidence based review and guidelines on the identification, management and prevention of occupational asthma. These are aimed at doctors and nurses in general practice, occupational health and respiratory medicine and at employers, safety representatives and workers who might be exposed to occupational asthmagens (http://www.bohrf.org.uk/downloads/asthevre.pdf).

35. GORDS allows for a dialogue between clinicians who see cases of respiratory allergy and HSE. It provides an opportunity for the early identification of any new workplace allergens.
36. The THOR scheme for reporting work-related respiratory and skin disease also presents a mechanism for the identification of new allergens, and provides a useful recurring reminder to NHS physicians of the need to consider the possible work-relatedness of allergic respiratory and skin disease.

37. Clinicians and others can also seek advice about specific incidents of allergic disease from HSE’s experts, including doctors, inspectors and hygienists. HSE works in partnership with the Local Authorities and is making scientific resource available to tackle occupational asthma and dermatitis in premises for which they are responsible (e.g. bakeries and hairdressers).

38. The HSC’s Advisory Committee on Toxic Substances and various Industry Advisory Committees also provide a route for working with key stakeholders in specific areas. Coordination and information sharing across administrations, departments and agencies dealing with risks from chemicals is well developed, and HSE plays a full part in this. The Government carries out a significant amount of monitoring for chemicals in the environment, in food and in biota. Much of the monitoring currently carried out is in response to legislative requirements, which increasingly is driven by Europe.

39. In its February 1999 report, an interdepartmental working group, chaired by HSE and constituted to review the arrangements in place across Government for monitoring the ill-health effects of pesticide exposure, noted the well-recognised difficulty in determining a causal link between chronic ill-health symptoms and exposure to hazardous substances such as pesticides. There is little evidence to suggest that pesticides are a significant contributory factor in incidences of allergy, other than a small number of cases of alleged multiple chemical sensitivity following exposure to, for example, pesticide spray drift. In the light of the known difficulty set out above, the working group recommended the continued use of studies to investigate alleged links between chronic ill health and pesticide exposure. The Government’s response to the Royal Commission on Environmental Pollution report Crop Spraying and the Health of Residents and Bystanders is at www.defra.gov.uk/environment/rcep/pdf/rcepcropspray-response.pdf.

**Patient and Consumer Issues**

*What impact do allergies have on the quality of life of those experiencing allergic disease and their families?*

40. Both occupational asthma and dermatitis can interfere with normal life and cause significant disability. It is generally accepted that a diagnosis of work-related allergic disease is often associated with economic disadvantage for the affected person, either because of the impact of the illness itself on sickness absence, ability to maintain employment or the need for job change to avoid further exposure. Individuals diagnosed with occupational asthma or severe dermititis can suffer financial and employment consequences as a consequence of having to move to a lower paid job, or leave the labour force, in order to avoid exposure. The diseases may significantly affect all aspects of life, particularly if the work-related allergen is a substance that is ubiquitous in the domestic situation—e.g. allergy to a fragrance present in cosmetic products, cleaning products, food protein.

41. For those with chronic symptoms and a minimum degree of disability, no-fault compensation is available in the form of state-funded Industrial Injuries Disablement Benefit (IIDB). IIDB provides compensation for disablement due to an industrial accident or prescribed disease. It is paid according to the degree of disablement and takes no account of factors other than the physical or mental condition of the injured person. It can be paid whether or not the person is working and is not taxable.

42. A number of prescribed diseases are allergic responses to substances encountered at work. They are:
   - extrinsic allergic alveolitis (EAA), including farmer’s lung;
   - anaphylaxis;
   - allergic rhinitis;
   - non-infective dermatitis; and
   - occupational asthma.

43. The Secretary of State for the Department for Work and Pensions (DWP) is advised which diseases should be prescribed by the Industrial Injuries Advisory Council (IIAC). It is a statutory function of IIAC to review all aspects of the current IIDB scheme. The Secretary of State will normally implement IIAC recommendations. For example, following an incident of occupational asthma at a major car manufacturer in the UK, IIAC have recently published a report recommending that the current legislative description of EAA be broadened to include exposure to the mists of metal working fluids. The Secretary of State has accepted the report and is considering its recommendations.
What can be done to better educate the public and to improve the quality of information that is available to patients and undiagnosed sufferers?

44. HSE is involved in a wide range of interventions in specific industries, to raise awareness of health risks amongst employers and employees and to provide information about how to control exposures in the workplace. We consider during the planning process the most effective way of communicating with individual groups, whether through a leaflet, detailed guidance, a website, interactive seminars or an inspector visit.

45. The Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 require the supplier of a dangerous chemical to identify the hazards of the chemical, give information about the hazards to their customers and package the chemical safely. In some cases, from HSE’s perspective, the information provided could be improved and we are working with suppliers to achieve this.

46. More emphasis could be placed within occupational training provision on causes of allergy and its prevention. This would be particularly relevant for those occupations where the risk of allergy is highest. Improvements could also be achieved through better training for primary care physicians on early recognition and diagnosis of work-related allergy. HSE is currently funding research to develop training for practice nurses on the symptoms and causes of occupational asthma, to empower them to give advice and guidance to patients as well as to reduce the time it takes to diagnose cases of occupational asthma.

Are current regulatory arrangements, for example, those governing private clinics offering diagnostic and therapeutic services and the sale of over the counter allergy tests, satisfactory?

47. The health and safety legislative framework is robust and comprehensive. Under the Control of Substances Hazardous to Health 2002 (as amended) Regulations (COSHH)—and an accompanying Approved Code of Practice for the control of substances that cause occupational asthma—employers are required to ensure that exposure to substances which may cause asthma or dermatitis is prevented or adequately controlled. COSHH also requires that all employees exposed, or liable to be exposed, to a substance that may cause occupational asthma or severe dermatitis should be under suitable health surveillance.

48. Some specific legislation has been introduced to address particularly significant workplace skin allergens—for example, marketing and use restrictions on the presence of chromium (VI) in cement were introduced in 2005. Experience from other countries demonstrates that this restriction will have a very significant impact on the incidence of chromium-related skin allergy in workers exposed to cement.

49. A key difference between work-related allergic diseases and the generality of these conditions is that it should be easier to control exposure, and monitor the effectiveness of preventive measures, within the context of specific health and safety legislation.

50. Changes to the COSHH regulations in April 2005 placed an explicit emphasis on the need to follow good practice to control exposure. HSE is currently making considerable efforts to enhance the effectiveness of these regulations by raising awareness, and providing free industry and task-specific COSHH guidance sheets tailored to a wide range of businesses and employees.

Annex B

Summary of Department for Education and Skills/Department of Health medicines guidance to schools

1. In March 2005, DfES and DH issued joint guidance, Managing medicines in schools and early years settings. This document updates, and extends to early years settings, 1996 DfEE/DH guidance on supporting pupils with medical needs in school.

2. The DfES/DH joint guidance sets out a clear framework within which local authorities, local health trusts, schools and early years settings can work together to develop policies to ensure that children requiring medicines receive appropriate support. It explains the roles and responsibilities of employers, parents and carers, governing bodies and management groups, head teachers and heads of settings, teachers and other staff, and of local health services. It considers staffing issues including employment of staff, insurance and training.

3. Other issues covered in the document include drawing up a health care plan for a pupil, confidentiality, record keeping, the storage, access and disposal of medicines, home to school transport, and on-site and off-site activities. It also contains a set of forms which can be photocopied by users.
4. The guidance takes account of the recommendations from the National Service Framework for Children (2004) to ensure safe practice in the management of medicines for children, the new duties on local education authorities, schools and early years settings under the Disability Discrimination Act, and latest medical advice.

5. Chapter 5 of the guidance provides brief information and guidance on anaphylaxis, including food triggers. A child’s health care plan should include information on:
   - anaphylaxis—what should trigger it;
   - what to do in an emergency;
   - prescribed medicine;
   - food management; and
   - precautionary measures.

Annex C

Housing policy and regulations—contribution from the Department for Communities and Local Government

Do housing policy and regulations governing the indoor environment pay enough attention to allergy?

INTRODUCTION

1. The Department for Communities and Local Government (DCLG) is responsible for two housing policy areas that have a bearing on the prevention of allergies: Building Regulations and the Housing Health and Safety Rating System, which relate to new and existing buildings respectively.

BUILDING REGULATIONS

2. The Building Regulations are intended mainly for the following purposes:
   - to protect the health and safety of people in and about buildings;
   - to provide access to buildings for people with disabilities; and
   - to conserve energy and water.

3. Apart from a few exceptions, the Building Regulations are applied uniformly and do not have different provisions for the needs of different building occupants. Building owners are free to add their own special requirements.

Part F—Ventilation

4. The part of the Building Regulations most relevant to allergies is Part F—Ventilation. The legal requirement of Part F is set out in Schedule 1 of the Building Regulations (2000), and is: There shall be adequate means of ventilation provided for people in the building. We interpret the requirement to mean that the ventilation system should be able to provide sufficient fresh air to maintain reasonable indoor air quality. This assumes the outdoor air is of reasonable quality.

2006 Revision of Approved Document F

5. Ventilation has a significant energy cost, so there is pressure to reduce ventilation rates to the minimum without jeopardising health. Technical guidance on ventilation to support the legal requirement of Part F is given in Approved Document F. This has just been revised to complement guidance on energy saving in the Approved Documents that support Part L—Conservation of fuel and power.

6. For dwellings, Approved Document F recommends the ventilation rate to be between about 0.5 and one air changes per hour. This is considered to be sufficient to control typical levels of the following: moisture (to prevent mould growth), nitrogen dioxide, carbon monoxide, total volatile organic compounds and bio-effluents. As there are probably hundreds (or thousands) of chemical compounds in indoor air, it is not easy to identify the main ones that adversely affect health.
7. The Approved Document F provisions are intended to limit relative humidity in dwellings to below 70 per cent, as current opinion is that this is sufficient to prevent mould growth and associated allergens. If the relative humidity is low enough (eg below 50 per cent), it could slow the development of dust mites (dust mite faeces are associated with triggering asthma attacks).

8. In order to inform the revision of Approved Document F, we have recently sponsored research at University College London (UCL) on the effect of ventilation rate on dust mite and mould growth. This was mainly a desk exercise but included some computer modelling. An extract from the executive summary of the final report is below:

(d) Of particular interest to this project, it appears that most existing data are inadequate for conclusions to be drawn regarding the direct association between ventilation rates and respiratory problems. It is noted that there are many real difficulties in attempting to establish such a relationship.

9. We have also contributed to research by Gaia Architects to develop guidance on *Affordable Low Allergy Housing*. The current research programme includes:

- work at UCL to refine understanding of the hygrothermal conditions (ie pertaining to heat and humidity) in real homes needed to prevent mould growth—which will consider transient as well as steady state moisture levels; and
- a feasibility study of introducing a scheme for labelling construction products according to Volatile Organic Compounds (VOC) emissions. There is already a voluntary scheme for paint.

10. The Building Regulations apply to England and Wales. Scotland and Northern Ireland have their own systems, which have broadly similar technical requirements.

**HOUSING HEALTH AND SAFETY RATING SYSTEM (HHSRS)**

11. As stated above, Building Regulations apply mainly to new buildings. Existing housing is covered by the Housing Health and Safety Rating System, which has replaced the housing fitness standard. HHSRS was introduced in England in April and in Wales in June 2006. It brings a prescribed list of 29 health and safety hazards into consideration for compliance with the Decent Home standard and also as a basis for statutory enforcement in the private sector.

12. One of the hazards covered by the system is “damp and mould growth”, and the statutory guidance to local authorities notes that mould spores can trigger allergic reactions, especially asthma. Another is “volatile organic compounds”, some of which are noted in the guidance as potentially causing allergic reactions, especially in people with asthma.

13. The HHSRS is based upon data from the Home Accident Surveillance System, the Home Accident Death Database and the English House Condition Survey. Some hazards (including excess cold, exposure to radiation and falling on stairs) are flagged as particularly relevant to older people, while others (including damp and mould growth, lead ingestion and electrical hazards) particularly the young.

14. The HHSRS regulations and supporting statutory guidance do not dictate the action that local authorities should take in response to particular situations. They provide support for local authority officers' professional judgement. The guidance would assist a local authority in considering how to deal, for instance, with damp in a dwelling occupied by an asthmatic person. In such a case, the authority might require a landlord to take more comprehensive or urgent action than it would require in a case involving an able-bodied and less susceptible occupier.

**Conclusion**

15. Through the Building Regulations and the HHSRS, current housing legislation brings into the mainstream a number of health and safety issues, including cold, exposure to radiation and features in a dwelling giving rise to fall hazards, that were neglected by the old fitness provisions. As it covers existing homes, Government regards the HHSRS in particular as a significant step forward, moving the emphasis from the condition of the fabric of a dwelling to the impact of any defects on health and safety.

16. Whilst the new system does not address allergies specifically, it does provide local authorities with more of the kind of guidance they need in order to make informed decisions for the benefit of people's health. Statutory guidance recognises that people with certain pre-existing conditions, such as asthma, may be more susceptible to certain hazards than the population at large.
17. Extending control provisions beyond those in Building Regulations or HHSRS guidance would be likely to have significant cost implications for local authorities and the house building industry. Subject to the Committee’s recommendations, this would need more detailed consideration.

18. There is a need for more research on the connection between health and indoor air quality, and we have made a start on this as stated above (paragraphs 8 and 9). In this context, we are committed to keeping the evidence base and guidance under review, and also to an evaluation of the impact of the new system—but it will take time for local authorities and landlords to come to terms with it and for its health and safety impacts to be quantified.

Examination of Witnesses

Witnesses: Professor Martin Marshall, Deputy Chief Medical Officer and Director General, Healthcare Quality Directorate, Professor Sally Davies, Director General, Research & Development, Dr Keith Ridge, Chief Pharmaceutical Officer, and Mr Alan Bell, Project Lead, Allergy Services Review, Department of Health, examined.

Q1 Chairman: Thank you for coming. Can I welcome our witnesses today. This is the first evidence session of the Select Committee inquiry into allergy. This is a public hearing and it will be webcast. There is an information note available to the public which states the declared interests of all Members, so we will not be declaring our interests each time. I just wonder if you would like to go along the row, please, and introduce yourself to the Committee, and then we will go through the questions. We have quite a lot of questions for you within the hour that we were planning on, so it would be helpful if you kept your answers concise, if possible, so we can get through them. We can always return to things if time allows.

Professor Marshall: Good morning. My name is Martin Marshall, I am the Deputy Chief Medical Officer and I am heading up the team.

Mr Bell: Good morning. I am Alan Bell, and I led the recent review of allergy services by the Department of Health.

Professor Davies: Sally Davies, Director General, Research, for the Department of Health and the NHS.

Dr Ridge: Good morning. I am Keith Ridge; I am the Chief Pharmaceutical Officer at the Department.

Q2 Chairman: I wonder if I could start off by asking you how the different government departments communicate with each other on allergy issues, including issues around education and training. Indeed, when was the last time they did?

Professor Marshall: Perhaps I could take that question, thank you. We clearly see collaboration between government departments as very important, particularly in an area like allergies where there are very clear interests from departments other than the Department of Health. We relate to each other in different ways, some of which are formal, through standing committees, some of which involve joint memoranda and some of which involve informal working at the policy officials’ level. If I could just give a couple of examples: in terms of a formal level, at memoranda level, the Department of Health has worked very closely with Defra on air pollution and the impact that might have on allergies. The second example would be our very close working with DfES on developing guidance for medication for school children, particularly around treatment of anaphylaxis. So we regard collaboration as very important, and I think it is fair to say that the process that we have been through in developing this review has highlighted the importance of collaboration for all of us.

Q3 Chairman: Who leads on those meetings?

Professor Marshall: Whoever is relevant to the particular area, usually at policy official level, for example, Alan’s level.

Q4 Chairman: Just picking up on what you said about atmospheric pollution, if there is a conflict of interest between departments I wonder if you could give us an example of how it might be handled, such as things like airtightness of buildings; when energy conservation would suggest that the building should be as airtight as possible but that might be detrimental to allergy sufferers.

Professor Marshall: I do not have any personal specific experience of any conflicts of interest happening, but in an example of the sort you have given what I would expect is close collaboration and negotiation between the two areas and then trying to find common ground.

Q5 Chairman: My next question is probably for others at the table. We do have the highest prevalence of asthma and allergy sufferers in the world, and I wondered what explanation the Department has for this phenomenon. Perhaps you would like to take it?

Professor Marshall: Yes, if you do not mind. I am sure the others will have an opportunity to answer some other specific questions in their areas. I am sorry, could you repeat the main gist of the question?
Q6 Chairman: We wondered how you could explain why the UK has such a high prevalence of asthma and other allergic conditions.
Professor Marshall: It is very difficult to know how the prevalence of allergy conditions in the UK compares with other countries. We think it is high. We also think it is high in countries like Australia, New Zealand and Canada as well. The problem is having good quality comparative data. I think we need to accept that the prevalence is high in the UK, but how high it is relevant to others we do not know. The exact causes of the high prevalence, again, are unclear; there is not good evidence in this area. So whilst the scientific evidence is very good at talking about the underlying mechanisms causing allergy, the actual aetiology—the causes of it—are less clear. There are a number of different hypotheses; some of them relate to environmental factors like pollutants and smoking, some are related to genetic factors and infective factors, but probably the most popular theory relates to the hygiene hypothesis that suggests that, particularly, children are not exposed to the dirt and specific allergens that they might have been exposed to in the past, and therefore their immune system is not primed to deal with them appropriately.

Q7 Lord Taverne: Other countries have high standards of hygiene, many other countries smoke more than we do, so it does not explain why we should have a higher incidence than others.
Professor Marshall: You are right, although I come back to my original answer that we do not know whether we have a higher incidence than others, but you are right absolutely that we cannot explain the high incidence. Certainly the incidence seems to be increasing over the last 30 years, although there is some evidence over the last 10 years that some specific allergies, specifically asthma, might actually be reducing in prevalence now.

Q8 Chairman: The Department of Health review on services for allergies, commented that there is a lack of information on the extent of untreated allergic conditions. I wonder what you can tell us about what the Department is doing to improve on its data and, in fact, have appropriate data collection to know about distribution of severity and unmet need.
Professor Marshall: There are very real problems with the quality of data in this area and, indeed, in some other areas as well. We are doing a number of things to try to improve it, but the principal problem, I think, is that some allergies are treated in other organic-specific areas. So, for example, data about asthma are more likely to be found in respiratory areas, or data about eczema are more likely to be found in dermatological areas than it is classified specifically as allergy. The main thing we did in 2002 was introduce an allergy National Code. I have to say that that introduction has not been entirely successful and I do not think we have seen particularly better quality data as a result of it because people are still classifying within disease-specific areas. We are hoping that the introduction of Connecting for Health, and particularly the introduction of a new nomenclature system called SNOMED, will help us to then classify the allergy in a much more specific way, actually in a semi-automated way, when clinicians enter data on to patient records.

Q9 Chairman: Would that classification separate out allergic from non-allergic, so that as there is a classification you will be able to capture better those which are thought to be allergic versus non-allergic causes?
Professor Marshall: At the moment it does not, but I think it would be desirable if it did. The problem, of course, is that allergy is not a label that hangs over a patient when they are first seen. So it would have to require entry into patient records at a later stage when the allergic component becomes clear.

Q10 Lord Colwyn: Does the Department make any assessment of the, I would have thought, hundreds of thousands of patients, who never actually get to see a doctor, a specialist or anybody, but who treat themselves?
Professor Marshall: The Department of Health itself has not. We are very aware that there are potentially a huge number of people with allergies out there who come nowhere close to formal health services. The extent to which that matters is unclear, from the epidemiological data that is there at the moment. All of us will know of people who have allergies who self-treat, perhaps who go to pharmacies, who actually do not want to get even close to the formal health services in order to treat them, so we do not know how important that is.

Q11 Lord Broers: The Government evidence notes that the Department of Health’s A review of services for allergy “identified good practice in the NHS, across the wide range of services available for people with allergies” but also acknowledged many “gaps” in the skills of clinical staff, planning of services, baseline data and research. Are these two statements contradictory?
Professor Marshall: Perhaps I could ask my colleague, Mr Bell, to answer that question.
Mr Bell: On the face of it they may look contradictory, but I do not think they are. I think what the review showed is that allergy services are provided in different ways around the country by a range of clinical staff. There are examples of excellent practice, we believe, in allergy care provided by all
those professions. There is no conclusive evidence that we found that establishes that one particular model of service delivery outstrips others. Nevertheless, although there are these pockets of good practice, undoubtedly, the evidence, including the views of the many stakeholders with whom we engaged on the review, does suggest that there is scope for improvement in the areas that you have highlighted. There are undoubtedly, as we have found, gaps in current knowledge around issues like service configuration, the best skill mix, the best balance of generalist against specialist services and, also, in data on cost-effectiveness. We believe that the next steps that we have set out in the report of our review will help to address some of these issues.

Q12 Lord Broers: There does seem to be a problem with the data, does there not? The review concluded that the absence of baseline data on allergy services made it difficult to develop a strategic national view of how and where services could be developed. What steps have been taken to combat this?

Professor Marshall: We think that improving the data is an absolutely fundamental thing that we have to do. We think that the best way of collecting data is at a local level. This is why one of our key recommendations, which perhaps we will come back to, is around improving commissioning. What commissioning involves is a very clear needs assessment, so we would regard PCTs as taking the lead in assessing the needs by performing formal epidemiological assessments of the needs within their local communities as well as prioritising those things alongside others. We hope that that, in conjunction with the other issue that I mentioned of a properly promoted National Code through Connecting for Health and SNOMED, will help improve the quality of the data that we have.

Q13 Lord Broers: Do you think this will allow us to collect basic demographic data in a standardised form? The thing that interests me here is your statement that we do not really know how we stand with respect to other countries. Is there an effort to get together, for example, across Europe at least, to standardise these data?

Mr Bell: We are aware of initiatives such as the Global Allergy and Asthma European Network which is busy, amongst other things, collecting data on allergies across different countries in Europe. Certainly the data that they have suggests, as Martin said earlier, that we are up there near the top of the table (or bottom of the table, depending on which way you look at it). There have been other research studies done, some of which are still ongoing, such as the International Study of Asthma and Allergies in Childhood, which has looked at data from children in, I think, something like 56 countries, which again is suggesting that certainly for asthma—less clearly for other allergic conditions—it is the UK, Australia, New Zealand and the Irish Republic which are, again, up there at the top. So there is some international research effort going on to collect relevant data on prevalence and incidence.

Q14 Baroness Platt of Writtle: Do General Practitioners have adequate training in allergy?

Professor Marshall: Perhaps I could take that question because, as a General Practitioner myself, I am acutely aware of it. I would say across the board probably not, is the answer. If I just give an example of my particular training: we had good training at undergraduate level in basic immunology and in applied immunology, and that has clearly got better in the last 20 years: very good training in taking history, in making a differential diagnosis, and good training in specific disease areas like asthma or like dermatology. I think the areas of weakness, where they exist, are, first of all, an awareness of allergy as a potential diagnosis—I do not think that is as good as it could be—and, secondly, understanding some of the second line issues around diagnostic procedures and treatment procedures. So I think General Practitioners are very good at first line, simple symptom control but perhaps not in the more complicated cases of allergy.

Q15 Baroness Platt of Writtle: Who is doing the training locally for them?

Professor Marshall: For General Practitioners, perhaps I could divide between higher specialist training, before somebody becomes a GP, and post-specialist training. In terms of higher specialist training, the main people responsible for setting the standards are a group called PMETB a regulatory body with responsibility for setting standards of training. They work very closely with the Royal Colleges, and with the Postgraduate Deans. So they are responsible also for providing the specialist training. Once somebody has qualified and in independent practice then, again, the Postgraduate Deans play a role and there are a number of specialist allergy courses that General Practitioners can attend around the country, particularly one in Southampton and one in Warwick, that have been around for some years and are very highly regarded.

Q16 Baroness Platt of Writtle: But not necessarily over all the country.

Professor Marshall: No, I think that is true, although people are very willing to travel to high-quality courses like the Southampton and Warwick ones, so I do not think they have to be in each locality.
Q17 Baroness Platt of Writtle: There are 13 million patients with allergic disorders, 7 million of whom would benefit from specialist care. To whom can the patient be referred in the absence of a specialist in the area?

Professor Marshall: It is an important issue, and I think it is, perhaps, where our allergy review came out as rather different from the recommendations in the Health Select Committee report and, prior to that, in the Royal College of Physicians report in 2003. They called very strongly for much larger specialist services, particularly a much larger number of specialist allergists. We could find no evidence that that was going to be a cost-effective way of using limited resources, and our argument is that what we need to do is skill-up the primary care services far more. So our argument is that if primary health care teams, which include General Practitioners, practice nurses and community dieticians as well, were working well then actually the need for specialist services would be far less. Having said that, there very clearly is a need for specialist services, and I think it is absolutely clear that there are inadequate specialist services at the moment.

Q18 Baroness Platt of Writtle: If you are going to rely on the GPs and the practice nurses, which I think is a good idea because it is local and near the people who have the problem, where are they going to get their specialist training, if it is not available locally? They are busy people.

Professor Marshall: That is a key issue, and I would agree with you that it is something we need to look at.

Q19 Chairman: Can I pick up on that and follow on, because you cite the courses in Southampton and Warwick, but my understanding is that most of the people on those courses are nurses, they are not GPs, and they are not actually providing clinical experience on those courses; they are not monitoring the practitioner’s clinical practice either even back at base.

Professor Marshall: You are certainly right about most attendees being nurses rather than General Practitioners, and I think in many ways that reflects the nature of the skill mix and delivery of primary care over the last 10 or 15 years. I think you are correct that in terms of assessing the quality of services at a local level I do not think that happens adequately at the moment.

Q20 Lord Soulsby of Swaffham Prior: Pertinent to GPs and their knowledge of allergies, are there regional differences that GPs should be aware of, that in the North of England, for example, this is more common than something in the South of England? If that is so, what special training and information is given to GPs to be on the look out for issues that may not occur in different parts of the country?

Professor Marshall: Do you mean regional differences in the epidemiology of allergies or the provision of services?

Q21 Lord Soulsby of Swaffham Prior: Regional differences in the causation of allergies, more than the administration.

Mr Bell: Perhaps I could just comment on that. The epidemiological data that we pulled together for the review did not show any clear differences between different parts of the country in the proportions of people who might develop different allergic conditions. We do not think that really is an issue.

Q22 Lord May of Oxford: If I could come back to the Review of Services for Allergy, it made some recommendations and I would like to ask you about two of the recommendations: what has been done towards implementing them and on what timescale. The first suggested thinking about commissioning the development by NICE (which I think is the National Institute for Health and Clinical Excellence) of guidelines for allergy, and the second recommendation was that there might be some work with the Royal Colleges on guidance for referral and care. What actually has happened and on what timescale do you see that happening?

Professor Marshall: Could I apologise for our use of acronyms; it is a disease that we all have within the Department of Health system.

Q23 Lord May of Oxford: I apologise for not knowing it!

Professor Marshall: Yes, we regard the development of guidelines as being one of the more important of our recommendations. We have worked up proposals which have been submitted to NICE in order to develop allergy guidelines. We have submitted them to two of the NICE consideration panels, to the Long-term Conditions Panel and to the Maternity, Children and Adolescents Panel, and we understand that they are going to be looked at around about now, certainly before the end of the year. If they agree that it is important, and our understanding is that they probably will, then it needs to be taken to a national committee in January, which prioritises it alongside other demands for guidelines, and then taken to Ministers to be signed off. If it is signed off then the development of guidelines usually takes between 18 months and two years. So, as far as NICE is concerned, we have taken action. We did make a specific recommendation about involving the Royal Colleges in developing further guidelines. We decided, after discussions with NICE, that it would be better for the Royal Colleges
to feed into the NICE process, so we do not have parallel processes going on. We have done some specific work with the Royal College of Paediatrics and Child Health over developing care pathways, and we have just started talking to them. They are apparently very keen on working with us, and that work will be taking place over the next few months.

**Q24 Viscount Simon:** Stephen Ladyman, in evidence to the House of Commons Health Committee, said that he was going to ask the Chief Medical Officer to oversee an allergy “action plan”, in effect to guide and support local allergy commissioning. Do you know what has happened to that?

**Professor Marshall:** Yes. As a Government we are very committed to ensuring that any policies that we make or any action that we take is based as firmly as possible on research evidence, and we felt there was insufficient research evidence to take action immediately after the House of Commons Health Select Committee. That is why the decision was made by the Chief Medical Officer to undertake a further review, and hence the review that we have submitted to you. Now that that review has been published (it was published in July) you will see a series of next steps or recommendations, many of which are in line with and address the issues recommended by the House of Commons Health Select Committee.

**Q25 Viscount Simon:** Have any PCTs commissioned any allergy services?

**Professor Marshall:** To our knowledge, not yet—to our knowledge. We have sent them copies of the review and we are going to be doing work with them, as we mentioned, on one of our recommendations around commissioning.

**Q26 Viscount Simon:** Do the local commissioners have the money, the expertise and other resources—and I stress those words—to co-ordinate appropriate allergy services?

**Professor Marshall:** This is the key question. I think it is the right question because action needs to be taken at a local level. Whether PCTs have the capacity or capability at the moment to undertake commissioning of the quality that we would like them to undertake, I think, is questionable, although we are putting steps in place to support them and make sure that they skill up much more rapidly. That is a general issue in terms of commissioning. Specifically in terms of commissioning allergy services, it is up to the local PCTs as commissioners to decide on the priority of allergy services alongside the many other priorities that they are going to have to look at. I would not be at all surprised if PCTs decided that cancer services, cardiovascular services, liver services and chronic obstructive pulmonary disease are higher priorities for them than allergy services will be.

**Q27 Chairman:** You are asking them to commission for services but without baseline data of the level of need. All you have got is that perception of demand, which may be quite different to need.

**Professor Marshall:** Commissioning is a complex process; it is not just about, as you are well aware, contracting for services. The first step of commissioning is needs assessment. We are asking them to undertake the needs assessment first before they then decide what their local needs are. That process is not just about looking at the epidemiology in their local areas, it is also about consulting with key stakeholders, of which we regard the public as being an absolutely key one. If the public regard allergy as being a priority then that is something that the PCT will have to take on board.

**Q28 Chairman:** Without the coding how can they collect the data, without doing an original research project, which they do not have the resources to do?

**Professor Marshall:** They are going to have to look at other codes that might be related to allergy services. It is the weakness and a deficiency, as we have already identified.

**Q29 Chairman:** Can I go back to another gap, possibly, that you have highlighted, which relates to training? If you are wanting GPs to undertake the larger part of the services and there are not adequate training courses for them (and indeed they are not on them at the moment) then it seems that you have got an enormous amount of training to do, and yet if specialist services do not have the capacity to provide that training you do not have anybody to provide the training which would be needed to get them up to the level to be able to provide the service.

**Professor Marshall:** I agree that that is a particular issue. What we are doing is working very closely with the Royal Colleges and with the Deans to try to address that issue. I think we are starting from a fairly low baseline in terms of allergy services. One specialist allergist committed to teaching can teach many hundreds of GPs over a period of time, and therefore what we would expect is a cascade process. So I agree that there are insufficient allergists to be able to move things on very quickly, but we believe that action can be taken.

**Q30 Chairman:** However, you do still need to have specialists coming up in the system particularly to replace those who take time out to do teaching.
Lord Taverne: Yes.

Q31 Lord Taverne: The UK Health Research Analysis carried out by the UK Clinical Research Collaboration analysed spending on health research in the UK, but because allergy is a multi-organ disease it fell across several disease categories. What should be done to ensure that you get a grip on the results of the research and that it does not suffer from being compartmentalised?

Professor Marshall: Perhaps I could ask Professor Davies to answer that question.

Professor Davies: Thank you. I am glad you have seen this report. I chair the UK Clinical Research Collaboration and I am very proud of the work we have done in this. It is the first time anywhere in the world that we have looked at how research funding is spent, and this takes in all the major public sector funders and the major charities. It was a very intensive, 18-month project and we split it down, as you have seen, into a number of areas which did not include allergy—you cannot do everything. Here, where the bits most relevant to allergy are respiratory, what you will see was perhaps expected, but what was worrying was that when we compared the research spend with the disease burden there was an imbalance. However, we cannot do much more in depth with the data because it is a limited data set that was collected there. What we are doing with most of the major public funders is continuing to categorise present and future spending in this way, so we will collect that. I think the highlight around the respiratory, much of which is COPD or asthma, is very important. That shows that there is an imbalance that needs to be looked at, but it is high level. We are clearly doing a lot to try and make sure the funding goes where it should, and you will know that at the end of January we launched the new government strategy for health research in NHS, Best Research for Best Health, that opens up a lot of funding opportunities in this area for allergy or other diseases where they need to do clinical research.

Q32 Lord Taverne: What about the cost of the research? Research is national and goes beyond PCT boundaries. How will this be accounted for when you have practice-based commissioning?

Professor Davies: Research is a national good, so it is not money that we devolve down. Indeed we are, as part of Best Research for Best Health taking money out that was given historically to hospital trusts—over £500 million a year—being spent on research and supporting research, and putting it back totally transparently over a three-year transition period. Where necessary that will be competitive, but all transparently. So in the future we will know much better where the money is going and it will have been subjected to much stronger quality thresholds and relevance thresholds than it is at the moment.

Q33 Chairman: I wonder, Professor Davies, if you could tell us how much research is going on into food allergies and anaphylaxis? You have referred to respiratory problems.

Professor Davies: We do not know and it is not data we can get at. When we look at what we know we are funding, we fund a unit at Imperial for £2 million over four years looking at allergy and asthma; we are funding five projects within the Health Technology Assessment Programme for a total of £2.2 million and they are doing studies like comparing inhaled corticosteroids with leukotriene receptor antagonists and, interestingly, a trial of ion-exchange water softeners for the treatment of atopic eczema in children. On reviewing the reports that we receive from hospital trusts for those allocations that are historical we know that there are five major programmes which are working in the allergy field, including Guy’s and St Thomas’, King’s College Hospital, the Royal Brompton, Southampton and South Manchester. However, to break it down further we cannot do at this stage.

Q34 Chairman: My understanding is that the majority of those are respiratory-based.

Professor Davies: I can see from the data I have that four out of the five are definitely respiratory-based. The Southampton one we do not have data on.

Q35 Lord Broers: The indirect costs of allergic diseases are potentially huge. How does absence from work due to allergic conditions compare to that of other conditions, for example back problems, mental illness and repetitive strain injury?

Professor Marshall: The indirect costs are absolutely potentially huge. We do not have any good comparative data comparing issues related to allergy with the other conditions that you mention. One of the problems with allergy is that it does not tend to be a diagnosis that is put on sick notes, for example, in the way that back pain might be. So we do not have any direct comparative data here. I suspect and hope that colleagues from the Health & Safety Executive might be able to give you more data than we have available here.

Q36 Lord Broers: Do you think the Department of Health response to the diagnosis and treatment of these conditions is proportionate to their impact on work, education and quality of life?

Professor Marshall: I think that is a difficult question to answer in absolute terms. If all we are doing is looking at allergy services then I would probably argue that our response is not appropriate. If we
compare it with other priorities then I think it is appropriate.

Q37 Lord Soulsby of Swaffham Prior: You may have answered, in part, this question: what is the level of support given through grants under Section 64 of the Health Services and Public Health Act 1968 to not-for-profit organisations that support people with allergy?

Mr Bell: Perhaps I may answer that one. We looked at that on the database and apparently over the last decade we, in the Department of Health, have awarded grant funding under Section 64 (the general scheme of grants) to voluntary bodies in the allergy field totalling over £532,000.

Q38 Lord Soulsby of Swaffham Prior: What are the criteria for receiving these grants?

Mr Bell: Essentially, the Section 64 general scheme gives the Secretary of State for Health the power to make grants to voluntary bodies in England whose activities support the Department of Health’s policy priorities. Needless to say, the competition for available funds every year is extremely strong and we give priority to applications with innovative proposals of national significance that will complement statutory services and so help to secure the provision of high-quality health and social care and, by so doing, promote the nation’s health.

Q39 Lord Soulsby of Swaffham Prior: You mentioned approximately half a million in funding. To my mind that does not seem an awful lot of funding for what we are talking about. In answer to Lord Broer's previous question it is a major problem, yet half a million seems an extraordinarily small amount of money to put into this.

Mr Bell: You could certainly argue that. As I say, it is always very competitive who is going to get grants, but I could say that to my knowledge three organisations—Allergy UK, Asthma UK and the National Eczema Society—have all had grants in that period, and the main beneficiary out of the three is Allergy UK, which has had four different grants totalling nearly £400,000. Section 64 funding is very much regarded as pump-priming; we do not look to fund, on the whole, the core administrative, ongoing costs of these bodies; we are looking to help them with particular projects.

Q40 Lord Colwyn: We hear, that levels of allergy have soared in recent years and that GPs, perhaps, do not have an ideal training and cannot always cope with it and specialists are few and far between. Having said that, I do want to put a word in for my own profession, that of dentists, because in fact I recall having a fairly comprehensive training on allergy and certainly continuing professional education. It is something that we have to be very careful with; dentists are providing more invasive treatments, and it is a problem that we have to be aware of. So patients tend to go to high street counters for their treatments. Is there any evidence that treatments of no particular value are being offered over the counter in high street shops?

Dr Ridge: In terms of the tests that are available over the counter, the regulation of that, as you will see from the memorandum, is largely based on whether the product is a medicine or whether it is a medical device. For actual medicines, those that are classed as medicines—creams, and those types of things that are classed as medicines—those are regulated in the normal way. For pharmacy itself there are professional standards in place which are currently being revised as pharmacy undergoes, if you like, a revolution in terms of how care is provided on the high street, and a new regulatory framework for pharmacists should be with us next year in terms of professional regulation. For other professionals we are likely to bring forward regulation of acupuncturists and herbal medicine as soon as possible. We have also asked the Prince of Wales' Foundation for Integrated Health to develop voluntary self-regulation amongst a range of other currently unregulated professions. As far as pharmacy is concerned, can I say a word around pharmacists in terms of their training? The pharmacy undergraduate course contains elements on allergy and conditions associated with allergy. Allergy is also in postgraduate training which is well taken up. Therefore, I would expect a pharmacist, from a professional point of view, to be recommending medicines or medical devices which have a proven use.

Q41 Lord Colwyn: I may be wrong but I recall that the prescribing of antihistamine had to be done on the script and now you can get it over the counter. Has that changed? That must make a lot of difference to the products that are available.

Dr Ridge: Absolutely. There are a range of products, licensed medicines, which are available over the counter. I think in the memorandum there is a figure which states that about £60 million a year is spent on over-the-counter therapies associated with allergy.

Q42 Lord Colwyn: Can I come back to the problem of the complementary therapies, because this is something of great interest to me. Of course, many of the complementary therapists are, actually, regulated (you mentioned the ones who are looking for regulation). Is there any evidence that treatment in a complementary way is harmful in any way?
Dr Ridge: I am not aware of any evidence that it is harmful. I guess we could look further at that. However, homeopathy, for example, as I guess you will be aware, is a recognised system of medicine and regulation, and in fact we have just brought forward new regulations around homeopathy in terms of the requirement for products to satisfy a safety and quality test, and those regulations came in on 1 September this year.

Q43 Lord Colwyn: The treatment of allergy is all about arming one’s immune system. That is the aim of complementary therapies. I do not know if you would comment on that.

Dr Ridge: In terms of whether complementary therapies cause any harm? Is that the question?

Q44 Lord Colwyn: Yes.

Dr Ridge: I am not aware that they cause any harm.

Professor Marshall: May I just add to that? In terms of direct harm from complementary therapies, there is not a lot of evidence, but Professor Edzard Ernst’s team in Exeter has done some interesting work looking at indirect consequences of using complementary therapies, particularly in terms of delayed diagnosis and delay in receiving evidence-based therapies. So there is some interesting evidence here but it is contested, I think it is fair to say.

Lord Colwyn: I think it is very minor evidence on that.

Q45 Lord May of Oxford: You must be aware that recently in the House of Lords, in the debate in fact sponsored by Lord Taverne on the regulations on the labelling of homeopathic medicines, a variety of people of expertise in various relevant walks of life—the kind of expertise you find in the House of Lords—voiced very strongly the belief that the regulations had confused anecdote with established canons of controlled scientific evidence in what was allowed on labelling. In the light of that, can we have confidence that if you are going to move to produce regulations for these alternative things they will be done with a bit more thought and rigour?

Dr Ridge: As you may be aware, there are two existing reviews of healthcare professional regulation, at the moment. One is associated with the medical profession and one with non-medical professionals. Consultation on that has just finished and the principles associated with both of those reports, I would imagine, would apply to certainly the herbalists and the acupuncturists in terms of their statutory regulation forthcoming. As for the others, if it is a self-regulatory system then I would hope to see similar principles apply, but it is still a self-regulatory system.

Q46 Lord Taverne: You will be aware that when it came to the homeopathic regulations introduced on 1 September concern was expressed by nearly all the professional societies—including the Royal Society, the Academy of Medical Sciences and the Pharmacological Society—that for the first time regulations were being introduced which allowed claims of efficacy to be made which were not scientifically tested. Is that something which is going to be part of future regulation or not? Some concern was expressed to us at the seminar which was held before we started hearing witnesses that there was some misdiagnosis or delayed diagnosis, and the Royal College of Pathologists seems to have expressed concern that the regulation of non-NHS clinics is not adequate and that misleading advice can be harmful and costly for patients. I hope these representations are being taken seriously, and that we are not going to resort to non-scientific approaches to medicine on something as important as allergies.

Dr Ridge: You are right in terms of how the regulations are set up and in terms of their requirement or not to demonstrate efficacy. I think that you are right to be concerned. However, there is clearly a need for complementary therapies, and the regulation of the professionals associated with those, I think, is in the process of being enhanced.

Q47 Lord Taverne: Enhanced but not in the way in which it was enhanced to promote the homeopathic industry in the recent regulations. I hope that the regulation will be based on scientific tests. Can we have an assurance on that one?

Dr Ridge: I would need to go back and talk to people about that assurance. I am sure we will provide you with a note.

Q48 Lord Broers: May I ask whether there have been studies of the effects of prolonged allergic disease and the consequences of that? It would seem to me that severe asthma puts great strains on one’s heart. I am not an expert on this, I am an engineer, but it would seem rather obvious; I have watched people with sustained asthma and it seems to put great strain on their system, so anything that delays treatment would seem to be harmful.

Professor Marshall: There is evidence that untreated asthma can lead to long-term lung disease. So there is certainly evidence about that. Whether there is evidence in other areas of allergy, I am not sure.

Professor Davies: No, I am not sure. Of course, long-term bad lung disease can have an impact on the heart, but you go through the lung disease before you impact on the heart long term. There is evidence that we all recognise as clinicians, of the allergic skin conditions it can lead to, lichenification, thickening,
and itching and unpleasantness. So we are all aware of long-term consequences. Have I seen a study that tells you the magnitude of that problem? No, but this is not my speciality area; I am a haematologist.

**Q49 Chairman:** Dr Ridge, could I follow up on the line of questioning that was directed at you previously? If we look at the patients who go into their local chemist shop and ask to see the pharmacist because they have symptoms that they believe to be allergic in nature, what training does that pharmacist have to give the advice and recommendations that are given?

**Dr Ridge:** Pharmacists now undergo a four-year training programme at undergraduate level. I have confirmed with the Royal Pharmaceutical Society of Great Britain, who are the regulators of the pharmacy profession, that the components of allergy and treatment are within the indicative curriculum at the undergraduate level. It is also within the pre-registration year. At postgraduate level, the Department of Health funds the Centre for Pharmacy Postgraduate Education based at the University of Manchester, and they provide a series of learning materials associated with allergy, and looking at the figures in terms of uptake it seems reasonable.

**Q50 Chairman:** Do they have any input from the clinical experts in allergy?

**Dr Ridge:** In terms of the Centre for Postgraduate Pharmacy Education and how those packs are constructed, yes, is the answer to your question. I think it is also worth mentioning that as roles change within pharmacy (and, for example, pharmacists with a special interest will be with us quite soon), clinical specialists associated with a particular speciality working alongside and within a network associated with specialists in a hospital environment), then I expect to see that those people will be accredited in terms of how their training will take place. That is a requirement.

**Q51 Chairman:** It seems to me there is an enormous training load that is emerging in this session: training of the GPs, training of nurses and training of pharmacists. Yet that requires a body of specialist knowledge to be informing that training process otherwise you will have constant repetition of what was the level of knowledge at one time but without integrating all of the research and, indeed, being involved in modern clinical practice, that will eventually become increasingly out of date. So there is a concern. I think, about the number of specialist services and specialists that will be brought forward if they are going to undertake the amount of training that is going to be demanded of them with these changes you propose.

**Professor Davies:** Perhaps I could give you some good news. As you will know through the UK Clinical Research Collaboration, we went through a process which acquired the name of Walport, from Mark Walport, of looking at the training of clinical academics and agreed with Modernising Medical Careers a schema for training clinical academics which would be clinical fellowships and clinical lectureships. We are, at the moment, looking at the bids from university/NHS partnerships for training these people and accrediting those training programmes. We have agreed 11 programmes in allergy, which is not insignificant.

**Q52 Chairman:** That is not insignificant, and thank you for bringing some good news to the table. Professor Davies, could I move back to government policy and just ask you how the policy is formed in terms of giving advice to patients? For example, if we take the report from the Committee on the Medical Effects of Air Pollutants, does the Department now advise the public that air pollution is an important factor in allergic disease?

**Mr Bell:** If I may answer this one, obviously in any area of government policy we would want to be informed by the available evidence. We believe that having done the review of allergy services we have done a lot to provide evidence for further development of policy on allergy. Referring to the particular report from COMEAP, my understanding of it is that that report showed that exposure to air pollutants does not in itself cause asthma but it may produce a worsening of the symptoms. Our colleagues at Defra provide an air pollution service on behalf of the UK Government and the devolved administrations. That air pollution service for the public involves making hourly updates available to the public through the Internet, a freephone helpline and TV teletext, and those updates show the current levels of air pollution and air quality forecasts. Defra also issues hourly updates to the media and other subscribers. So there is that information which we make available to the public about the levels of air pollutants. There is also a free booklet which you can get through the Defra website, which was produced by Defra in collaboration with us and some other government departments, which will give you advice as a member of the public on what particular levels of air pollutants may mean for you and your health.

**Q53 Chairman:** What about advice to pregnant and lactating mothers over diet?
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**Mr Bell:** I am not an expert on that area. I know the Department of Health has issued advice on that area. I think that may be something we would need to follow up in writing to you.

**Chairman:** It would be helpful because there are questions over the evidence base for it and indeed, if it is no longer underpinned by the evidence base, whether it has been made quite clear that that advice should no longer be given to women who are pregnant or lactating.

**Q54 Viscount Simon:** You talk about air pollution, which is a very, very wide term. By what is air being polluted?

**Mr Bell:** I would have to look at the COMEAP report to narrow down which pollutants are being talked about. There are all sorts of different things in the air, and I would need to check what the details are and what the Government’s air pollution service therefore gives you information on. I am sorry I cannot answer that.

**Q55 Chairman:** Thank you. We are just about at the end of our questioning. I have one thing, but you may want to supply this as a supplementary later, and that is who is actually responsible for determining the coding with the disease codes? The coding issue emerged early in our questioning.

**Professor Marshall:** A combination of Connecting for Health, and that is directly through the clinical lead for Connecting for Health, a gentleman called Michael Thick, and the Chief Medical Officer’s team, and I would take direct responsibility for that. So it is a combination of the two of us.

**Q56 Chairman:** Perhaps you might like to take away our concern about the current coding system. Is there anything else you would like to tell us about that you feel that, perhaps, you have not had a chance to explain adequately in the questions we have put to you?

**Professor Marshall:** No, we are happy, thank you.

**Chairman:** Can I thank you for coming. If there is anything else that comes to mind, please feel free to send it in and it will be published with your evidence. Thank you all for coming and giving evidence today.

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**Supplementary letter from the Department of Health**

At the oral session on 22 November, we undertook to submit additional material to the Sub-Committee on three issues—the proposed statutory regulation of complementary medical professions, advice on diet for pregnant and lactating mothers, and pollutants in the air.

**The proposed statutory regulation of complementary medical professions**

The Government is committed to the regulation of acupuncture, herbal medicine and traditional Chinese medicine practitioners. We have set up a Joint Working Group, chaired by Professor Mike Pittilo, Chancellor and Vice Chair of the Robert Gordon University in Aberdeen, to prepare the ground for statutory regulation of these professions.

The Joint Working Group draws together feedback from all stakeholders, whose involvement is crucial to achieve a successful way forward. Inevitably, this does take time. Experience of regulating new professions suggests that we are unlikely to be in a position to bring forward legislation until 2008-09 at the earliest.

Once legislation is in force, practitioners in these three disciplines will only be able to practise if they are registered with the regulatory body. In order to do this they will have to satisfy agreed standards, such as holding recognised qualifications and/or evidence of safe and effective practice. People will be able to confirm the bona fides of a practitioner by checking whether they are registered with the regulatory body, and will also be able to make complaints about a practitioner’s fitness to practise.

**Advice on diet for pregnant and lactating mothers**

The Department of Health’s advice for pregnant and nursing mothers is set out in *The Pregnancy Book* and in *Birth to Five*, which are given free to first time mothers. Both provide information and advice on peanut allergy as follows: “if you, your baby’s father or any previous children have a history of hayfever, asthma, eczema or other allergies, you may wish to avoid eating peanuts and foods containing peanut products”. In general, women are advised to read food labels carefully and, if still in doubt about the content, to avoid these foods and also to check with a health professional about diet during breastfeeding.
22 November 2006

Our current advice is based on the conclusions of the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), based on the best available evidence when it reported in 1998. We recognise that the then available evidence on development of peanut allergy during pregnancy and weaning was not conclusive but, noting the uncertainty and the potential for risk of life-threatening anaphylaxis, our advice on peanut allergy is precautionary.

We are aware of ongoing research, by both the Food Standards Agency and other organisations, and keep abreast of emerging evidence. We shall ask the COT for further advice when a reasonable body of evidence is available, and will update our own advice as appropriate.

Pollutants in the air

According to the 1995 report of the Committee on the Medical Effects of Air Pollutants (COMEAP) on Asthma and Outdoor Air Pollution, air pollution refers to the presence in the air of gases or particles of matter, which are not natural to the atmosphere at such concentrations. These are generally man-made, though the term also applies to unusual natural events, such as the eruption of volcanoes.

The COMEAP report was confined to the effects of non-biological pollutants. It excluded aeroallergens (pollens, mould spores), although it recognised that they are important causes of respiratory problems—including outbreaks of asthma—and, being to some extent influenced by man, could be included as pollutants. The main ambient pollutants which have been studied in relation to respiratory diseases are particles, sulphur dioxide, nitrogen dioxide and ozone.

The bulletins issued by the Government’s air pollution service show current levels of air pollution and air quality forecasts. Measurements are given for ozone, nitrogen dioxide, sulphur dioxide, carbon monoxide and particles.

11 December 2006

Examination of Witnesses

Witnesses: Mr Patrick McDonald, Chief Scientist and Director of Corporate Science and Analytical Services Directorate, Health & Safety Executive; Mr Steve Coldrick, Head of Disease Reduction Programme, Health & Safety Executive; Mr Chris Wells, Deputy Director for Special Educational Needs and Disability, Department for Education and Skills; Dr Peter Wright, Deputy Director and Principal Scientific Adviser, Health Work and Wellbeing Directorate, Department for Work and Pensions, and Ms Anne Kirkham, Head of Decent Homes Finance & Co-ordination, Department for Communities and Local Government, examined.

Q57 Chairman: Can I welcome you here to our first day of taking oral evidence for our Committee inquiry? I would like just to remind you that this session is being broadcast and also that the individual Committee members have completed a declaration of interests which is available to the public, so we will not be formally declaring our interests to you as we ask you questions. We will ask you questions and if there are supplementary issues that you wish to submit later to this evidence session then we will be very happy to receive them. I wonder if you might start by each introducing yourself.

Mr McDonald: I am Patrick McDonald, the Chief Scientist at the Health and Safety Executive, and with me this morning is Steve Coldrick, who is looking after our Disease Reduction Programme.

Mr Coldrick: I am Steve Coldrick, Head of the Health and Safety Executive’s Disease Reduction Programme.

Mr Wells: I am Chris Wells and I am the Head of Special Educational Needs and Disability at the Department for Education and Skills.

Ms Kirkham: I am Anne Kirkham and I am Deputy Director in DCLG responsible for Decent Homes Finance and Mixed Communities.

Dr Wright: I am Peter Wright, the Principal Scientific Adviser at the Department for Work and Pensions.

Q58 Chairman: I would like to start the questions, if I may, and it is specifically really for the Health and Safety Executive and the Department for Work and Pensions. In the evidence submitted to us you say that it is difficult to estimate the proportion of workers who have lung and skin problems that are actually allergic related—asthma and allergic contact dermatitis. I wonder what plans there are to try to record accurately the number of workers who are suffering from these allergic conditions.

Mr McDonald: If I may start with a description of where we get our data from. The lead data source for occupational illness is a population-based survey on self-reported work-related illness, and from that we derive population estimates. Despite using what is
the biggest survey system available to government statisticians, this picks up fairly few cases of occupational illness, and the bulk of those are musculoskeletal problems and mental health problems. There are just too few cases of occupational lung and skin disease in the survey on which to base any reliable estimates of particular types of skin and lung disease, so we rely quite heavily on the voluntary reporting scheme which is run for us by Manchester University, and it relies on GPs and other consultant specialists. The scheme is called The Occupational Health Reporting Scheme, and we also take into account other administrative data sources such as the Industrial Injuries Scheme, and it is on these figures that our assessment of trends are based. That is broadly adequate for monitoring whether or not we hit the Health and Safety Executive’s targets but it is not adequate for targeting our interventions very closely, so we have just commissioned an addition to the THOR reporting scheme which is based on GPs who have had occupational health training, and we are rather hopeful that that will improve the accuracy with which we can report on occupational asthma and contact dermatitis. There is also a broader engagement by the Health and Safety Executive in trying to measure the awareness and attitudes to specific health and safety issues within firms and monitoring consequent improvements in health and safety outcomes. I hope with time we will be able to draw more firm conclusions on self-reported occupational asthma and contact dermatitis.

Q59 Chairman: Are these going to be GP indexed practices that you are going to be using to collect the data?
Mr Coldrick: I cannot say for certain whether it is that, but what I do know is that we have to make sure that GPs are fully aware of recognising particular conditions, and that is why there has been this training. It has been an issue of concern for some time so I expect the training to be for GPs at the indexed practices rather than for all GPs.

Q60 Chairman: Because it makes a difference.
Mr McDonald: Volunteers for the scheme will get extra training at Manchester University who are running the overall core scheme for us.

Q61 Chairman: Right, and how can you ensure that workers have access to occupational health services and occupational health physicians across the board, or are you now going to be relying on GPs who you are upskilling, which raises the question, what about other members of the workforce and how adequate is their access to advice?
Mr McDonald: I think there is a general issue here where, certainly compared to other countries in Europe, access to occupational health advice is not as extensive. It is an issue that we need to consider, particularly in the context of our EMAS statutory duties.

Q62 Lord Taverne: To follow up, on the information about those suffering from allergic conditions do you have any information about people whose genes may predispose them towards particular allergies like occupational asthma?
Mr McDonald: Certainly there is a genetic component to allergies, things like hayfever and asthma do tend to run in families, but I do not think the evidence base available to us is wide enough to be able to tell specifically whether a particular genotype is responsible for allergic reactions.

Q63 Baroness Platt of Writtle: What action is the HSE taking to prevent individuals from developing occupational allergic diseases? My mind flies to hairdressers because there is no doubt about it there is a certain amount of connection there, is there not?
Mr Coldrick: In fact, yesterday on the specifics of hairdressers we launched the first National Hairdressers’ Day, which was aimed specifically at dermatitis which, as we know, includes irritant contact dermatitis and allergic dermatitis, and that is one of our major target audiences in respect of skin disease which includes the allergic response. We have put together, if you like, an alliance of the people who supply the materials, the people who actually work with the hairdressers themselves, the trainers, and also looking at the local authorities who enforce. What we have learned in preparation for this campaign is that it is not straightforward. If I give you a specific example: some hairdressers feel that it is part of the job to have dermatitis and in some cases asthma. In fact, we had an e-mail from somebody who had been doing it for 34 years saying, “Stop whingeing and just get on with it and accept it.” so there is an attitude problem. The second problem that we have is that when it comes to taking what are very sensible and simple precautions for protecting against allergic skin disease, dermatitis, hairdressers and salon owners shy away from that because they believe that the customers will not like hairdressers to wear, non-latex disposable gloves. So this campaign has been about dispelling some of the myths, and to get an attitude change, not only amongst the salon owners, not only amongst the hairdressers, but also amongst the clients, and that is the whole thrust of the campaign of which the Hairdressers’ Day is a part. The campaign goes up to 20 December, but we
are continuing because when you are talking about behaviour and attitudinal change we measure that in years rather than weeks.

**Q64 Baroness Platt of Writtle:** What proportion of employers comply with legislation to provide a safe workplace for allergy sufferers and what procedures are in place to deal with employers who do not comply?

**Mr Coldrick:** It is very difficult to answer the first question because within that there is a presumption that we know everything about everybody and that also there is a turnover of business from year to year, so there are businesses which are in business now which we and others do not know about, so it is very difficult to answer that question. What we do have, though, is a targeted approach. In the context of hairdressers, if I may stay with that, we have got a suite of approaches. First of all, we are trying to raise awareness and get people to understand causation and be committed, because it is just commonsense. Part of that is for the local authority environmental health officers (who are the regulators in hairdressing of health and safety matters) who as part of the disease reduction programme are visiting about 20,000 hairdressers over the coming year. Initially they will be taking the bag of materials which will demonstrate the use of gloves and moisturising cream, which is an essential component, but later in the programme we will be turning to enforcement. We want to give everybody the chance first to see the light before those who will not then need to feel the heat.

**Q65 Lord Broers:** According to your evidence The Health and Occupational Reporting Network have reported a decrease in new cases of occupational asthma and work-related contact dermatitis in recent years. How robust are these data?

**Mr McDonald:** As you will gather from the answer to the first question I was asked, there is some variability in this data and trying to find the numbers from the generality of common, multi-causal illnesses is a real challenge for us. What we do is collect information from a fairly broad range of sources and carry out a semi-quantitative integration, which is a rather fancy way of saying it is a well-informed judgment, and we use the important lead source for each of those data and then use other sources to guide our interpretation. Because it rests so much on judgment, we have been very keen to make sure that this work is peer reviewed, so we had a workshop at the beginning of the revitalising health and safety statistics which started in 2000 to test the robustness of our approach. We subsequently then discussed the approach with the Government’s Statistical Service Methodology Committee and then there has been further external peer review as we have produced the figures. So our judgments on progress are published, along with our reasons for those numbers, as is the external peer review of what we are doing. What is important to us are trends rather than absolute numbers in what we do as an Executive. It is consistency over time which is the key criterion for us, for our robustness, and, as you say, THOR is the lead source for occupational asthma and contact dermatitis. We have asked Manchester University to do some further research and statistical modelling on these figures. The data are not perfect but they are certainly robust enough to support the general statements that we make about health and safety. Again, we are trying to look at this on a wider basis so we have a programme of evaluation that actually looks at the impact of our various interventions and assessing changes in good practice and changes in behaviour in our target groups. That way we hope to have a much more beneficial impact on the prevention of occupational asthma and contact dermatitis.

**Q66 Lord Broers:** The difficulty with trends is that it does not help us with international comparisons necessarily, does it, as we discussed with the previous witnesses, and you say the differences in data collection procedures make international comparisons of work-related allergy prevalence problematic, so what do you plan to do about it?

**Mr McDonald:** We are part of two EU working groups—the European Statistics of Accidents at Work and the European Occupational Disease Statistics—trying to standardise the position for work-related illness and injury. It is hugely challenging because we have all got very different systems of collecting statistics and we have very, very different cultural norms in terms of what is reported in workplace health. Whilst I welcome having established working groups, I do not think they are going to come to any useful conclusions any time quickly.

**Q67 Lord Colwyn:** So are you assuming that everybody who has contact dermatitis or asthma always goes to see a doctor?

**Mr McDonald:** It is a population-based survey. There is a real problem with these multi-causal illnesses and when somebody presents to the GP, the GP is not necessarily going to think of occupational health as the first cause, so that is why we rely on the self-reported survey which would have a tendency to over-report but at least gives us some confidence that we are picking up a reasonable indicator of the prevalence of illness.
Q68 Lord Broers: You have set yourself a target of reducing occupational asthma and allergic contact dermatitis by 10 per cent by 2008 from a 2004 baseline. What practical measures are you implementing to meet that target?

Mr Coldrick: That falls to the Disease Reduction Programme. What we have within that programme relevant to this inquiry are two projects, the respiratory disease project and the skin disease project, and we are targeting particular populations with the highest incidence. Just as I referred earlier to hairdressers, which is one of our target audiences, we are seeking to lead by working in partnership with all key stakeholders and influencers, including role models, i.e. in the case of hairdressing, to actually raise the level of awareness, get the understanding, gain the commitment, and achieve the behaviour change, and that is what the project is actually focused on. So it is a multi-stranded approach. It will be going through supply chain pressure, where possible, through trades unions’ support, where that is relevant, education, to catch the people as they enter the particular target sector, to make them aware as to what the right thing is to do, and then also to raise awareness by those already in that particular target sector, to get them to understand what they need to do and why they need to do it, and in most cases why it is relatively simple; it needs an attitudinal change. Finally, of course there is always the regulatory enforcement role. It is what you might describe as a best mix approach to those particular sectors.

Q69 Lord Cobyn: Do you have figures for the current level of industrial injuries disablement benefit being paid to employees from allergic disease and what sort of shape is the graph; is it rising rapidly? Could I also ask you at what stage is the employee labelled as having an allergic disease?

Dr Wright: The first part of that answer is the industrial injuries scheme essentially starts payments if disability or disablement is present on the 91st day, so the first 90 days are not covered at all. Then after that the level of payment will depend on the degree of disablement, and in most cases of people with allergic disease that is likely to be relatively low. You have heard earlier about the possibility of more severe disability through complicating asthma, for example, and there the permanent disablement figure will be rather higher. In general terms, given the fluctuating nature of the disease, the levels of payment are likely to be quite low. The standard for an 18-year-old and over at the moment who is 100 per cent disabled—that is really severely disabled—will be £127 a week, so we are likely to be talking about something substantially less than that, probably if there is a persisting disablement something of the order of 20 or 30 per cent, where you are talking of something around £25 or £30 a week. In a number of instances there will be, in essence, no permanent disablement but the potential to become disabled, and that may well fall below the 14 per cent threshold which applies and means that no payment is made. In terms of numbers, we are trying to get you some numbers. That may sound a bit lame but this is an old and rather small part of the benefits system and it is not on our computer systems, so we are trying to see if we can get you some figures and if we can we will send them to you, but the answer in general terms is that they are likely to be relatively low. As I have already explained, there are considerable restrictions by which people with allergic diseases are covered by the scheme and, of course, they have to meet the particular criteria of prescribed diseases that come within payment at all, so the numbers will be low. In general, numbers of people entering the scheme are staying roughly stable overall. We still have a situation that approaching 40 per cent are due to accidents. We are talking of no more than 10,000 new entrants a year and 40 per cent odd are due to accidents. 60 per cent are due to diseases. Vibration white finger and pneumoconiosis are the largest numbers; allergic diseases are very small numbers. There is no suggestion that there has been any great change in numbers, but that may not reflect the incidence of the disease because it is such a selective group that comes in. If we can get figures, and we have asked for them over the years, we will provide them to you.

Q70 Lord Broers: Could you give any details of what retraining schemes or other schemes are available to ease reduced earnings for these poor people who are unable to carry on their work?

Dr Wright: Reduced Earnings Allowance was in fact closed from 30 September 1990 so recipients either received it before that date or, if they are applying now, it is because they had an accident or a disease which started before that date. It is simply a payment towards loss of pay. I stress the word “towards” because it still exists for the reasons I have mentioned, and it was always capped, and in fact the current maximum rate for Reduced Earnings Allowance is £50.84 a week, so it is only a partial contribution. That is not to say that people who have a disability are not helped within the system. One of the things that happened when it was closed was that a parallel provision was made for anybody with a disability, so when Reduced Earnings Allowance was first introduced as a Special Hardship Allowance it only applied within the industrial injuries scheme. Disability Working Allowance, which is now part of the Employment Tax Credit, is available to anybody who has a disability which puts them at a disadvantage in the labour market, so those who
cannot receive Reduced Earnings Allowance would have access to the tax credit system to help them. In terms of saying programmes to help people, retraining and so on, that will be attached to Jobcentre Plus through the normal programmes for people who are unemployed or people who have a health condition and are on Incapacity Benefit, and you will be aware that there are proposals to change Incapacity Benefit and the extent and the amount of help that is offered to people on that benefit.

Q71 Lord Taverne: I want to ask about anaphylactic emergencies in schools. The Anaphylaxis Campaign is setting up a national training programme to educate school nurses on allergies because it feels the Government is not doing enough. What training is there for school nurses, and teachers for that matter, for dealing with such an emergency in a school?

Mr Wells: If I can take this question in a couple of parts, firstly just to answer it but then also to give you a bit of wider context as to how we would expect health services and educational and social care services to be thinking generally about work strategies that may help the Committee understand what we are about. First, as I am sure the Committee are aware, all school nurses are trained nurses and many are qualified children’s nurses, and this means that they will all have had some training and experience in the management of anaphylaxis. It is true to say that many nurses working in schools have access to training courses run by the Anaphylaxis Campaign, which is a well-regarded course, and to a certain extent although the way the question was framed is perfectly reasonable, I do not know that we should have a fear about them having to run a campaign or a course because many such organisations do just that. Lots of people will access courses run by the British Dyslexia Association or the National Autistic Society, so it is quite commonplace in fact for organisations with a particular specialism to design and run courses for the benefit of a whole range of professionals in different services, and that provides them with an income stream, so there is a value in that. In addition, it will be the case that primary care trusts and others will run courses which are relevant for nurses to access as well. It is in fact the case that any nurse who administers an immunisation in a school setting will receive anaphylaxis update training on an annual basis. That is a requirement of their own continuing professional development. School nurses who are involved in the delivery of such immunisations and other access treatments who have a particular knowledge will themselves be engaged in delivering training to school staff. I said I would give you a little bit of background context, if I might. There is a major government programme which is partly in answer to another question that you asked the earlier bodies about inter-departmental collaboration. The Every Child Matters Change for Children programme engages in a whole wide range of departments, and obviously as far as this particular inquiry is concerned the two departments, mine and the Department of Health, are critical. One of the key parts of the programme is to ensure that in every local area there is a Children’s Trust and that that Children’s Trust owns a children and young people’s plan. That plan is basically a commissioning plan, it identifies the key presenting needs in any area, it sets priorities for delivering better services to meet those needs and critically, in relation to my Lord’s question, there will be a local workforce strategy agreed by the various partners that are targeting a particular training initiative that is necessary, and indeed they may commission it themselves. The other thing I ought to just mention—and I am not sure if the Committee has got a copy—is we have recently produced some guidance called Managing Medicines in Schools. It is joint guidance from the Department for Health and the Department for Education and Skills. It sets out a framework in effect for ensuring that there is effective practice in schools to support children with a number of allergic conditions, including those who are prone to anaphylaxis, and there is guidance and advice in there as well which is of an information nature.

Q72 Lord Taverne: Thank you and what is the Department’s policy on the use of auto injectors by teachers and students?

Mr Wells: We would not want those to be used, as it were, just on the teacher’s judgment but where there is a child who is prescribed an Epi-pen or some other therapy, and there is an agreement between the parents and the school for a teacher to administer it in the case of anaphylactic shock, and the appropriate training can be delivered to that teacher, then we would support it. In other words, if we just step back again, the guidance I mentioned Managing Medicines has as part of its ambition that where we have children with particular medical needs that there is an individual health care plan, and if that plan identifies that a child carries (or one is held at the school for) an Epipen or adrenaline shot treatment, then there is no reason why the teacher should not deliver it. We would not advocate teachers just holding a stock of those “just in case” because they would not have the judgment, we believe, to decide whether or not the child in front of them is suffering from that shock or some other need.

Q73 Chairman: In your answer you outlined the training for school nurses and, to a certain extent, for teachers, but I wonder what ongoing audit is there to make sure that they do have appropriate level skills because we all know that you can take people into a training programme but that they have learned to apply those skills is not necessarily the case.
Mr Wells: No, that is fair comment. The answer to the question though has to be made through local judgment because, to a certain extent, it is rather impossible for a central department to make a judgment as to what is the best way of developing the school's workforce in 33,000 different settings. What we are expecting every school to have are a number of policies, including policies which are related to the support for children with medical conditions, medical health needs, and then to secure appropriate training for their staff on a needs basis. There is a significant amount of money at head teachers' disposal for just that purpose, to ensure that they are developing their school workforce to meet a wider range of demands in addition to teaching and learning, which is obviously their core business. Is does rather depend on the locality.

Q74 Chairman: Is there a requirement for those skills to be assessed regularly because you could take a school and have people trained, the boxes are ticked, you then have a child who has an anaphylactic reaction, but although the boxes have been ticked the skills are not there at the time?
Mr Wells: I would certainly agree that the key thing for us is to ensure that there is a depth of understanding of the need and the risk that the school is trying to address. We are very, very keen to ensure that people do not just have tokenistic strategies, tokenistic policies, against which they tick boxes, indeed to that extent we are rather against model policies because they tend to weaken people's engagement in understanding what particular risk they have in their setting and indeed to ensure there is a wider ownership. In fact schools have got a number of statutory duties which we believe are necessary for that child to have the necessary training. It is a head teacher's responsibility to ask themselves whether the cadre of teachers and support staff they have is capable of delivering across a broad range of issues, not just allergy, if I can say so.

Q75 Lord May of Oxford: I have a question which, in a sense, is a continuation of this but in the specific context. If another of DfES's good schemes goes well there is one category of an anaphylactic shock which is going to be on the marked increase, I would guess, namely the programme on transforming school food, replacing unhealthy snacks with healthy foods. We all know from the tabloids it is having what we might call "teething problems" with concerned parents turning up to feed their kids junk food through the fence. But supposing it does go well, then the snacks kids eat are more likely to be the sort of thing I have just been eating at the morning break, seeds and nuts, which is one of the major causes of worry in this area. Specifically, against the background of the discussion we have just had in general, to what extent do you see a particular need to really ramp things up a little bit and address very seriously some of the questions which have been asked, not just about ticking boxes of procedure, but making sure people really are on key for this?
Mr Wells: There are a few things, if I might. First of all, we would expect the parent of the child who has the particular allergy to ensure the school understands that the child has that particular allergy. If I can refer back to one of the answers I gave earlier, that is then the starting point for agreeing an individual healthcare plan for that child.

Q76 Lord May of Oxford: None of these kids may ever have eaten a nut or a seed.
Mr Wells: If I can move on, they are going to have eaten one once. If I can at least work on the assumption that the vast majority of parents are likely to become aware of a child's allergy before a school is presented with the reaction to not knowing. The first thing is to make sure the knowledge is shared and the knowledge is understood by a wide group of adults within the school setting so that if they see the incident, if they see the reaction, they can react. The second thing, of course, is to make sure that teachers generally are aware of the likelihood that certain nuts and other foodstuffs can indeed give rise to a shock. I think it is important to recognise, although I respect the question, that nuts are not the only likely cause of anaphylaxis, eggs are, cows' milk can be, fish can be, indeed I heard a reference earlier on to latex, latex can be; you cannot ban everything that could give rise to a shock. What is important is that, first of all, there is a clear understanding that a child is at risk, that the child itself understands it is at risk, and that adults are looking for incidences that could give rise to it. In that sense, we are very clear as a general nature of training and updating teacher’s knowledge that must be part of the school's expectation of itself and, indeed, that we are helping schools understand the need for good hygiene generally because in extreme cases, as of course you will know, very allergic children could react to traces of allergens which have just been left on furniture, et cetera. It is a rich question which requires a rich answer. I think, and we are trying to make sure there is a good level of understanding across the piece.

Q77 Lord Colwyn: It is a question I probably should know the answer to. If a child is given a shot with an epipen and, in fact, they are just suffering from a temporary obstruction, apart from an increase in heart rate, does it cause any harm?
Mr Wells: I am not competent to answer the question. My understanding is in general no, and in general, in any case, back to the answer I gave earlier, even where
we do have a child where there is an agreement that the use of an epi-pen is advisable is, there is also a requirement that a medical service is called instantly. I think where we are being more careful here is that we do not want to encourage the general use of that treatment amongst untrained folk, and that is after all what teachers are. My understanding is that what I am saying would also apply to, for example, doctor’s receptionists. They would not just use it without some prior knowledge of its likely success. In relation to your particular question, I am afraid I do not know the answer to the extent if it could cause harm.

Chairman: If I might intervene, I think it is dose-related so that if you give an overdose, and that would happen if you used the wrong pen, the wrong dose for a particular child, then you certainly could run into problems, possibly cardiac problems too. They are not things just to be taken lightly.

Q78 Lord Colwyn: Would a school have supplies of different pens with different doses?
Mr Wells: No, it is child-specific.

Q79 Viscount Simon: Again, just going a little bit further, what procedures are currently in place to help students go about their everyday life with allergic diseases in schools and universities?
Mr Wells: If I can take the university bit first, if you do not mind, because it is a relatively short answer. They are adults and there maybe a number of different services which would help them manage their own conditions. To a certain extent, we would expect the arrangements that would be made within the university to mirror those you would expect to find in the workplace. There is clearly an expectation amongst adults that they would carry their own treatments and they would be aware of their own condition. Nonetheless, universities are large institutions, they will have access to health services, they will want to make sure they are promoting the well-being of their students, and they may very well have their own arrangements. It is not something that we regulate, however, or establish from the centre. As far as schools are concerned, there is a relevance to the answer I just gave. As a child becomes older it becomes an expectation that they will become more able to hold and indeed administer their own treatment and every support should be given to that. We would be looking to school nurses and other health professionals to work with the child, the parent and the school to ensure that as a child is able to take greater control of their own health, they are enabled to do so. That might, for example, mean helping a child know where it can store certain medicines. Some medicines are controlled, as, of course, you will know. My general point comes back to an answer I think I have given twice already, so apologies, that we would expect every school, whether the child is five, 15, 19 or indeed younger than five, every school to have an individual care plan for that child, and there is an agreement updated periodically to make sure that everybody knows how to deal with that case on its own terms. It is quite critical, of course, that the family is involved in these circumstances themselves. It is quite critical to recognise that some parents will encourage a greater level of school involvement in their child’s health than others. Indeed, some might be actively resistant to the school being involved in the delivery of the basic treatments et cetera. We have to try and respect all those different shades of opinion against a clear understanding that there is a health and safety requirement on all schools, just as there is in any other public building, and there is a duty in the Education Act to promote well-being.

Q80 Viscount Simon: Going on one step further in this particular aspect, are other students or undergraduates made aware of the allergic conditions that some other students or undergraduates might have?
Mr Wells: Not automatically.

Q81 Viscount Simon: The Royal College of Paediatrics and Child Health has expressed concern with the fact that hay fever sufferers under-perform quite regularly in their end of term exams in the summer. Is there any particular reason why these exams are held at the peak of the hay fever season? Should they not be changed?
Mr Wells: I think you have asked a question that is asking me to undo centuries of history, and I rather suspect the answer is no.

Q82 Viscount Simon: Not to mention the seasons of the year!
Mr Wells: It is historical; there is a whole host of different reasons. Accepting that it is a serious question, seriously put, to which I do not have an answer which is likely to change the examination timetable, with the greatest respect, I think what is critical, from an educationalist’s point of view, is that we are, first of all, very, very clear that a teacher’s job is to differentiate the way in which they teach across the year to help to suit the child or the young person’s particular circumstances and, secondly, that when it comes to exam times of course, young people do have the right to particular support if they have a condition which is going to seriously affect their likely performance. The extent to which universities or schools make sure that they use well ventilated rooms, not right by a source of pollen, I guess is a local issue which I cannot regulate, sorry.

Q83 Chairman: I wonder if we can move on and possibly, Ms Kirkham, a question for you relating to housing health and safety. I am wondering how the Housing Health and Safety Rating System regulations support local authority officers dealing
with environmental health issues which affect tenants who suffer from allergies?

**Ms Kirkham:** If I may try and answer the question in two parts. First of all, very briefly I will try to explain how the Housing Health and Safety Rating System operates and then how local authorities would implement it in relation to different parts of the rented sector. In terms of the Housing Health and Safety Rating System itself, it is a series of 29 different hazards that you could find in domestic premises and which would impact on the health or safety of residents. If you simply look at the 29 hazards as prescribed in the regulations, none of them specifically relates to allergies, so allergy does not appear on the face of the regulations. However, when you look at the operating guidance which supports the implementation of the Rating System, there are four hazards where the health outcomes specifically relate to the possibility of allergic responses by the occupants of the building. Of those four different hazards: the first relates to damp and mould growth, which specifically references the impact of mould spores and dust mites; the second is in relation to fuel-combustion products where the impact of nitrogen dioxide and sulphur dioxide is also referenced; the third relates to volatile organic compounds and the potential allergic responses, and the final one is the hazard which covers domestic hygiene, pests and refuse, which again picks up on allergic responses some people might have to pests. Therefore, any local authority officer engaged in the operation and the implementation of the Rating System has their attention drawn to the possibility of allergic responses in relation to specific housing conditions. The system was newly brought into force in April this year. It is a much better tool than its predecessor, the old fitness standard, in helping assess the health and safety impacts of many aspects of a home on its occupants. In particular, those implementing the Rating System in terms of what action they might take, are particularly asked to look at the circumstances of the individual occupant. It guides people to differentiate between people in different circumstances. For example, somebody in a home where there was evidence of mould, and therefore the possible hazard of mould spores, may take different action if the occupants of that home were healthy young people as opposed to somebody who may be asthmatic. That is very clearly set out in the guidance. In terms of how that impacts on specific people and specific conditions, if we take the private rented sector, then a local authority would only become engaged in response to a complaint from somebody living in that property. They would then inspect the property, determine what hazards were present, and determine the severity of those hazards in relation to the likely health outcomes. The hazards are graded in terms of categories. Category one and category two hazards have the more severe health or safety outcomes for people. Where you have a category one or a category two hazard the local authority is able to take action of differing degrees of severity, depending how you look at it, from the simplest, which is simply serving a notice on the person responsible for that building, called the Hazard Awareness Notice, pointing out there is a hazard and what action might be taken to remedy that, going right through to a prohibition order which says all or part of that building should be closed.\(^2\)

**Q84 Lord Soulsby of Swaffham Prior:** I think the final question is on your evidence, where you state that there would be cost implications for local authorities and the building industry if control provisions were extended beyond those in Building Regulations or HHSRS guidelines. What are these?

**Ms Kirkham:** Again, if I may give an answer in two parts. They are two issues related to costs: one would be extending the scope of either Building Regulations or the Housing Health and Safety Rating System to cover a much wider range of potential allergic responses than the current regulations and guidance cover. If I take the Rating System, that is an evidence-based system and those assessing it are dependent on the evidence that is available which determines a very clear linkage between a particular problem in the building and the likely health outcome. The evidence for a number of other potential allergic things is much weaker and we do not have that very strong base of evidence in order to help people come to a judgment. A cost would be in trying to establish and deliver that much broader and wider evidence-base. That would be the first point. The second would be a cost in relation to taking action. In terms of, for example, the Building Regulations the provision of adequate ventilation is a key aspect of reducing the possibility of health outcomes from mould, and an aim of the present regulation is to try and maintain not more than about 70 per cent humidity in the building, which tackles mould spores. To tackle dust mites, you would have to get humidity down to something like 50 per cent. Ventilation systems to do that would be more expensive to implement, it is something of the order of £1,000 to £1,500 per property. In addition, the more complex the ventilation system, the greater energy use of that system, and therefore there are other implications in terms of the Climate Change Agenda by having

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\(^2\) The powers of local authorities to take statutory enforcement action following HHSRS assessments are available in respect of owner-occupied properties and those in the control of private landlords. In the case of properties in the control of local authorities and registered social landlords, HHSRS assessments form part of the Decent Home standard, which requires a property to be free of category 1 hazards.
systems which consume considerable amounts of energy.

**Q85 Lord Soulsby of Swaffham Prior:** Is there any system of including into new buildings guarantees against allergic problems lasting a period of years, before the house or the building, whatever it is, gets into operation? It may not be identified at the time when it is built, opened and occupied but due to damp and mould and the build-up of various things, due to poor building practice or poor architecture, it would become apparent in three, four or five years time. Is there anything in the Building Regulations that would look at that sort of situation?

**Ms Kirkham:** As far as I am aware, Building Regulations will not specifically pick up those things if they occur later than 6 months after completion. If it was a significant problem, as all new homes are covered by a guarantee, it is a question of whether a severe problem would be noted and the occupier would be going back to the builder to seek redress for whatever that particular problem was. For existing buildings, you do have the Housing Health and Safety Rating System but, again, it would be going back to the builder to seek redress for whatever that particular problem was. For existing buildings, you do have the Housing Health and Safety Rating System but, again, it would be dependent on a local authority officer being brought in to look at that property to pick up whether there are any specific problems.

**Q86 Chairman:** If you are talking about a ventilation scheme costing about £1,000 per property, is that to install it?

**Ms Kirkham:** That is to provide the additional ventilation over and above what is normally provided to reduce humidity to below 70 per cent.

**Q87 Chairman:** If you compare that with the cost of a hospital admission, that seems to be very cheap.

**Ms Kirkham:** On an individual property basis, yes, clearly it is a relatively small cost, but to put that into every single property where not every single property is occupied by people who would need that additional ventilation, there are other ways people could do that, by installing dehumidifiers themselves which, again, are perhaps more cost-effective.

**Q88 Chairman:** Dr Wright, you were talking about those people who are eligible for a benefit and I wondered how the information that you have over people eligible for benefit, and indeed receiving benefit, feeds into the information to the environmental health officers in relation to the workplace in which they are working because if their exposure is decreased then the severity of their allergic response will decrease.

**Dr Wright:** The Industrial Injuries Advisory Council advises us on the scheme, both the future of the scheme and the administration of the scheme and figures, such as we have them, are published and are looked at regularly by the Council. The Council has a representative there from the Health and Safety Executive who can feed back and it can be fed through the Executive, as I understand it, to environmental health officers insofar as they carry out health and safety inspections. I am looking at my colleague and fortunately he is nodding.

**Q89 Chairman:** It strikes me that you could have a situation of someone claiming benefits with an ongoing allergic-related disease and if there is nothing done to modify the workplace or feed back to the workplace, you are never going to decrease that morbidity.

**Dr Wright:** There will be a feedback to the workplace if we have a situation where somebody is claiming and is at work because we would approach the employer, as part of assessing the claim, to ask the employer their perception of what has been going on, what the exposure is, and so on and so forth. The assessment process obviously involves a claim from the individual, and if the individual is still at work in the workplace where the exposure occurred, then the employer’s view would be sought. The employer would surely be aware that the allegation that occupational asthma was occurring in his workplace had been made.

**Q90 Lord Colwyn:** You mentioned your four main hazards from a list of 29; can I ask you whether electromagnetic toxicity was included in that list at all?

**Ms Kirkham:** I do not know. The guidance manual is a relatively thick document so without looking back at it I would not be able to say. I do not think it was, from my recollection, but we would have to confirm that to you.³

**Chairman:** Can I thank you all for coming and helping us by giving this evidence as we explore the different issues before us. I would like to invite you, when you go away from here, if there are other issues which you would like to draw to our attention, you are welcome to send them in writing. In the light of our discussion they will be drawn to the Subcommittee’s attention, and written material, like oral evidence and other written evidence, will be available to the Committee and published alongside the transcript. Thank you very much for coming today.

³ In the Housing Health and Safety Rating System, electromagnetic toxicity is included under “Radiation”, which covers threats to health from radon, microwave leakage and electromagnetic fields.
Supplementary letter from the Department for Work and Pensions

When Mr Patrick McDonald, Mr Steve Coldrick and Dr Peter Wright appeared before the Committee on 22 November 2006, they promised to provide you with written supplementary evidence, which is enclosed.

Data on the number of people claiming Industrial Injuries Disablement Benefit suffering from allergic diseases is included in Annex A. As Dr Wright explained at the time, the benefit has not been computerised so that data is neither as complete, nor as promptly available as for other benefits. In addition, the numbers claiming for allergic disorders are low, in part as most do not cause significant disability for at least 90 days and so reach one of the criteria for disability.

In Annex B, you will find additional information from HSE in relation to absences from work due to allergic conditions.

### Annex A

#### Table 1

IIDB CASELOAD FOR “ALLERGIES”

<table>
<thead>
<tr>
<th>Allergy</th>
<th>March 2003 All</th>
<th>Working Age</th>
<th>March 2004 (Provisional) All</th>
<th>Working Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extrinsic Allergic Alveolitis (B6)</td>
<td>130 P</td>
<td>90 W</td>
<td>130 P</td>
<td>90 W</td>
</tr>
<tr>
<td>Allergic rhinitis (D4)</td>
<td>2,150 P</td>
<td>1,120 W</td>
<td>2,140 P</td>
<td>1,180 W</td>
</tr>
<tr>
<td>Asthma (D7)</td>
<td>4,230 P</td>
<td>1,150 W</td>
<td>4,330 P</td>
<td>1,280 W</td>
</tr>
<tr>
<td>Contact dermatitis (D5)</td>
<td>3,880 P</td>
<td>1,740 W</td>
<td>3,900 P</td>
<td>1,840 W</td>
</tr>
</tbody>
</table>

**Notes:**
- Data shows claims/cases recorded as shown, there may be other allergy cases not included in the above.
- All data has been rounded, therefore figures may not sum to total.
- **Table 1** Caseload figures are based on a 10 per cent sample and are subject to a degree of sampling error and should only be used as a guide.
- Caseload figures for March 2004 are provisional only and are subject to change.
- Working age has been defined as males below 65 and females below 60.
- Pensionable age has been defined as males 65 and over and females 60 and over.

### Annex B

The indirect costs of allergic diseases are potentially huge. How does absence from work due to allergic conditions compare to that of other conditions, for example back problems, mental illness or repetitive strain injury?

Additional information from HSE

There is a wide range of estimates for total working days lost due to these conditions. However, stress, and musculoskeletal disorders, account for the largest proportion of the total number of working days lost due to work-related ill health, according to the Self-reported work related illness survey.

**ESTIMATED DAYS (FULL TIME EQUIVALENT) OFF WORK DUE TO A SELF-REPORTED ILLNESS CAUSED OR MADE WORSE BY WORK, BY TYPE OF COMPLAINT, 2001–02**

<table>
<thead>
<tr>
<th>Type of Complaint</th>
<th>Sample cases</th>
<th>Days lost (millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Central 95% C.I</td>
</tr>
<tr>
<td>Bone, joint or muscle problem</td>
<td></td>
<td></td>
</tr>
<tr>
<td>—mainly affects the back</td>
<td>380</td>
<td>5.5</td>
</tr>
<tr>
<td>Breathing or lung problem</td>
<td>86</td>
<td>1.1</td>
</tr>
<tr>
<td>Skin problem</td>
<td>30</td>
<td>0.2</td>
</tr>
<tr>
<td>Stress, depression or anxiety</td>
<td>637</td>
<td>12.9</td>
</tr>
</tbody>
</table>

HSE does not have any data on the extent to which allergic disease in general gives rise to work absence. It does have information on the extent of sickness absence due to all types of self-reported work-related respiratory diseases from its population based surveys. An estimated 1.1 million working days were lost in 2001–02 from work-related “breathing or lung problems” but the relatively small number of cases on which this estimate is based means that the true extent could range between 700 thousand and 1.6 million cases. The reporting network of occupational health trained GPs within the THOR scheme mentioned in HSE’s evidence is collecting information on sickness absence and HSE anticipates that it will be able to provide information on sickness absence specifically arising from work-related asthma and contact dermatitis when it has been running for longer.
Memorandum by Professor Peter Burney, Professor and Hon Director Social Medicine and Health Services Research Unit; Deborah Jarvis, Senior Lecturer; Seif Shaheen, Asthma UK Senior Research Fellow Respiratory Epidemiology and Public Health, National Heart and Lung Institute, Imperial College

1. Definitions

1.1 Allergies are conditions that arise from immunological responses that are not of obvious benefit to the person experiencing them. The majority are mediated by immunoglobulin IgE. This is a normal part of the immune response which is of particular importance in protection against parasites. In a proportion of people this is too easily raised against other foreign proteins that are not normally harmful. These are mostly associated with airborne proteins from pollens and animals, including the microscopic house dust mites. These proteins are referred to as allergens. In children the response is often first seen against foods, though these often fade out as the children grow, though if they persist they can lead to severe reactions.

1.2 There are several clinical conditions that are more common in those who raise this type of response to common airborne allergens. These include rhinitis (hay fever), asthma and eczema. These are often known as “atopic” conditions. All these conditions are also found in people who do not appear to have an increased production of IgE, and not all people who have raised IgE levels have clinical consequences. The form of the disease that is not associated with IgE is often referred to as “non-atopic” or “intrinsic”. “Intolerance” is often used to indicate a non-immunological response particularly to a food, or is used when it is not known if there is an immunological basis to the condition or not.

1.3 In what follows we shall refer to raising IgE against specific allergens as “sensitisation”.

2. Increasing Prevalence

2.1 An increasing prevalence of asthma was first noted in studies of Birmingham school children, starting in the mid 1950s. Between these studies and the mid 1990s almost all studies that measured the prevalence of asthma or wheezing in children in the same population on two or more occasions found an increase. The findings were very consistent and amounted to an estimated doubling of the prevalence approximately every 14 years. There was less evidence on other atopic conditions but where there was evidence these also seemed to be increasing at the same rate.

2.2 There was debate as to the extent to which this was due to changes in diagnosis or reporting. From the early 1980s doctors have been encouraged to make the diagnosis of asthma and prescribe treatment, though this would not explain the increase in wheeze. Subsequent evidence has shown that the prevalence of sensitisation has also increased. This would in part explain the increase and confirms from a more objective measure that the increase is likely to be real.

2.3 Since the 1990s the recorded increases have been less consistent and for the first time there are some studies that have shown a decrease in prevalence in children. The evidence is not, however, entirely consistent. In the UK there was a significant fall in the prevalence of self-reported asthma and rhinitis, but not eczema, among 13–14 year olds. There was, however, no fall among 6–7 year olds. There are no measures of sensitisation.

2.4 The UK has a high prevalence of disease when compared with other countries. This is true for reported disease, symptoms and diagnoses and for markers of disease such as specific IgE to common allergens and airway responsiveness (a marker of asthma). Other places with a high prevalence include other English
speaking countries such as the USA, Canada, Australia and New Zealand, possibly indicating a common cultural origin.

2.5 In developing countries there is a much lower prevalence of allergic disease in the poorer rural areas. Such evidence as there is suggests that this is not due to a lower prevalence of sensitisation (IgE to specific allergens) though it is accompanied by fewer positive skin tests. Although the ISAAC study shows little association between per capita gross national income and the prevalence of rhinitis or eczema in children, very high levels of asthma are only found in the moderately rich or rich economies and the allergic forms of the disease (with positive skin tests against allergens) are also found more commonly in the richer countries.

3. **Future Trends**

Although the more recent findings in children are encouraging, the prediction is that the problem will become worse still over the next decades. It is commonly believed that atopy is less common in older people than younger people because as they age people are less able to mount allergic responses. This interpretation is, however, based on cross-sectional studies that have examined younger and older people at one time. Longitudinal studies show little evidence that atopy disappears as adults age. This means that the prevalence of atopy and probably allergic diseases in older people is likely to increase over the coming years, reflecting the longer term effects of the increases in atopy and allergic diseases that were reported for children during the late 20th century.

4. **The Causes of the Epidemic**

4.1 We have yet to discover what changes in western lifestyle and environment have been responsible for the rise in allergy and asthma over the last four decades. Clarification of the factors responsible should provide opportunities for primary and secondary prevention. The reason why the UK, along with other English speaking countries, has one of the highest rates of asthma and allergies in the world is also unknown. One unsolved puzzle is why only a proportion of individuals with atopy (as measured by skin test positivity or specific IgE in the blood) develop atopic disease (asthma, hayfever, or eczema). Some patients with asthma are not atopic, and the causes of this condition may be different to those for allergic asthma.

4.2 **Hygiene**

Epidemiological research over the last 10 years has been dominated by two main hypotheses. The hygiene hypothesis, proposes that the rise in atopy has occurred because exposure to protective infections in early childhood has declined, through reductions in family size and other changes in lifestyle. To date, there is no definitive evidence to support this and in parts of rural Africa, which are presumably “unhygienic” in this sense, there is no problem in raising IgE to environmental allergens such as grass. Nor are there convincing data to suggest that vaccinations, antibiotics, or changes in bowel flora have been responsible. Whilst the apparently protective effects of growing up on a farm might be explained by infections resulting from animal contact, there are other possible explanations. Despite the lack of convincing epidemiological evidence, research is underway to see if giving Mycobacterial vaccines might reduce the severity of allergic disease, though the long-term safety of manipulating the immune system in this way is uncertain. The jury is still out on whether parasite infestation reduces symptoms of allergy and asthma; one recent trial has failed to support this idea.

4.3 **Diet**

Evidence that the rise in asthma has occurred because of an increase in intake of n-6 relative to n-3 fatty acids has been unconvincing, and trials of fish oil supplementation (rich in n-3) have been disappointing. Alternatively, it has been proposed that the rise is attributable to a declining intake in dietary antioxidants. However, epidemiological evidence in support of this hypothesis is conflicting, and recent trials of vitamin and selenium supplementation in adults have been negative. Given the complexity of nutrition, and the many ways in which diet has changed in recent decades, further research is required to investigate the possible role of other nutrients and to see whether food-based interventions might hold more promise for secondary prevention. We know less about the role of diet in childhood. Birth cohort studies in the UK are underway to study the possible role of nutrition in pregnancy and early childhood to see whether this might lead to strategies for primary prevention.
4.4 Other risk factors

4.4.1 In recent years many epidemiological studies have identified obesity as a risk factor for asthma in children and adults. At present we do not understand what underlies this link, but it seems unlikely that the relation is causal. Obesity is, however, associated with poorer lung function and this is a concern for those with asthma. It is clear that the obesity epidemic is a major public health problem in the UK which needs to be tackled for many health reasons other than asthma.

4.4.2 There is no evidence that the rise in allergy can be attributed to increases in allergen exposure in the home, nor that house dust mite exposure causes asthma. Trials of dust mite avoidance in the home have been unsuccessful in reducing asthma symptoms and, paradoxically, may even lead to an increase in allergic sensitisation in children.

4.4.3 Smoking is associated with wheezing in adults, and passive smoking and maternal smoking in pregnancy have been linked to asthma in children. However, smoking is unlikely to increase sensitisation and may even reduce sensitisation to some allergens. Air pollution in general has been declining sharply over the time of the increase in allergies, though some have speculated that the increase in pollution from traffic sources may have been responsible. There is little direct evidence for this.

4.4.4 Evolving areas of research include understanding links between paracetamol, a commonly taken pro-oxidant, and the pattern of disease in women and how this is influenced by sex hormones. There are reports of increased asthma in women who use hormone replacement therapy and in those with evidence of gynaecological morbidity.

5. The Consequences of the Epidemic

5.1 The likely increase in allergy in an aging population raises several issues relating to public policy apart from the obvious need to provide adequate services. Those who are allergic are more vulnerable in many ways and with almost half of the population now being at least to some extent sensitised to common allergens, this needs to be taken into account when setting standards in several areas.

5.2 Treatment

Although treatment is not the subject of the current review it is important to point to the evidence that good treatment may also be preventive of later problems. One of the primary goals of the treatment of asthma is the maintenance of good lung function. One of the most important treatments for asthma is inhaled steroids which have been shown in randomised controlled trials to reduce symptoms and improve quality of life. Long term randomised controlled trials to look at their effect on lung function over a long period of time are unlikely to be performed as their efficacy in the short term renders the use of “placebo” over a prolonged period unethical. An observational study of young adults has however shown that over a period of eight years regular use of inhaled steroids is associated with a lower rate of lung function decline especially in those who have evidence of an allergic aetiology (raised total IgE) for their asthma.

5.3 Indoor environment and home ventilation

5.3.1 Most adults spend substantial amounts of their normal day indoors. Good quality indoor air is imperative for good respiratory health although randomised trials to demonstrate this clearly are lacking. Adults living in homes with mould report more asthma symptoms, particularly if blood tests show they are allergic to mould species. In the UK we have shown that the use of gas for cooking is associated with more symptoms particularly in women, particularly in those who are allergic to allergens and particularly in those who do not ventilate their homes by using doors and windows. People who regularly open their windows at night also have lower levels of dust mite allergen. Good ventilation is required for good respiratory health and this may be a particular issue for those who are allergic. The current emphasis on household energy efficiency may lead to lower standards of ventilation and the implications of this need to be reviewed.

5.3.2 Unpublished work suggests that people with atopy who are exposed to cats have more reactive airways (bronchial hyper-responsiveness), most likely because of worse “airway inflammation” than those who are not atopic, even if they are not specifically sensitised to cats. As cat allergen is very pervasive (it is found in homes that do not own cats) this raises a difficult problem of how to deal with exposure of an increasingly allergic population to general allergens.
5.4 The outdoor environment

Currently air quality standards are set in relation to their effects on cardiovascular morbidity and mortality, where the effects are very clear. Despite common beliefs the effects of air pollution on asthmatic patients are not clear. There is some evidence that allergen in air may be important for patients with asthma. Mortality from asthma in the summer months, when allergen levels may be high, is high among young asthmatics who have the highest prevalence of allergy. Rarely major outbreaks of asthma have been observed when levels of allergen in the outdoor air are very high. There is further evidence that there is a continuous low level of effects from allergens in air, but the nature of these allergens is uncertain. Many of these would probably be very difficult to control, but some are likely to be from man-made sources and need further investigation.

5.5 The work environment

5.5.1 It is estimated that around 10 per cent of patients with asthma have asthma that is of occupational origin. With an increasingly allergic population this is likely to be an increasing problem. It may be compounded by the fact that many processes are now carried on in small firms where problems may be more difficult to identify and where there is less likely to be a professional occupational health service. Almost 3 per cent of young adults in one study said that they had had to change a job because of breathing problems at work.

5.5.2 There are occupations that cause respiratory problems that are due to exposure to irritants. These are not specifically associated with allergies but may be important as some of the exposures are common and found in dispersed workforces such as cleaners.

5.5.3 The recent banning of smoking in the workplace will certainly have made the workplace more tolerable for allergic members of the workforce and is extremely welcome.

5.6 Diet

5.6.1 The role that diet has in possibly contributing to the asthma epidemic has been outlined above. This effect is still controversial but may be important not just in the causes of allergy but also in maintaining the health of those who are allergic.

5.6.2 Less controversial is the problem that food allergens pose to those who are sensitised to them. Food allergy has important consequences for those who suffer from the condition, for their families and for food manufacturers, and caterers including, for instance, those providing school meals. This is in part because the consequences of ingesting hidden allergen can, on rare occasions, be catastrophic. The steady increase in the rates at which people are admitted to hospital for food allergy and anaphylaxis probably reflects the general increase in allergy in the population.

6. Priorities for Further Research

6.1 Monitoring of trends

It is important to know what the trend is in sensitisation, particularly in children and among the elderly. It is also important to know more of the effects of allergy among the elderly.

6.2 Early life environment

Evidence is accumulating to implicate the environment in utero and infancy in the aetiology of asthma and allergy. A number of birth cohort studies are under way which will hopefully shed further light on causes of asthma and allergy which operate during pregnancy and postnatally. The ultimate goal is to devise strategies to modify the early life environment in order to prevent asthma and allergy developing in the first place.

6.3 Gene-environment interaction

One promising way forward in epidemiology is to identify interactions between genes and environmental/lifestyle risk factors. If relevant gene variants can be shown to modify the effect of such risk factors this provides more compelling evidence that the risk factors are causing allergy or asthma.
6.4 Occupational asthma

A priority area of research should be occupational asthma. This is under-recognised and makes a substantial contribution to the total burden of adult asthma. Furthermore, it is amenable to prevention and “cure”—removal of relevant allergens from the environment will lead to improvement in asthma symptoms.

6.5 The effects of outdoor allergen

More needs to be known about the effects of outdoor allergen, its sources and the effects that it has on sensitised individuals.

6.6 Adolescence

For many children, asthma seems to “go away” during adolescence, for reasons which are unclear. We need a better understanding of the natural history and prognosis of asthma through adolescence, a time when physiology and lifestyle change markedly. Improved understanding of “remission” may lead to opportunities for prevention.

6.7 Gender

The relation between sensitisation, disease and gender is still poorly understood as are the consequences of increased exposure to endogenous, therapeutic (oral contraceptives and hormone replacement therapy) and environmental oestrogens.

6.8 Trials

Definitive evidence on whether risk factors are causes of asthma and allergy can only come from randomised clinical trials—the setting up of a respiratory/allergy trials network in the UK, or more widely, would facilitate recruitment and faster completion of trials.

7. Further Reading [not printed]
food allergy in infancy to asthma in the pre-teen years as the “allergic march”. I wonder if you could explain to us what are the mechanisms of the allergic march and how we can halt it.

Professor Warner: It is a clinical observation that many infants who develop food allergy and eczema go on subsequently to have asthma and allergic rhinitis and there appears to be a progression from one disease to another which has been termed the “allergic march”. Whether having eczema per se makes you more likely to go on to have asthma I think is not clear because it is more probable that there are common underlying factors that predispose you to both conditions, but for some people they only inherit and are exposed to environmental factors that predispose to one and not the other. At the moment we are still unclear about all the mechanisms that are involved in the generation of the individual diseases within that allergic march, but one thing we can say for certain is that if an infant starts with evidence of allergy there is a very high probability that they are going to show one or more problems associated with that.

Q93 Chairman: You suggested in your answer that there are certain unknowns about the origin and progression of allergic disease. I wonder if you could highlight where you feel the main unknowns are and how we could find out about them.

Professor Warner: I think we have got a long way in identifying the genetic components. What we do not know is how genetic factors interact with environmental factors in individuals, to lead to disease, so it is focusing on how the geno-type is influenced by the environment to create the clinical manifestations.

Q94 Chairman: Do people suffering from allergic disease ever lose their sensitisation?

Professor Burney: Not once people have become adult. People tend to accumulate their sensitisation during childhood and early life. One of the things that is noted in cross-sectional surveys is that older people have less allergy, but the important thing is that if you follow the same people as they get older they do not generally lose their allergies. The explanation for the lower prevalence of allergies in older people is that people who were born towards the beginning of the 20th century tended to get less allergy during their early years, so they are people who never became very allergic rather than people who have lost their allergies. The importance of this is that it helps us to predict what will happen to the allergic epidemic that we have at the moment and how soon it will start to subside.

Q95 Lord Taverne: Just following that up, you mention in your paper that 80 per cent of asthmatics tend to lose their allergy during puberty and then start recovering some of it again. Have you any idea why that might be?

Professor Burney: I do not think that I said that. That might be from someone else’s paper. Maybe.

Professor Warner: Perhaps I can add a bit to that. There are infants who show various food allergies who lose their allergies once they get to four, five, six years of age. However, once they have reached about seven to eight years of age, if they retained the allergies then in general they persist for evermore and they might actually increase the range of allergies. However, even amongst those who lose sensitivity, say, to egg or to milk, which is very common in infancy and less common in older children, they are still at higher risk of developing new allergies to inhalants like house mites and pollens. As far as adolescence is concerned, yes, there is no doubt that particularly boys tend to improve their asthma and many of them lose their symptoms, although the majority, if you do sophisticated lung function tests, still show an abnormality and many of those come back in their late twenties with a recurrence of problems. We think part of that is physiological in that the lungs are at their best in early adulthood and, as they begin to lose some of their elastic recoil with age the problem shows itself again.

Q96 Lord Taverne: The suggestion seems to be that there is still a net decrease after puberty. Only some then develop the allergies again. Is that right?

Professor Warner: It is always very difficult. The problem is that paediatricians lose sight of their patients. I think it has been said that they are more likely to outgrow their paediatricians than their asthma. From the longitudinal studies a pretty high percentage, even of milder asthmatics who lose their symptoms in adolescence, by 30 have had a recurrence of symptoms, not necessarily as severe as they were in childhood but certainly they are wheezing again and they are requiring some treatment for their asthma.

Q97 Chairman: Are there any specific measures you feel should be recommended routinely for children to prevent the development of asthma and eczema?

Professor Warner: I would love to be able to say that there were measures right now that one could recommend but there is none other than saying, “Do not smoke in pregnancy”, and, well, “Do not ever smoke”, not only because of the adverse effect it has on the child’s health but also because of the bad example it sets for the children who then take up smoking themselves, which in turn increases the risk
of relapse of asthma if it has improved. Other reasonable recommendations are “Sustain a good diet”, and, “Breast feed if at all possible”. I think beyond that at the moment we do not have enough evidence to make any other statements.

Q98 Lord May of Oxford: Can I ask a question in this context for which one of the data points is myself? When I was 12 I missed half the school year with asthma and since the age of 18 I have essentially never had it, and I know other people like that, so may it not be that the word “asthma” embraces quite a wide range of things? It is not something like measles. There will be some that are allergy based and some that have other bases, so it is difficult to make generalisations. Is that true?

Professor Burney: I would agree with that. One of the confusing issues, particularly in childhood, is that there are a lot of other conditions that are probably not allergic which make people wheeze. The view generally is that these are very common in infancy and in very young children, but I suspect that they actually continue for a bit longer than that so that throughout childhood you have probably got a mixture of people with other conditions, just as in older life you get people who get rather different wheezy conditions which can be confused with asthma, so I think your distinction between those that have an allergic basis and those that do not may well be a good distinction. One other thing which I think is sometimes missed, at least in relation to more severe disease, is that asthma gets worse among women during the child-bearing years so that from puberty up to the menopause women probably have a worse deal during that time of their life than at other times of their life.

Professor Sheikh: As the Committee may be aware, The Lancet recently published a very provocative editorial saying that the term “asthma” has outlived its usefulness; it is far too crude a term, so I think in due course we will have a more refined understanding and a more refined range of terminology because it is very much a catch-all at the moment. In relation to primary prevention strategies, which you were asking about, to try and stop the initiation or halt the progression of the allergic march, as Professor Warner has said, the key recommendations that we would suggest are suitable at a population level,—that is, taking all-comers,—are minimising exposure to tobacco smoke and breast feeding wherever possible. However, we do have some clearly high risk families and in these families there are some interventions which appear to be promising. One in mothers who are unable to breast feed, for whatever reason, is the use of hydrolysed formula milk preparation. What is happening there is that the cows’ milk protein is being broken down. There is evidence now from a few randomised control trials to show that this can halt the progression of allergic problems and the other area that seems quite interesting and promising is looking at the role of pro-biotics. This involves giving particular forms of lactobacillus and bacteria in early life, perhaps in combination with other approaches, and again there is early evidence that these may be promising interventions, but overall as we are advocating intervening in healthy individuals at the moment before they have developed any disease in early life the burden of evidence for intervening is very high if we are advocating primary prevention strategies. What underlies this is that we are at the early stages in terms of our understanding of which interventions work and there needs to be far more work done in building on those early trials.

Professor Warner: This is a very difficult area. Recently there has been a meta-analysis of all studies using hydrolysed milk formulae in allergy prevention and, whilst there are clearly some trials which have shown an impact, at the moment the conclusion is that more work is required. It is a promising area, but before making recommendations in particular groups there is a lot more research to do; likewise with pro-biotics but now the more exciting area looks to be pre-biotics, that is, just creating the right environment in the gut for organisms to grow normally, and there are one or two trials in process at the moment and one has just been published with what looks like very good results.

Q99 Lord Colwyn: You covered the point about smoking and breast feeding. I pulled something out of The Telegraph a month ago saying that there is evidence that maternal diet and maternal exercise are important in the development of the child’s in utero lungs. Is that correct? Are you aware of that?

Professor Warner: Yes. Dr Devereux has done a lot of work in that area as well, but that is nutrition rather than trying to avoid food allergens. There are lots of nutrients that may be important. Dissecting out which are important is what is difficult, but Dr Devereux can answer that question better.

Dr Devereux: The work we have been doing in collaboration with people in America is that it looks quite promising that maternal diet during pregnancy is influencing the development of asthma in children. I am not talking about maternal ingestion of allergens; I am talking about maternal ingestion of nutrients, particularly vitamin E, possibly vitamin D and even zinc. There are now two studies showing associations that low maternal intake of vitamin E during pregnancy is associated with the increased risk of children having wheeze, asthma, reduced lung function and increased markers of lung inflammation. The $64,000 question is what happens
if you intervene to change women’s diet in pregnancy, and that is a study that needs to be done.

Q100 Lord Rea: I wonder if you can bring us up to date about recent trends in the UK in the incidence and prevalence of allergic diseases.

Professor Burney: Amongst children the main evidence comes from a study called the ISAAC study, which is an international study that has studied children about 10 years apart and looked at the difference between not individual children but schools of children, so they are looking at the same age groups, 6 to 7 year olds and 13 to 14 year olds on each occasion. In the UK among younger age groups there were insignificant increases in asthma and rhinitis during that period, and there was a significant increase in eczema. That is important in a way and it has got a lot of attention because up until those studies and studies published over the last few years almost all the studies that had looked at trends in disease had shown upward for asthma, eczema and rhinitis, so it looks as if there is a flattening off of this trend, though this is not seen in all countries. In some places the prevalence is still going up, in some places it seems to be going down, so for the first time there is a rather mixed set of evidence. That is for children. The other issue is the issue that I referred to a little bit earlier, and that is what is happening in adults. In adults, as I say, the picture is dominated by what happens from cohort to cohort, in other words, from one birth generation to the next, and what we know about is people born up to about 1970. We know in this group that the prevalence of people who are sensitised to allergens has increased in each successive generation and that these are therefore likely to be increasingly affected by the kinds of diseases that follow from sensitisation. We do not have that information for children yet, so what is happening there is a bit of a blank and we cannot answer the question of when this increase stopped. The ISAAC study, the study that I talked about earlier, did not measure sensitisation. They looked just at the change in the resulting diseases.

Q101 Lord Rea: What further work do we need to do in order to explain further these trends in children, adolescents and adults?

Professor Burney: Explaining why those changes have happened is an even more difficult question. However, just to know how the epidemic is going to evolve there are two big issues that need to be reviewed. I have said that sensitisation is increasing from generation to generation from people born in about the 1930s to the 1970s. I think we do need to know what is happening to sensitisation in birth cohorts since then; that is important. We also need to know more about what happens to people who are sensitised in terms of disease later on in life. There would be a reasonable guess that things will get worse because by and large as you get older you get frailer, you pick up more complications, you pick up more problems, so we suspect that they would have more disease as well as this added burden of sensitisation, but we do not really know that and I think that will be important to know at the end of life. At the beginning of life, as I say, I think it will be interesting and important to know what is really happening to sensitisation rates.

Q102 Lord Taverne: In your paper you mention that there is this unsolved puzzle of why only a proportion of individuals who test positive for specific IgE develop atopic forms of allergy. Is this becoming more common or is this something which is a complete mystery? Does this have an effect on the development of allergies?

Professor Burney: As I say, it is a mystery. I do not think that we know. Someone else on the panel may know more. There are some hypotheses about why some people seem to be able to carry an allergy and not have a disease as a result, but most of them are really quite speculative at the moment and people have been looking at why these things may happen. I suppose the interesting results, which are not really relevant to the UK, are from places from where there are a lot of parasites and in some of those studies there is a suggestion that the parasites will provide some chemical signal for the body to dampen down inflammation and that might be an explanation in some places. Another reason might be, for instance, the diet, so that again we do not have a very specific answer to that question but it may be that diet is important in your response to allergen if you have an allergy. The short answer is that we do not know but I think it is a very important area to investigate.

Q103 Lord Taverne: Is it a high proportion or a very low proportion of those who do not develop as you would expect?

Professor Burney: Quite a high proportion. I guess 50 per cent of the population probably in some age groups will have sensitisation to a common allergen, but the proportion that will have recognisable asthma will be less than 10 per cent probably, so it is quite a high proportion.

Q104 Lord Rea: Are we making the best use, in looking into the epidemiology and course of allergic conditions, of the very considerable database that we hold in the NHS, particularly general practice
Q105 Chairman: Do you think the UK Biobank will have a role here?
Professor Sheikh: In terms of data linkage it could possibly because it is going to be a vast resource and the idea of linking with other national data sets would be very interesting.

Q106 Lord Haskel: When we were discussing the first question we spoke about the importance of defining terms. In oral evidence the Department of Health said that the introduction of the Systemised Nomenclature of Medicine, or SNOMED, as they call it, would help to classify allergic diseases in a much more specific way. Do you think that this will improve the way in which clinicians and researchers exchange clinical knowledge and aid research into national trends?

Professor Sheikh: Certainly SNOMED has the potential to do that and the advantage of SNOMED is that it has been developed in the US, together with the SNOMED CT version, the clinical terminology version, which has been developed in association with the NHS. It is being used in about 40 countries in the world at the moment and so in terms of international comparisons through routine data sets the potential is phenomenal. It also allows more specific coding because there is far more flexibility within this new coding structure in the way that the system is configured, so in terms of potential, yes. However, what I am slightly concerned about is that at the moment we need to get the allergy community involved in the range of terminology that exists to see whether it is fit for purpose and I do not think that has been done as yet. What also concerns me is that for use in real time settings there needs to be simulation work that as far as I know has not been done yet. Retrospective coding is one thing but, in terms of real term consultation coding, again, that work needs to be done to see whether this system is fit for purpose. We also need to ensure that there is training in place because a particular advantage of this is that SNOMED CT through Connecting for Health would be implemented across the NHS, so in primary care and in hospitals and NHS Direct, for example, and so we have a potential for linked data which is very powerful. What we need to ensure is that there is consistent training across all of those different NHS sectors to ensure that the data we collect are ultimately meaningful because in order for Professor Burney and I to correctly interpret data it is essential that these are collected accurately.

Q107 Lord Haskel: The problem with classifying data in this way, of course, is that if something new comes along you tend to miss it because it does not fall into any classification. Do you think there is any danger of that?
Professor Sheikh: I think there is less danger of that with SNOWMED-CT because it does allow you to construct codes using a number of fields. Also, there is a commitment to this being an iterative process, so, as with the current coding system, if there is a need there is the potential to include new codes, although at the moment this is quite a laborious process. With SNOMED-CT it has been thought through a lot better as far as I can see.

Professor Warner: In a way one of the problems in relation to feeding data into this system goes back to the previous question that was asked about being allergically sensitised and having a raised IgE as distinct from having IgE mediated disease. It is very easy for somebody to misinterpret information based on a history and allergy tests in relation to the patient’s individual problem and then the data go in
incorrectly and that rather destroys the whole object of the exercise. That is a feature of allergy practice at the moment, not being something that is uniformly included in undergraduate training or in postgraduate education programmes, means that there is not sufficient allergy expertise around to ensure that the data feed-in in the first place is accurate. Dr Devereux: As a chest physician I often see people who are sent to my clinic with a diagnosis of asthma and a huge per centage of them do not actually have asthma. This is where the database is going to collapse. It is so easy for a GP to make a diagnosis of asthma because it is the commonest thing that is around, whereas when they come to my clinic I will do the tests and find that some of them do not have asthma: some of them have bronchitis and emphysema, some of them are just overweight, so maybe out of 10 people I see with a GP diagnosis of asthma probably only about three or four of them turn out to have asthma in the end, so you are right.

Q108 Lord May of Oxford: What do we know about the incidence and prevalence of allergic afflictions compared with other countries, and particularly, in so far as it looks like we are high among the OECD countries, how much of this is real prevalence as distinct from differences in the definition of things we are talking about or, more importantly, the statistics? Professor Burney: Again, most of that information does not come from routine statistics; it comes from surveys, so they are relatively well controlled. There is a problem, obviously, in using questionnaires in being very precise about what people have and whether the questionnaires are working exactly the same way in one language as against another, but for the most part we can be fairly confident. If I go back to the ISAAC studies, which are worldwide studies of children, they are based on questionnaires essentially. Some of them are rather elaborate video questionnaires where the children are shown videos of something and asked, “Are you like that?” They took quite a lot of trouble to try and take out the effect of language problems that you might have. For the ISAAC studies it is quite true, certainly in Europe that the UK comes high in the lists. In the six to seven year olds I think there was nowhere that was higher, if we include the Channel Islands and the Isle of Man within the UK. I do not think there was anywhere that was higher in Europe for asthma and rhinitis in the reports that were made from these questionnaires. For eczema I think it was only Sweden that had a higher prevalence. For the 13 to 14 year olds, again, in asthma only Ireland was higher and in rhinitis there were a number of places that were higher, but by and large the answer is that for those questionnaire-based data we can be pretty sure that that is true. For the adults we have less information across the world, but certainly in western Europe, and here we have evidence from serology, from looking at specific IgE to allergens in the sera from people from different parts of Europe, again the UK has, or rather in the centres in the UK—I should be a little bit more precise because these are not universal studies; they do not try and capture the whole population of England—they had amongst the highest prevalence of sensitisation, and that was pretty well true for all of the centres that we looked at, and they had correspondingly higher levels of disease, so I think we can be pretty sure that that is true. The only places in the ECRHS, the European study that looked at adults, which had as high or higher rates of sensitisation were other English speaking places like Australia and New Zealand, which had very high rates as well, so we can be pretty sure about that. In the ISAAC study, which looked at more places worldwide, the other hotspot was Latin America where they seemed to report very high levels, but for those we do not have the equivalent data yet on sensitisation rates, so we do not have an objective measure to measure that against, but that will come.

Q109 Lord May of Oxford: What are the ideas that are floating round about the underlying reason for our being higher than others? Professor Burney: There are a number of reasons. It has been very difficult to demonstrate a reason in a lot of different kinds of studies. When you actually get to the data you say, “Let us adjust for the following things”, and then look to see whether that explains the difference, and almost always the answer is that it does not explain it, so explaining the differences has been extremely difficult. There are general thoughts around.

Q110 Lord May of Oxford: We have, of course, heard some of them. I wondered what your view of their comparative merits was. Professor Burney: I would probably at the moment put quite a lot of emphasis on diet. I think diet is probably important, but the detail of what in the diet is much more difficult to disentangle at the moment. There could be genetic differences. We know that there are, but whether they are relevant in this case I am not sure. It has been noted, for instance, that by and large genes follow language and quite a lot of the places with high prevalence are English speaking. Against that the Australian centre in the ECRHS is Melbourne, where the population is very largely of south European origin, so maybe this is not a good explanation.
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Professor Peter Burney, Professor Aziz Sheikh, Dr Graham Devereux
and Professor John Warner

Q111 Lord May of Oxford: It is not really part of
Australia.
Professor Burney: The other hypothesis that is causing
a lot of interest at the moment is the so-called hygiene
hypothesis. Again, we are not entirely sure what it is
in the hygiene hypothesis that is explaining the
diVerences. It is still really a hypothesis and, to be
truthful, it is probably lots of hypotheses which are
adapted to ﬁt diVerent stories and I think that has to
mature a bit. We need to know a little bit more about
exactly what it is about “hygiene” that is important.
I suppose those would be the two main hypotheses,
diet and hygiene, that people are most interested in at
the moment.
Q112 Lord May of Oxford: What about the playing
in dirt hypothesis?
Professor Burney: That is the hygiene hypothesis.
There are a lot of separate bits of information about
that. Some of the early theories on mechanisms really
do not seem to stack up so well but the basic original
data were that if you have older brothers and sisters
you are less likely to be allergic, and that seems to be
very consistent in all the data sets. That was the
original part of the hypothesis. It has since been
expanded in various ways so, for instance, one of the
interesting groups that have been looked at, mostly in
central Europe, is farmers and it is noted that people
who are brought up on farms, particularly farms with
animals, are less likely to become allergic, which was
a bit of a surprise to some allergists who thought that
being in amongst all those allergens might have had
the opposite eVect, but it does not seem to. That is a
strong part of that hypothesis. In other parts of the
world the hypothesis does not stack up so well. If you
go to Africa where the environment is completely
diVerent hygiene does not seem to explain the
distribution of disease. People have tried to explain it,
for instance, by looking at parasites as part of this
general hygiene hypothesis. In fact, parasites do not
protect against sensitisation, as predicted by the
original hygiene hypothesis, but have a diVerent
eVect and on a diVerent part of the mechanism, so
that is probably a diVerent story.
Q113 Lord Soulsby of SwaVham Prior: Having
started oV on the hygiene hypothesis, I have two
questions. The ﬁrst one is what practical advice
should the Government be giving to parents
regarding hygiene to minimise the risk of their
children developing allergies?
Professor Burney: My view would be none. Again, we
have been into this a little bit before. You have to
have a very high level of understanding of something
before you start giving advice to people. One of the
things that people should be a little bit aware of is
that there is a hint in some of the studies that the same

risk factors, that protect you from allergy are also
associated with lower lung function, so it may well be
that nanny is right, that playing in the dirt is not such
a good thing. It may be good for your allergies but
you really need to know across the board what the
eVects are going to be before you start giving advice.
Professor Warner: I think the word “hygiene” is now
probably the wrong one to use to explain this
hypothesis. There was a very nice paper published in
the journal that Professor Kay edits very recently
where it has been suggested by the authors, and
indeed other people, that we should talk about
microbial exposure or microbial deprivation
hypothesis. Hygiene hypothesis gives out the wrong
message to people, and the problem is that it is
interpreted as suggesting that you should roll your
babies in dirt. The consequence is all kinds of
nightmares of infections that we have eVectively
eliminated by good hygiene, and that is not what we
want. It also gives out a very bad message, for
instance, in relation to immunisation. This is an area
where there is enormous worry that families are not
immunising their children because they have got the
message that immunisation means less infection,
means more allergy. That is an incredibly bad public
health message and we have got to counteract that. In
fact, all the studies that are being done, and I have
been involved with one that we are just putting
together a paper on at the moment, show quite the
converse, that if you immunise babies eVectively
there is, if anything, marginally less allergy. This is a
complex area and we have to disentangle all the
diVerent components. I still think it is an interesting
area in relation to potential for intervention but we
are going to have to understand what microbial
factors are involved and how they can be
administered to reduce allergies.
Q114 Lord Taverne: Is it the new Liu & Leung paper,
the paper you mentioned?
Professor Warner: The paper I mentioned is by
Bloomﬁeld et al. I am sure Professor Kay would be
able to give you the details. It is Clinical and
Experimental Allergy 2006, volume 36, pages
402–425.
Q115 Lord Soulsby of SwaVham Prior: I just want to
come back on the hygiene hypothesis. There has been
a suggestion that domestic pets, dogs and cats and
maybe other pets, play a role in this. Would you
subscribe to that?
Professor Burney: There is certainly some evidence
that children brought up with dogs have less
sensitisation. I think we probably need a little bit
more evidence to support it, but that seems to be true.


Q116  **Lord Soulsby of Swaffham Prior**: Because this country, the United Kingdom, has a high companion animal population but it is not the only country in the European Union that does, of course. France and Germany have high populations too, and then there is the reverse of that: countries that do not keep domestic animals because of religious reasons. What is the issue there? For example, in a Muslim country domestic animals because of religious reasons. What is the reverse of that: countries that do not keep animals but it is not the only country in the non-Muslim country?

**Professor Burney**: I do not think we know much about that. I should also add another issue over the pets, and that is that, again, there is misunderstanding about this. Pets can be a problem for people who have already been sensitised, so they are not an undiluted joy in this way. I think the answer would be that in Muslim countries by and large they are often exposed to allergens but cats are kept outside the house and therefore they have a much lower exposure. That may not be such a good thing as some people believe that very high doses of cat allergen may be protective and lower levels are more likely to sensitise but that is talking about the allergen, so there is a paradox about this. Cats carry allergen but they also probably carry some of this microbial exposure that might be protective as well, so it is a paradoxical issue. I cannot really answer your question about the countries in the Muslim world. I do not have any data on that.

Q117  **Lord Taverne**: Is there anything in the suggestion “dogs good, cats bad”?  
**Dr Devereux**: The first data were with cats and most of the studies have shown that cats are beneficial; you are less allergic to cats than you should be, but also there is some dog work. On the stuff about Muslim countries, there is a study from Saudi Arabia showing that Saudi Arabians, if they live in the cities, have a very high prevalence equivalent to what we have in the westernised countries, whereas the ones living out in the deserts with a nomadic lifestyle have a very low prevalence of asthma and allergic disease. It is not Muslim; it is where you live. It depends where you developed or whether it was in the traditional lifestyle.

Q118  **Viscount Simon**: Is that the same in, let us say, central Africa?  
**Dr Devereux**: In Africa there are studies showing very similar things, that populations living in the towns and cities have more asthma and allergic disease. People living in the townships in the bush are less likely to have asthma and allergic disease. However, the first studies in the 1970s showed that there was quite a big gap but now the gap is narrowing and it is thought that people in the townships and the bush are taking on westernised lifestyles and that is maybe why the gap is disappearing now.

Q119  **Viscount Simon**: Or maybe second homes.  
**Dr Devereux**: I suspect that if you are poor in Africa you cannot afford a second home.  
**Professor Burney**: No, but movement between urban and rural areas does happen, particularly with children. Children will be sent from the towns in some places to the country to be educated because it is a less dangerous environment, so that is a complication.

Q120  **Baroness Platt of Writtle**: Does everyone agree that the prevalence of allergic disease will continue to increase?  
**Professor Burney**: As I was saying, I think it is probably true in the older age group that that is almost inevitable, but I would hesitate in one sense. It is very likely to be true for sensitisation, for the reason I have given, that the younger adult generations of people who are now going to get older have a higher burden of sensitisation, so I think that probably is going to happen. I would put a lot of money on that. I think the issue that follows from that, which we are less clear about, is what will happen to disease as a result of that increase in sensitisation. As I say, my guess would be that disease would also increase and be more of a problem, but there is less evidence on that.

Q121  **Baroness Platt of Writtle**: You talked about the young compared with the old but would there be a difference on a gender basis, males and females?  
**Professor Burney**: I think much the same for men and women. As I said though, there are differences between men and women and I think, particularly in the child-bearing years, women have a high burden of asthma. The answer to your other question, what is happening in children, is that we just do not know and that is going to be very important, but it will be very important for the more distant future. If there is genuinely a decrease in sensitisation amongst these generations, this will then reverse the trend, but in another 20, 30, 50 years’ time.

**Professor Sheikh**: I think with this current generation of children, where the data in the UK show that between and 30 and 40 per cent are experiencing allergic symptoms, it is reasonably safe to predict that this generation will continue throughout adult life to experience allergic symptoms of one sort or another, so I think in the short to medium term the prevalence is going to be high and it is going to have an impact on all sectors of healthcare provision.
Q122 **Chairman:** I wonder, Dr Devereux, if I could pick up on what you were saying previously about some of the animals and whether it is true to say that being brought up with cats may give you tolerance, but that there is a different cohort who are allergic and get very severe symptoms when in contact with cats and they may be in the same house living with those animals? Have we got two populations?

**Dr Devereux:** I suspect we probably have. I suspect that the way the cat protection phenomenon is explained is that when you get exposed to cat allergen your immune system responds with a tolerogenic response in that it tolerates the cat allergen, whereas you have got another group of people who, when they get exposed to cats, for whatever reason, genetic, environmental, diet, then develop an allergic response, so it is likely that you may have brothers and sisters living together and one may derive protection and one may derive harm from the cat.

Q123 **Lord Colwyn:** We move on now to the burden these diseases are causing. The carrying has obviously increased a lot since the 1950s and I think I have read in my papers that it just about doubles every 10 years or so.

**Professor Burney:** It doubles about every 14 or 15 years.

Q124 **Lord Colwyn:** The written evidence we have got has highlighted the significant personal, social and economic impact of these disorders. Are there any key measures that you think perhaps the Government or other public bodies should implement to try and reduce this burden at home, at school and at work?

**Professor Burney:** I will have a first go at this. I think it is very difficult, for the reasons we have given, to give very specific answers to that. Good healthcare would be good. Beyond that one of the things I would say is that it would be useful, given the high prevalence of disease, if this were something that was always considered by departments when they develop policy. I think that people tend to forget that there is this very large group of people who are specifically at risk, so I think that if all government departments, when they were developing policy, actually had a check, “Have we thought about what the influence would be on allergic people?” that would be good. As for giving very specific advice I would be pretty much at a loss to give strong advice at the moment.

**Dr Devereux:** I think there is something that can be done. At the moment the allergy provision service in the NHS is not good. There is no allergist north of Manchester. There is no allergy service for the whole of Scotland or the north of England. What we have is a significant proportion of the population with allergic disease who are getting ad hoc advice from non-experts like GPs, respiratory physicians, dermatologists. These people are desperate for help and they are seeking help in alternative medicines, all sorts of things, so one thing could be to try and increase allergy provision so that a correct diagnosis of allergy is made so that the correct treatments can be instigated and the correct avoidance measures taken.

**Professor Warner:** I agree with what Graham Devereux has said. I think that is the most important thing. There are some other issues though. It is about raising awareness across the whole of Government. For instance, recently the Department for Education has been recommending that the junk food which is sold in vending machines at schools should be replaced by nuts and peanuts as healthy foods. That is failing to consider the impact on the peanut and tree nut allergic child in that school. It is a question of joined-up thinking between different departments that might take account of this very common problem.

Q125 **Baroness Platt of Writtle:** What about the problem of children with rhinitis and exams, because in two lots of evidence it said that they are achieving one grade less due to their allergy?

**Professor Warner:** Yes, very much so. There is now good evidence for that. Exams are virtually always in the middle of the pollen season and that brings down grades appreciably. People have now done studies looking at results of mock exams, which are out of the pollen season, and comparing them with the results that have occurred in the real GCSEs and showing that pollen allergic children do drop a grade.

Q126 **Lord Colwyn:** I am surprised to have read in our evidence that there is not any evidence that the increase is attributed to allergen exposure or even the famous house dust mite at all. The gaps in our knowledge could perhaps be dealt with by having better training at undergraduate level, courses for doctors and more specialist allergists. Would that solve it?

**Professor Sheikh:** Undergraduate training is a key issue. We have been looking in detail in Edinburgh at our undergraduate training provision. For example, allergy diagnosis is not covered at all. Food allergy is not covered at all in the curriculum. Multiple allergies are not covered at all. This is a reflection almost certainly of what is going on in most other medical schools. At postgraduate level there is very little training provision at the moment. In response to your previous question, what else can be done, one of the pieces of work that we are currently doing is looking at anaphylaxis management in schools. Schools are, on the whole, at a loss to know how to deal with this problem. They are saying, “This is a healthcare issue;
we are educationalists”. GPs and, where they are involved, consultant paediatricians are saying that it is not their remit to go into schools. Children are therefore falling through the gap. For those with life-threatening allergies and with severe allergies one important step would be to think about case management. Case management now exists for a number of other long term disorders. Everything needs to be done within an evaluative context because there can be unintended consequences, but it would be one step forward to begin thinking of these as long term disorders, which the NHS historically has not done.

Q127 Countess of Mar: Before I ask my question I should declare my interest because I am not a member of the Committee but I am allowed to come in on it. I am a farmer. I produce raw goats’ milk, which we have quite a lot of custom for, and I also have an interest in toxic chemicals arising from organophosphate poisonings from sheep dip. Do you think that the Government’s and the European Union’s efforts now to control the proliferation of chemicals and chemical exposures, and particularly chemicals that are used in domestic situations, are worthwhile? I know that there is a lot of research now which is showing that the placenta is not as protective of the unborn child as it was thought to be. Do you think there might be some connection between the effects on the immune system that might have happened in utero and the subsequent allergies that are showing up? That is rather a lot of questions all together.

Dr Devereux: The goats’ milk—

Q128 Countess of Mar: You need not answer that.

Dr Devereux: No, no. The work from Switzerland, Austria and Germany showed that one of the protective effects of living on a farm was from consuming unpasteurised milk before the age of one. Whether you want to advocate that as a widespread measure I doubt because of the problem with tuberculosis.

Q129 Countess of Mar: No, in fact I never recommend goats’ milk to a child under the age of one and we know that our goats do not have TB.

Dr Devereux: If you put it in context that is quite an interesting point. There is increasing interest in the possibility of environmental pesticides and things like that. There is this interesting work from various groups around the world showing that you can detect these chemicals in the blood of newborn babes and the exposure seems to influence the neonatal immune system responses. Whether these translate into current disease we are not really sure. I did look at one paper. The problem was that the levels of some of the chemicals have gone down, so it would be difficult to link. The other aspect of this is your cleaning agents thing. There is a study from ALSPAC associated with internal exposure to various chemicals and whether that needs to be all firmed up. Moving on to a different phase of investigation, we have looked at the allergen phase and most people would accept that probably the increase in asthma and allergy is not due to increasing allergens. Dealing with the hygiene and the dietary hypotheses at the moment, I think the things in the future are going to be the environmental pesticides, environmental chemicals and cleaning agents. That is where the research is going to be going to.

Professor Warner: Certainly that is something where we need more information, but also we need to think about the other pollutants or other factors to which people are exposed where maybe there is a bit more evidence. We know that allergic sensitisation can be increased and the allergic reactions themselves can be increasing if you have simultaneous exposure with an allergen and, say, diesel particulates or ozone or nitrogen oxides, and so there are air pollutants that might be adding to the burden and certainly increasing the severity of disease. Pollutants may be also contributing to the increasing prevalence as well, although the data are a bit more tenuous, I think.

Professor Sheikh: Can I come back on the raw milk point because there are data now from a number of studies which show that raw milk consumption may be protective, including data from the UK which have recently been published. The point here is that now we need prospective work and interventional work to understand this phenomenon better. One of the issues of relevance is that if we do introduce legislation around milk or other issues it is important, bearing in mind how little we know about early life influences, that that work is in an evaluative context. For example, raw milk sale, as you are no doubt aware, is banned in Scotland, so the scope for any interventional work is therefore very limited, but was there any evaluation put into place to look for unintended consequences which may have resulted from that ban? We need to be thinking much more broadly.

Dr Devereux: The other thing is that people who purchase farm milk, unpasteurised milk, have different lifestyles from the rest of us and so it may not be the milk; it may be some other factor that they are exposed to or not exposed to. It may be a mark of lifestyle.

Countess of Mar: It is quite interesting. Our customers come from a very wide range and generally they have children who are allergic to “dairy”, as they call it. With my reading, apparently there are two different sorts of casein. There is alpha casein and beta casein, and I cannot remember which way round
it is, but there is one that is found in goats' milk and Guernsey and Jersey cows, and the other is found in the black and white cows that nearly everybody's milk comes from. It may be that since the fifties farmers have tended towards having Holstein herds, the black and white cows, rather than the Channel Island cows, and there is a possibility there that it may have changed the metabolism somehow. The other one is the altered protein on pasteurisation, where the protein itself is altered on pasteurisation. Cheese-makers know that pasteurised milk does not make the same sort of cheese as unpasteurised milk.

Q130 Lord Soulsby of Swaffham Prior: Can we talk about housing conditions and poor housing, and whether that contributes to the burden of allergic disease by way of, for example, increased dust mites, moulds and other environmental bacteria organisms? If there is anything there, should that danger in housing accommodation and other buildings be reflected in the Building Regulations?

Professor Burney: Yes, I am sure that is true. I think there is quite good evidence that damp housing with mould causes problems, particularly for patients with asthma. Clearly, that is an avoidable risk that they run. That certainly could be important. We know that also, for instance, in some places, where you get very high build-up of, for instance, oxides of nitrogen from gas cooking—particularly with gas stoves—that can have an adverse effect on patients with asthma. That is quite easily remedied by having proper ventilation. I think it goes back to what I was saying about regulatory bodies always taking account of the fact that a very high proportion of the population is allergic, and I think Building Regulations should reflect that.

Professor Warner: I think it is important, however, to distinguish between housing conditions that may contribute to the development of allergy in the first place. After all, everybody lived in damp, cold housing one hundred years ago and there was much less allergy, so it is not necessarily increasing the risks of being allergically sensitised. However, once you are allergic and have a problem there is no doubt that living in damp, cold housing makes your problems worse. For instance, in the United States, the inner city deprived population have infinitely more severe and even life-threatening asthma at higher prevalence than those living in better housing. So there is certainly a need to address that, but we need to think about whether in changing the indoor environment, this which might increase the risk of allergic sensitisation. I know that sounds a paradox but there are very different influences between creating the problem in the first place and aggravating it once it has occurred. There is, again, more work to be done to understand the indoor environment and how it contributes. By having energy saving we are creating tight homes which are increasing the levels of nitrogen oxides and volatile organic compounds which might be contributing to enhancing sensitisation in the first place. If we are going to have tighter housing for energy saving then we need proper ventilation systems with heat exchangers in order to achieve benefit for everybody.

Q131 Lord Soulsby of Swaffham Prior: It is interesting what you are saying. The question naturally arises, are the people who are making proposed regulations aware of the dangers of energy saving and things like that? If they are not, how do you get that information to them?

Professor Warner: Many years ago, I was involved in research with the Building Research Establishment, and at that stage they were very aware and doing quite a lot of work, but the BRE is not now predominantly government-run or sponsored; it is an independent organisation and I am not aware of what they are doing. There are other countries, notably Denmark, that have put quite a lot of work into housing design and its effect for allergy sufferers.

Q132 Chairman: Can you clarify for me from your answer whether you are saying that low-allergen housing is actually unlikely to prevent allergy?

Professor Warner: Based on studies so far done, the low-allergen housing is almost certainly not going to prevent allergy because you are not just reducing exposure to the allergen. There are other knock-on effects of reducing allergen exposure such as reducing exposure to bacterial products, which might increase allergy risk, with ventilation systems, and reduced exposure to irritants might reduce allergic sensitisation. So there is a bit of a balance: some things are perhaps not making any difference and others may actually be having some benefits. Studies that have looked at, say, reducing house mite avoidance in early life to prevent disease have shown that there is a reduced rate of early wheezing illnesses not associated with allergy, but later with no difference or, maybe, marginal increases in allergic-associated wheezing.

Q133 Viscount Simon: For the last 15 years or so, I think it is acknowledged, there has been a year-on-year increase in hospital admissions for anaphylaxis, which suggests an underlying change in the epidemiology of this sort of allergic emergency. What can be done to reduce the number of people admitted suffering from anaphylactic shock?

Professor Sheikh: You are absolutely right the data show very dramatic increases over the last 15 years or so, and these are year-on-year increases, and they continue. There are three issues that need to be
considered primarily. One is that in those presenting with acute anaphylaxis in hospital accident and emergency departments we know that very many of these patients are still getting sub-optimal care, so many of them will still not receive adrenaline, which is a potentially life-saving treatment; they will often get other forms of treatment, in the form of antihistamines or steroids, and here there is emerging evidence to suggest that we may actually be doing more harm than good in those cases. One of the things we need to do is developing a far more secure base around how we manage this in an emergency context and seeing if that will improve outcomes. That is challenging to do because this is a life-threatening emergency, so it needs an appropriate regulatory framework and it needs ethics committees to think more flexibly than they have done hitherto. That is one issue. I think the second issue is about long-term provision for those who have a history of anaphylaxis. We have tended to think about this as an acute problem only, but this condition has life-long implications and multifaceted implications. One of the things we could be thinking about is developing anaphylaxis long-term management plans, as is now common in some other allergic problems, such as asthma or other chronic disorders, and that needs to be done, but again within an evaluative context. There needs to appropriate incentives in place in general practice, but I think with a will we could probably devise these. That would commit us to identifying the allergens that are responsible for provoking anaphylaxis so patients know how to avoid these products, and also training them in appropriate emergency provision if they do get exposed. Taking that twin-strand approach would probably help us in reducing some of this burden.

Q134 Chairman: In your response to Viscount Simon you were saying that the current management where they are not going to use adrenalin early may be doing more harm than good. I wonder if you could expand on that.

Professor Sheikh: Certainly. Adrenaline is internationally recognised as the treatment of choice in anaphylaxis. Unfortunately, very many patients who present with anaphylaxis still do not receive adrenaline. Having said that, there have been very few empirical studies on which to base the decision to treat with adrenaline, so we do not know the correct dose to be using, we do not know what the correct route of administration is, and we do not know when is the appropriate time to give the next dose of adrenaline. So there are massive gaps. What people do get when they walk into an A&E department is antihistamines, and they will be given antihistamines intravenously, typically. There are some data which suggests that, particularly in hemodynamically compromised individuals, they may be increasing the risk of arrhythmias in these patients. They are also often getting steroids, which, if given intravenously, again, are going to have virtually no impact on the acute illness. Again, there are no real scientific data on which to base those treatments, so in such a case we need to be rethinking some of these guidelines. I am, together with colleagues in Canada and the US, involved in those discussions, so I think we will get progress internationally in the next few years.
confident about their ability to manage asthma at home. As you said, they are more confident, the medication and management plan is in place and fewer people are getting referred.

**Q136 Lord May of Oxford:** So the severe wheezing attacks that previously would have had them admitted are now managed at home.

**Dr Devereux:** Yes.

**Q137 Viscount Simon:** Following what Professor Sheikh was saying, I have two questions: one is personal, I am afraid to say, and the other one is more to do with this inquiry. You were talking about cetirizine and allied medicines and, also, adrenalin. I take a huge doze of cetirizine every day of the year and I carry adrenalin with me. From what you are saying, should I use the adrenalin in an emergency? The second question, which is the general one, is do you think it would be worthwhile starting or instituting a national anaphylaxis surveillance programme?

**Professor Sheikh:** Maybe I can try and take both of these questions together. In terms of your personal question, if you are experiencing symptoms of anaphylaxis then certainly use your adrenalin and get some help. I think everybody would be in agreement about that. In relation to hospital admissions, hospital admissions are the tip of a clinical iceberg, so studying those is subject to all sorts of potential variables. However, we are on reasonably firm ground, when we have got data pointing in the same direction irrespective of the data source, as in asthma for example—we know that hospital admissions are declining and we have got a pretty good idea of what is happening in general practice as well—really what we are seeing is a decreasing burden, or at least a stabilising in the disease burden. In relation to anaphylaxis, what we are seeing is that hospital admissions are going in a certain direction, very clearly. When we have investigated the possibility of diagnostic transfer taking place, and it seems that is unlikely to be taking place, we have looked for regional differences and it seems, again, that there are similar patterns all across England. We have looked across different age groups and, again, it seems that there are similar patterns in most age groups. In terms of primary care data, which are as yet unpublished but hopefully will be within the next few months (once I have finished with this I can get back to writing the paper), what we see there is that there is improved diagnosis taking place in general practice but, over and above that, there is an increased number of people with anaphylaxis. Failing that, the only next step that remains in unpicking this jigsaw is going back and doing some validational work, so looking at people who are admitted with anaphylaxis and then extracting some of their individual case records, subjecting them to a panel of experts and seeing to what extent the data are valid. That work, again, is on my agenda—we need to do that. In relation to surveillance, with these numbers and this rate of increase then surveillance is entirely appropriate. Our estimates, at the moment, are that in England there are some 38,000 people (these are unpublished data) who have had a history of anaphylaxis at some point in their lives. These are still relatively small numbers, so a surveillance programme for anaphylaxis could prove feasible. Some kind of longitudinal tracking of a sample of these individuals would help us to far better understand the epidemiology of this condition. I am part of an international group looking at the epidemiology of anaphylaxis, and you are right to point out there are massive gaps, but in the UK we are probably the most developed in terms of our understanding.

**Professor Warner:** May I make some comments? Firstly you are not doing yourself any harm taking regular cetirizine and you might actually be helping some of your allergic manifestations, which is rather different. In relation to the increasing rates of severe, acute allergic reactions, particularly in relation to food allergy—clearly there has been a dramatic change in people’s eating habits and what kind of foods they are accessing. It would be relatively easy to avoid peanuts if everything you ate was cooked yourself having bought fresh food in the market and from the butcher. Of course, that is not what happens now and people are buying products that have gone through a whole series of processes and been manufactured and packaged. Under those circumstances the potential for there to be unexpected peanut within those products, unfortunately, is significant and creating a problem, but in the end, have an impact. Yes, we have to understand why the whole problem has increased but, at the same time, to help people that are suffering now I think there are things we can do.

**Professor Sheikh:** The degree of distress that some young people experience by being confronted with labels saying “may contain traces of nut” is something I think we underestimate. Let us turn that on its head. I think there is a market now for products which are guaranteed to be nut-free and similar other products which are guaranteed dairy-free, for example. Some work needs to be done to look at that and that would, again, be something that would be very useful to a lot of people.
Chairman: We have quite a lot of questions still and I am aware of the time, so I think we are all going to try to be concise with our questions and appreciate if you could with your answers. It would be really important to get through questions on primary prevention and research.

Q138 Lord Taverne: Turning to research, in an area where there is so much uncertainty, what are the most promising areas of research into primary prevention? What would be likely to produce best value for money? For example, would it be diets of pregnant mothers, pre-biotics, pro-biotics? What is your view?

Dr Devereux: I am very biased. I think there is increasing evidence that we should look at maternal diet during pregnancy. I am being encouraged by various people to actually go ahead and try and do an intervention study. Whether I get funding for it or not—it is clearly going to be a hell of a job to get funding. Pro-biotics certainly. If you speak to people who make pro-biotics, they think the case is made, with a couple of well-designed intervention studies in pregnant women showing a reduction in eczema with pro-biotics. So I am biased, and that is my biased view. I would go for maternal diet, but I am sure other people will go for other things.

Professor Warner: I would agree. I would put diet as number one, although I prefer to call it nutrition rather than diet because it is nutritional enhancement rather than avoidance. After that I would still focus on pre-biotics, not pro-biotics—I do not think the case has been made for pro-biotics. I think the interactions of all the different organisms in the gut are very complex but pre-biotics look more promising. After that it is some form of immune modulation using other microbial agents to induce an appropriate immune response. Those are the three areas I would focus on.

Q139 Chairman: I wonder, too, what you feel about maternal smoking and the effect of maternal smoking on the risks of a child developing allergy.

Dr Devereux: It is well known and accepted; it is well documented and I think everybody accepts that.

Q140 Chairman: There is no controversy about it.

Dr Devereux: No.

Q141 Chairman: I am really glad to have that on the record.

Professor Sheikh: I agree with the points made, but the other area is that we have so many potential risk factors we need to be thinking more about multifaceted interventions in early life. So this may involve a combination of immune modulating treatment and allergen avoidance, for example. There are some data which suggests that these multifaceted interactions may be particularly promising.

Q142 Baroness Platt of Writtle: Are grant funding bodies distributing money for research into allergic diseases in the most promising areas? Could we be getting better value for money from investment in research? In two lots of evidence we have had, including Professor Warner’s, there is a recommendation for a central funding body. I am slightly nervous about that as it might be bureaucratic, but perhaps you might like to refer to that in answering.

Professor Warner: At the moment, most funding for allergy research is handed out on the basis of judgments about what is the best scientific proposal, and therefore there is not any strategy behind that; it depends on the individuals submitting from an area that they wish to investigate rather than one which necessarily might be, in the end, the best thing to do from a public health perspective. My suggestion was maybe one should think about having some kind of co-ordination identifying target areas for research. I do not mean being intensely bureaucratic but just inviting people to apply in target areas that are seen to be important from a public health perspective.

Dr Devereux: The Food Standards Agency (?) did put out a call for studies of early life diet and respiratory outcomes in children, and we thought we were in a good position to get this because we are probably leading the community in doing this sort of research, but we were turned down on some fairly weak grounds. I have been banging my head against a brick wall for the past few years trying to get money to fund a study into nutrition and asthma, and I have a real headache now after banging my head against a brick wall for so long.

Q143 Lord May of Oxford: It might be helpful, just quickly, to clarify. The Medical Research Council, in particular, has three categories of grant: one is the responsive mode, as you have just suggested; at the other extreme are occasional things where they do pick out an area and, I think, very interestingly, in between them is this third category of highlighting an area, where they do not exactly set aside a pot but they say: “Here is something where we think perhaps it might be useful if you could start lobbying”.

Dr Devereux: I have been told that in the next year or so respiratory medicine will go up the list of competing priorities, but I will wait and see what happens.

Professor Sheikh: One of the problems here is that we do not have a level playing field with that we do not have a major allergy charity that the academic community can turn to. Allergy UK and Anaphylaxis Campaign have no money for research, unlike the Cancer...
Research UK or Macmillan, for example. In the absence of dedicated charities, some kind of central highlighting of the need for dedicated research funding and a dedicated pot for the important translational health services research really needs to be done. We are not in a position to answer hardly any of these questions that you have posed, unfortunately, because there is nowhere to go to get any substantial money to do this kind of work. In terms of primary prevention, we need long-term follow-up; we need 15–20 year studies. The Scottish Executive have not, for example, prioritised this and they have got a ceiling on project grants of £150,0001. There is no way you can do this kind of work on that kind of money.

Q144 Lord Colwyn: This is a question that comes from the helpful paper from Professor Burney and the outdoor environment. I wonder whether you could make any further comments on your statement: “there is a continuous low level of effects from allergens in air, but the nature of these . . . is uncertain.” Then you say that some of them are likely to come from man-made sources and need further investigation. Can you follow up on that at all?

Professor Burney: The evidence so far is in rather general terms. The difficulty is that an allergen is very specific to a particular person. There are things that are commonly allergic to many different people, but everybody has their own allergens. So it is quite a difficult area to study in that way; it is not like studying air pollution from, let us say, nitrogen dioxide, which is something you can measure and it is the same for everyone. What we know now is that allergens in air do cause exacerbations, and we can say that it is an allergen but we do not necessarily know what the allergens are. The other part of your question is something we can speculate on. We know it is very likely, for instance, that moulds in the atmosphere are part of the problem—I cannot tell you exactly how much of the problem—but the other thing that we know, from rather spectacular epidemics that have happened, is that these can occur because people are storing and releasing large quantities of allergen. So, for instance, one of the more recent epidemics happened in the 1980s in Barcelona where they were storing soya beans in silos in the dock. The silos were uncovered, so when they dumped large quantities of soya bean in they released soya bean allergen into the air. Under the wrong atmospheric conditions in which the soya bean was spread around the town you got really serious epidemics. So we know that there are sources of allergen. Such events are quite rare but in order to find them you have to have these big epidemics, and then they are obvious; you do not need an epidemiologist to tell you there is a problem, you just go into the casualty departments and they are filling up with asthmatic patients. We know that this has happened, also, with castor bean from processing places. We don’t know whether this happens on a smaller scale. So it is really speculation. We know that there are conditions under which this can happen, and I think it is an area we need to know a lot more about. We need to know what allergens can cause such problems and we want to know, really, whether they are controllable. If they come from an industrial source they are probably controllable; if they are natural allergens there is probably not a lot you can do about them.

Q145 Lord Colwyn: It is advantageous to live in areas of non-pollution.

Professor Burney: Yes, in a way, but it is a different kind of pollution.

Q146 Lord Colwyn: One other thing is a subject I have spoken about in the House of Lords, probably for 25 years now. Have you anything you can comment on in relation to electromagnetic pollution?

Professor Burney: No, not in this context.

Q147 Lord May of Oxford: I think probably the most useful thing I did while I was the Chief Scientific Officer was promulgate rules for handling science advice in policy making and giving advice to the public, but these things are much more easily said than done. This is a very good example, it seems to me, where, as we have heard, there are so many of the issues where there are various ideas and conflicting evidence. How do you see, against that background, in this particular instance, formulating the advice we give to the public—guidance?

Professor Sheikh: One of the issues we can do is we can advise which interventions are not working, and that can be useful advice. For example, taking measures to avoid aero-allergen exposure domestically is very unlikely to prevent allergic disease. A number of people are doing this with no clear evidence base. In terms of the positive recommendations that we can make, I think we need to appreciate that we are at a very early stage in this story. Overall, advice has to be evidence based and this evidence will accrue. If you can help in allowing us to do the research in any way then certainly we can feed into that process.

Professor Warner: I have had my fingers burnt over this. I was on the Committee in the Department of Health that made the suggestion that in families that have allergies it would be sensible for mothers to avoid eating peanuts and tree-nuts and not giving them to their babies for the first three years of life. That advice still stands, but evidence is now accruing which suggests that that might not just be having no

1 This has since been increased to £225,000
effect but it might actually be having the opposite effect. So although it was made in good faith at the time, based on evidence available, it was indirect evidence rather than direct evidence. Perhaps we have to be very cautious about any recommendations we make until we have got good evidence from controlled intervention rather than just observational studies.

Q148 Lord May of Oxford: Can I ask a follow-up, mounting another of my hobby horses? I am very down on the wasteful and energy-consuming over-packaging of food in supermarkets, and so may I ask you if there is any reliable evidence to show that preservatives used in plastic food packaging increases the risk of allergic diseases? If so, should the public be advised of this?

Dr Devereux: There are some preservatives that will exacerbate your asthma. There are some, like tartrazine and metabisulphite, which will exacerbate your asthma and make it worse, but whether they actually cause asthma is a different matter.

Q149 Chairman: Did you want to make a comment, Professor Warner?

Professor Warner: No, we just do not know, really.

Lord May of Oxford: If you were to offer such advice you have to say you cannot be sure.

Q150 Lord Haskel: Would you advise that we should inform the public that we do not know an awful lot about this, or do you think that is very dangerous?

Professor Warner: I do not think it is dangerous. There is a great tendency for people to think that there should be an absolute answer, and yet actually I think the public are perfectly capable of understanding when we do not know and therefore cannot make a recommendation.

Professor Burney: I think the real danger is in coming out with these pronouncements based on indirect evidence. A lot of these hypotheses are very intriguing, they catch the imagination, and we want them to be true because they are rather beautiful ideas, and we are in danger of going beyond the evidence. Then we give advice and people are disappointed; they say: “You told us one thing last year, it is a different thing this year”, and I think we lose credibility. The public can tolerate ignorance. That is not to say that we cannot find an answer, but it will take time.

Professor Sheikh: Ideally we would like to see newborns in very large numbers entering into the trials that are so urgently needed. So any advice that you can give to say that we do not know would be very helpful.

Q151 Lord May of Oxford: I would gratuitously add that the guidelines on science advice say: “If you are not sure you say you are not sure”. My personal belief is, as you said, it is confidence enhancing.

Dr Devereux: It works with patients when you do not know what is wrong with them and you tell them you do not know.

Q152 Lord Rea: We move on to another wide area which is the association between diet and allergic diseases. I found Dr Devereux’s review article that we were circulated with extremely useful in this area, particularly with regard to the diet of the pregnant woman and the effect on the foetus and the subsequent child. Could you develop this theme?

Dr Devereux: We have been conducting a study for the last four or five years where we recruited a large number of women up in Aberdeen, looked at what they ate during pregnancy and then have been following their children up. We have done it for five years so far and have been able to show that in mothers who had a low vitamin E intake it affects the core blood immune responses, it affects their children’s wheezing outcomes at the age of 2 and it affects outcomes at the age of 5. You have got objective associations with things like lung function measurements and we have got associations with measures of airway inflammation. These have been repeated by an American study very much along similar lines, called Project Viva in Massachusetts, which is showing very similar associations with vitamin E and core blood responses and wheezing at the age of 2. We have also more recently looked at the data showing associations between zinc and vitamin D. Vitamin D is particularly interesting because there is this latitudinal association with asthma. If you look at the map of where asthma prevalence is high it tends to be the extreme northern and southern hemispheres. Vitamin D intake has gone down, and vitamin D has some very interesting properties on the immune system. So what we are coming up with is early evidence to suggest there is an association. There is not enough to make a recommendation yet but it is probably enough for us to want to go ahead and do an intervention study to see whether intervening has an effect and whether it is practical to intervene during pregnancy, and whether pregnant women would be willing to change their diet in order to prevent their children developing asthma. We have looked at the magnitude of the effect and we have worked out that if we could get pregnant mothers to increase their vitamin E intake during pregnancy from what it is now to what it was in 1950 you would halve the prevalence of childhood asthma at the age of 5. Those are big claims and it needs to be backed up with some intervention.
Q153 Lord Rea: You said earlier that you were searching for funding to do an intervention study like this.

Dr Devereux: I would like to, yes.

Q154 Lord Rea: Would this have to involve big numbers? Is that why it is going to be difficult to get the funding?

Dr Devereux: The numbers are going to be about 1,000, I think. The problem is (a) getting somebody interested in a nutritional theme—there have been lots of studies looking at giving antioxidants, like big, big doses of vitamin C, to prevent cancer and heart disease and they have all turned out to be ineffective if not detrimental, whereas we are thinking along a different line here; we are thinking of small doses of vitamin E, maybe changing diet rather than giving a supplement—and (b) the duration. You are going to have to recruit pregnant women during pregnancy, intervene and follow the children up for at least five years, and that is a big study; it takes a lot of money to do that sort of study. So it is a question of funding bodies’ interest and funding—the actual cost.

Q155 Lord Rea: We have discussed on a number of occasions the role of pre-biotics and pro-biotics. Do you think if pregnant women take these it is worth looking to see what the result is, and is there any evidence that there is any benefit?

Professor Warner: There is for pro-biotics at the moment. The pre-biotic work is only in progress at the moment. The studies have tended to give the pro-biotics to the mothers in the last month of pregnancy and then also to the babies for the first few months of life if they are being bottle-fed rather than breast-fed. So we do not know whether it is an ante-natal effect or a post-natal effect, or both. The difficulty is if you have the kind of studies that Dr Devereux is proposing funding, say, for two or three years—which is what tends to happen—and then he goes back in two or three years to say: “Now can we sustain the follow-up, and give me the extension funding to get it through to five and six years of age when we can be more certain about the diagnosis of asthma?” the grant-giving bodies turn round and say: “What is your hypothesis?” You say: “It is to carry on what we were previously doing”, but they may well come back and say: “The situation has changed now; we are working on a whole new area; we are no longer interested in this any more.” That study loses any opportunity to derive meaningful information because of that. I think that is something that many people suffer from—not being able to sustain cohorts for long enough to get the proper results at the end. There is a large number of studies that have faltered because of that in recent years.

Lord Rea: Thank you very much for making that point.

Q156 Chairman: Can I ask you, Dr Devereux, in relation to food, is there any evidence of a difference in, particular vitamin E which you have been talking about, in its content between locally produced and locally ripened fruit and vegetables versus those which are imported, picked relatively unripe and artificially ripened and transported large distances?

Dr Devereux: I am not aware of any data for vitamin E but there are one or two very obscure papers that purport to show that with food that is transported a lot and is old, the vitamin C content goes down in pineapples, and also in food grown out of season in poly-tunnels the flavonoid content is meant to be altered as well. These are pretty obscure, German-type, papers which you have to get translated, but it is not very strong data. However, common sense would tell you that the diet we are eating nowadays is different to what we were eating during the war, and just after the war.

Q157 Viscount Simon: Can vaccines and drugs be used to prevent as well as treat allergic diseases? If they can, what sort of advantages or disadvantages does this approach have compared to dietary manipulation?

Dr Devereux: I would point out that 100 years ago we were not vaccinating children against allergic disease. Also, as a father, if I had a choice between getting my wife to eat a diet which was healthy and having my child vaccinated, I would go for getting my wife to eat healthily. There are also the concerns that you are doing something to a newborn child, and there have been scenarios explained here today where allergen avoidance has given you exactly the opposite to what you expect. We have to be certain that any proposed vaccination schedule doesn’t have the opposite effect to what we want. So you have to be very careful about using vaccination as a primary prevention.

Q158 Lord Rea: There is, surely, a case for desensitisation in cases where anaphylaxis is the problem. I know personally, because I had an anaphylactic reaction to a wasp sting and the Brompton Hospital very nicely desensitised me. Of course, I do have an EpiPen but I have not ever had to use it. Other than wasp stings, are there not several allergens that it is worth desensitising from?

Professor Warner: Yes, indeed. There is good evidence that house mite vaccines, pollen vaccines and vaccines against cat and dog will have benefits in people who are already allergic. So as a treatment, yes. The issue for this country and a number of others is generating vaccines that are safe and are not going to cause adverse reactions whilst they are being
administered; there is the potential for them to cause an anaphylactic reaction as they are being administered. The new developments are to find safe vaccines to generate components of the proteins that will immunise without causing an allergic reaction. I am sure that is going to come. There are some very exciting developments in that area. The other thing is whether these vaccines might have a role somewhere earlier in the process. There is evidence from a trial conducted around Europe of giving pollen vaccines to children who had just allergic rhinitis but not yet asthma, which showed that less asthma developed in the children that received the vaccines compared with those that did not but had similar allergies. There is potential for looking at it in an earlier stage in the evolution of disease but I think we would have to be very cautious about starting in the newborn baby. This is in children who have already showed the first signs of allergy, where it looks as if this might change the longer-term outcomes in a way that no other pharmacotherapy has been shown to be able to do.

Q159 Viscount Simon: Would a strong family history, perhaps, be sufficient? Professor Warner: One of the things that a colleague of ours in Swansea has wanted to do is look at early BCG vaccine in a trial in babies born into allergic families, to see whether that would reduce outcomes in relation to allergy. He has applied repeatedly for money to support that study and it has never been supported. I think the state of knowledge has moved on now and there is, perhaps, less evidence to support him doing that than there was five years ago, but people have tried to suggest these sorts of studies and, hitherto, have not been supported. There is one study just about to start which is being funded from the United States—Professor Gideon Lack to do a study of administering peanuts in very young children who are just showing the first signs of allergy. These are very small babies who are beginning to show eczema but are not peanut-allergic, and giving them large doses of peanuts in a controlled trial. So these sorts of studies are being thought about and are just beginning.

Q160 Lord Colwyn: Do you think that complementary and alternative medicine has a role to play in the prevention of allergic disease? I am not going to allow any of you to say yes or no on that; I want to widen it a little bit. In my view, complementary and alternative medicine is about immune system enhancing. To my mind, that includes nutritional supplements, which Dr Devereux has talked about already, herbal medicines, ayurvedic medicines and, of course, the anti-stressors—chiropractic, osteopathic and acupuncture. Take it from there. Professor Warner: All one can say is that we have to work with evidence. We have talked all along about evidence, and the issue is, have these therapies undergone sufficient scrutiny with proper controlled studies to demonstrate that they have an effect? The answer is, for the vast majority, they have not. That does not mean we are closing our minds to the potential for them to have some benefits, but I think it is incumbent on the people who recommend them to do good studies to demonstrate that they are effective. That is the treatment side. I can say very emphatically on the diagnosis side—that is, where complementary practice is trying to diagnose allergy—it is utterly and totally without any validity, and in many cases has been shown to be totally bogus.

Q161 Lord Colwyn: I will not take that up with you now, but I disagree with that.

Professor Sheikh: I will not answer yes or no, but in relation to your question about preventing allergic disorders I think the answer is we do not know because the studies have not yet been done.

Q162 Countess of Mar: Do they not have exactly the same problem as you have, in that they cannot get funding to do the studies? Professor Warner: That is true.

Dr Devereux: Yes, exactly.

Chairman: I do not know if anyone on the Committee has any other questions they would like to put to our panel.

Q163 Lord Rea: On nutrition, we should perhaps discuss the role of breastfeeding and weaning patterns: whether partial breastfeeding or total breastfeeding is best and what should be advocated. Professor Warner: It is a very difficult area. There is no doubt that exclusive breastfeeding for at least the first four months of life reduces the rates of early food allergy and eczema. There is rather less evidence that it has longer-term effects on the later allergic manifestations, but there is no doubt about those early ones. How long should breastfeeding go on, should it be partial, how rapidly should weaning occur—I think we just do not know. There is a current recommendation in many countries that in allergic families weaning should be slow, with a particular delay in the introduction of the allergenic foods. Actually, what evidence is now accumulating would suggest that that is totally wrong and that it is better to wean early on to allergenic foods and to diversify the diet quickly, and it may even be better to do so while breastfeeding continues because there might be factors in the breast milk which might help modulate the response to the foods as they are
introduced. Again, research is required in order to establish what really is the best recommendation.

Q164 Lord Cobywn: Introduce nuts and things in very, very tiny doses as early on as possible?  Professor Warner: Yes, perhaps. The research needs to be done. I am not recommending it now.

Professor Sheikh: In relation to the delayed weaning issue that has been advocated in the past, again, there has really been no firm evidence underpinning this, and currently with a three-month-old born into a high-risk allergic family at home, who is screaming at night because he is hungry, we are not following that guidance.

Lord May of Oxford: I thought this was a super

Chairman: Thank you. Do you have comments you would like to make?

Professor Sheikh: One of the issues is that when you have relatively small pots of money for allergy what it can do is promote quite a lot of rivalry between groups. When you are vying against other disease areas, if there is that internal rivalry you are actually shooting yourself in the foot quite a lot of the time. If in your recommendations you can think of any ways of promoting more collaborative research—because some of these studies we are talking about will need very large numbers; they will need a collaborative ethos—and you can give some suggestions along those lines that would be very welcome.

Q166 Chairman: You lead me into a question I have, which will be our last question this morning. You did speak earlier on about the charitable organisations that do not have research funding. I wonder whether they do not fund research partly because they do not feel confident in sorting out who to fund and partly because they feel that somehow patient information leaflets, and so on, are more important. Do you feel that some of those charities should be encouraged to be specifically fundraising towards an aggregated research pot over and above the pots that already exist?

Professor Sheikh: I would certainly encourage that. One of the things we have had in respiratory medicine recently is the formation of a national respiratory
research strategy committee which is bringing together different funders—government and charitable. Something similar in the allergy field would be a very useful way forward. Maybe I could ask John, because you sit on the Anaphylaxis Campaign as a trustee, I think.
Professor Warner: Yes, I am a trustee of the Anaphylaxis campaign, and they have relatively limited resource. Rightly, because the campaign was established by families and patients with severe, acute allergy, the first effort is devoted towards helping people here and now with appropriate support and advice. As the funds increase then they have to move into supporting research. I think they are very aware of that, but actually the environment for raising funds from charitable sources is very different to what it was 10 or 20 years ago. It really is quite difficult for them to get funds these days.

Chairman: Can I thank you for coming and giving us evidence today. If there is additional information that you would like the Committee to know about, that you think about when you go away, please do send them in and we will circulate them to the Committee. Thank you all very much indeed.

Supplementary letter from Professor Peter Burney, Professor of Respiratory Epidemiology and Public Health, Imperial College, London

I promised a further brief note on the current problems of undertaking epidemiological research.

The principal difficulty is in accessing good representative samples of the population at reasonable cost. Previously this was possible by accessing the names and addresses of people registered with general practices. A computerised list of these was kept together with sex and date of birth by the health authorities and age-sex-specific samples could be drawn by post code. No clinical information was kept on these files. Other sources such as electoral lists were more limited and less complete and are even more so now.

Although use of these data was acceptable to the public, the data are now regarded as not only confidential but also “sensitive” and access is denied.

The nearest alternative now is to approach individual General Practices and invite their collaboration. The first difficulties with this approach are:

1. General practices that refuse (for many different reasons) are not the same as those who do not and so samples are often unrepresentative. Particularly in research into health care this can be a fatal problem.

2. Even if it were possible, it is far too expensive in time and resources to approach all GPs and get small samples of patients from each. Studies therefore need to be of a “clustered” design and this leads to loss of power, or the need for larger more costly studies.

However, even if general practices are in principle willing to help they are very often unable to. Under the current arrangements they have to write to their patients to ask whether they are willing to participate and this involves 1) drawing an appropriate sample (which they are generally not qualified to do), 2) printing out the letters and posting them (a process that requires not only time but space), 3) marking off those who have replied and 4) sending reminders to those who have not.

Under the current rules, because we cannot have access to the names and addresses until the patients have replied to say that they are willing to participate, we are unable to help with any of this process. For a busy general practice this is all but an impossible task and it is amazing that we have any volunteers. In addition we have none of the valuable information about the age, gender and postcode of the non-respondents.

In all of this I see a large scale repeat of the legal nonsense that held up anonymous testing for HIV and any chance of understanding the spread of AIDS in the UK for some years. What we need is permission to use the names and addresses of patients registered with GPs together with their dates of birth and gender providing:

1. The programme of work, including the letter of invitation to participate and questionnaire, has ethical committee approval.

2. The staff are adequately trained and have honorary contracts with a health authority or trust.

PIAG was asked to allow us to take on some of this work for a particular project either outside the surgeries or sending our staff into the surgeries to help. This would have been only a partial solution at best but was turned down on the grounds that the study was “too small” to warrant an exception. That is a judgement that
in my view PIAG was not qualified to make. The relevant perception of the size of the problem is that of the general practitioners and they certainly saw the problem as one that made their participation impossible.

Further absurdities are also now creeping into the research governance. Recent advice to us about a questionnaire survey included an injunction to send a separate consent form with the questionnaire and a separate letter and “patient information sheet”. These may seem simple requirements, but there is a world of difference between sending a two page questionnaire with a letter giving a brief explanation and asking the recipient to fill it in return it, and sending a legal document with an extensive “information sheet” with what many of the public would see as “small print” and asking them to “sign” that they have agreed to the “small print”.

The upshot of all this is that we are organising a European wide survey of allergic conditions this summer and may well not be able to comply with the survey design ourselves. The irony is that a properly designed and well vetted study to improve our knowledge of public health is forbidden, but any company can ring me up at home and conduct surveys or try and sell me whatever they please. If your committee were able to find a solution, this would be greatly and widely welcomed.

10 January 2007
The British Society of Allergy and Clinical Immunology is a non-profit professional organisation that has 450 members. The society's aims are to support its membership in providing a high quality, NHS based service for the treatment of people with allergic diseases.

Research is a core value of our society. Many of our members are engaged in research into the causes of allergic diseases and understanding the underlying mechanisms, in order to identify and develop potential novel therapies. Other research interests include primary and secondary prevention of allergic diseases through allergen avoidance strategies, dietary modification and development of novel vaccines to modify the course of allergic diseases.

In response to your “Call for Evidence: Allergy”, the BSACI held a “Think Tank”, chaired by Professor Tak H Lee, on 30 September 2006, in order to address research priorities in Allergy. The attached suggestions are representative of allergists, clinical immunologists, paediatricians, rhinologists, chest physicians and colleagues from primary care, from a wide geographic distribution within the UK.

BSACI is a small society and unable to fund research directly, whereas the society could and should facilitate a network of NHS-based research centres to support DH initiatives for research in allergy. However, without capacity building within NHS-led allergy services and without a critical mass of well-phenotyped NHS patients there can be no effective research into prevention or treatment of allergic diseases, or research into optimal NHS care pathways (at both primary and secondary care level). In this regard, the recently published Department of Health Review of Allergy Services gives no cause for optimism.

**APPENDIX**

**Research priorities for prevention, treatment and improved service delivery for allergic diseases**

The following BSACI members contributed to the list of research priorities:

Dr C Brightling, Dr A Clark, Dr C Corrigan, Professor S Durham, Professor A Frew, Dr R Gore, Dr Y Karim, Professor T H Lee, Dr S Nasser, Professor DS Robinson, Dr G Scadding, Dr A Simpson and Dr S Walker.

1. **Identification of Provoking Causes**

*Genes*

Many genetic polymorphisms have been identified that are associated with allergy, but these do not necessarily translate into allergic disease. Additional genetic factors contribute to organ specific allergy, for example, independent genes for asthma risk. Studies must identify how these interact with other genetic factors and the environment, in populations that are well characterised phenotypically.
Intrauterine environment

Further study is required of the influence of maternal health, nutrition, environmental exposure, pregnancy related factors, eg placental function, and genetic diversity on the development of allergy in the offspring.

Postnatal environment

Research should focus on nutrition and exposure to allergens, infection, and pollutants in infancy. The hygiene hypothesis proposes allergy risk is influenced by early life exposure to infectious agents. The timing of exposure, nature of the agents, how they interact with the immune system and host genetic variability is unclear. Data suggest that the dose and route of allergen exposure, amongst other factors such as genetic predisposition are important in determining offspring’s allergic risk. Studies have been limited by small numbers of subject studied and heterogeneous populations. The lack of definitive conclusions have prevented clinicians from providing effective public health advice on allergy reduction measures or identifying high risk individuals.

Identification and characterisation of genetic, environmental and gene by environment interactions in early life which provoke or protect against allergy will require study of large birth cohorts. This is urgently required to identify susceptible individuals in whom cost-effective public health interventions may reduce the allergy burden.

2. Measurement of Provoking Factors (Indoor, Outdoor Aeroallergens and Pollutants)

Acute episodes of rhinitis and asthma can be caused by exposure to inhalant allergens (eg pollen, dust mite, animal dander etc). Prior exposure to air pollutants such as ozone, nitrogen oxides or fine particulate matter (PM) reduces the threshold for response and at higher levels, can trigger attacks of asthma in its own right. There is some evidence that exposure to PM (especially PM from diesel exhaust) can drive the immune response toward making allergic-type antibodies (IgE). Measuring environmental levels of allergens and pollutants is difficult. Most allergens are contained on or within small particles, which vary in their biological impact depending on where they impact (in the nose, the lung or both). Particle size is a critical issue, as only particles with specific aerodynamic properties will impact in any given area. Studies of the effects of allergen exposure on disease severity must take into account the level of personal exposure, but current methods often rely on fixed samplers, which are affected by disturbance of the air, the movement of pets around the house, changes of bedding, or fluctuations in humidity and temperature, all of which will cause variation in the measurement of allergen concentrations, and may not reflect to true allergen burden experienced by the patient. Some newer methods are being developed to measure smaller numbers of particles in air as it is breathed in. However, much work remains to be done to validate these tools and apply them to individuals going about a range of representative daily tasks. We also need exposure information for other allergens which may be important, but about which little is known (eg mould and fungal allergens) and on the effects of allergen transfer from one place to another. Once epidemiological surveys have identified possible triggers and interactions, these will need to be explored in mechanistic studies work to provide a plausible biological explanation for any observations made in survey work.

3. Interventional Studies: Primary Prevention

Clinicians and researchers have been designing studies to prevent the development of asthma and allergies for many years—so called primary prevention studies, which start at or before birth. Ideas for prevention strategies come from observational studies of (modifiable) risk factors for the development of asthma and allergies. For example, having an allergy to house dust mite is a major risk factor for asthma as is having parents with asthma. There is nothing that can be done about the latter, but it is possible (although difficult) to design changes to the home to reduce exposure to house dust mite. There are six ongoing studies around the world that have looked at modifying the home environment to reduce exposure to mite allergens in children at high risk because of parental disease. However these studies have produced mixed and, at times, confusing results and based on current evidence it is not possible to recommend a single strategy for prevention or to define a clear public health message. What is emerging from current observational studies is that to understand the development of asthma and allergies, one needs to study both the genes and the environment and look for interactions. Future primary prevention studies will likely assign risk based on genotype and target the intervention accordingly. It is likely as a consequence of such studies that public health messages will emerge.
4. **INTERVENTIONAL STUDIES: SECONDARY PREVENTION**

Sensitisation to allergens (such as house dust mite, cat and dog) is associated with asthma and exposure to allergens in those asthmatics who are sensitised is associated with more severe symptoms. Investigators have therefore studied the effect of changing the environment to reduce exposure to allergens on the severity of asthma—so called secondary prevention. Although some studies in children have shown a benefit, studies in adults have generally been too small or have been aimed at practical approaches such as changing only 1 facet of the environment (eg fitting mite proof encasings) and have shown no benefit. There is an urgent need for a large adequately powered study of a multifaceted intervention in adults to definitively examine the effect of a comprehensive mite avoidance program on asthma control in adults.

5. **PREVENTION OF OCCUPATIONAL ALLERGIES AND ASTHMA**

Asthma and allergic dermatitis arising as a direct consequence of exposures in the workplace are common in UK industry; for example approximately 10 per cent of UK supermarket bakers (a workforce of around 8,000) have bakers’ asthma and a similar proportion of those engaged in pharmaceutical research develop an allergy to laboratory animals. A recent report by the HSE estimates that the total lifetime costs to society of the c 600 cases of occupational asthma reported each year range from £71.7 to £100.1 million; since recognised cases are believed to represent only a third of the true incidence, the real costs could be as high as £133.5 million (http://www.hse.gov.uk/RESEARCH/rrpdf/rr474.pdf). The pattern of these cost burdens suggests that employers are imposing a large “external” cost on the rest of society. There are in addition high individual “costs” of occupational disease including, frequently, unemployment and reduction in income. The causes of these diseases are, by and large, well understood and experience in a small number of settings (eg latex in NHS workplaces) suggests that, with sufficient and appropriate effort, primary preventive interventions are feasible. Extending the breach in this “application gap” will require close collaboration between industry, occupational health and safety services (where these exist) and clinical researchers. This at present can be very difficult to achieve; and is increasingly so given that there is now virtually no available external funding for such work. This clearly represents an urgent unmet need.

6. **INFLAMMATION AND REMODELLING**

Research into basic mechanisms of rhinitis and asthma, much of which has been pioneered in the UK, has led to the identification of potential therapeutic targets for intervention and the development of several novel and effective therapies that include anti-IgE monoclonal antibody (Omalizumab), anti-leukotrienes and the testing and introduction of known immunomodulatory treatments in asthma including Cyclosporin A and anti TNF-alpha. The role of aberrant repair and remodelling processes in the progression of asthma is increasingly recognised. There is an urgent need to address why some atopic (skin test positive) individuals develop asthma whereas others do not. It is also important to understand the differences between mild and moderate-severe asthma, the similarities and differences between childhood and adult asthma and why some asthmatics progress to severe, progressive and ultimately irreversible disease whereas others do not. These questions may only be addressed through multi-centre studies with adequate funding for research clinicians and scientists working in collaboration and with access to well-characterised patients via adequately resourced NHS allergy clinics.

7. **IMMUNOMODULATION AND IMMUNOTHERAPY**

Asthma represents a spectrum from mild to potentially life-threatening disease. Rhinitis, although frequently trivialised represents a common cause of morbidity, with impairment of quality of life and work/school performance for over 12 million people, a quarter of the UK population. Whereas intranasal corticosteroids and antihistamines are effective for rhinitis, and inhaled corticosteroids and bronchodilators for asthma, there remains a proportion of patients who fail to respond to these treatments. Furthermore these medications do not influence the underlying progression of disease such that relapse occurs within days of their discontinuation. Allergen immunotherapy (desensitisation) involves the repeated administration of allergen extracts to allergic individuals, in order to induce a state of clinical and immunological tolerance. Widely practised in US and Europe, this therapy has not been widely adopted in UK. Recent work has shown that allergen injection immunotherapy is highly effective, safe when performed by trained persons, and, unlike inhalers and nasal sprays, may induce long term remission, reduce the onset of new sensitisations and prevent the progression from rhinitis to asthma. The sublingual route of immunotherapy (under the tongue) has
recently been shown to be effective and suitable for home use in adults and there is encouraging preliminary
data in children. There is an urgent need for research to address whether the sublingual route may also induce
long term remission and have disease modifying properties. Research into the mechanism of sublingual
immunotherapy, the development of biomarkers to predict the clinical response to treatment, and the
development of novel “adjuvants” to improve the efficacy of both injectable and sublingual vaccines are
urgently required.

8. Diagnosis and Monitoring Disease Severity

Improved diagnostic accuracy and more targeted therapy tailored for individual sufferers will help our battle
to hold back the “allergic march”. In this regard identification of objective and practical biomarkers applicable
diagnostic and prognostic tools, as well as therapeutic targets will assist in clinical management of allergic
disease. Biomarkers can be defined as measurements that are associated with the biology or physiology of a
clinical disease process. It is critical that biomarkers are relevant, and reflect or predict patient-centred
outcomes such as symptoms, quality of life, disability, exacerbations and death. A wide variety of biomarkers
have been associated with allergic disease, but few are well-validated and fewer still are used in routine clinical
care. For example, in asthma response to certain drug treatments are associated with genetic polymorphisms
(pharmacogenetics), and anti-inflammatory treatment titrated based upon markers of inflammation measured
in exhaled breath, sputum composition, and measures of airway physiology have all shown benefit compared
to standard therapy. Further scrutiny of these biomarkers and the development of simpler markers are
required so that these can be taken from the research arena and applied to the clinical care of sufferers with
allergic disease.

9. Difficult to Treat Asthma

Although asthma care has improved in the last 15 years with the advent of British and International treatment
guidelines and widespread use of preventive inhaled steroid therapy, a small proportion of asthmatics continue
to have severe limitation of their lives by the disease. These difficult to treat asthmatics represent about 10 per
cent of the total asthmatic population and include both adults and children, and a recent survey identified up
to 7,000 adults with difficult asthma reported by UK chest physicians. Studies have suggested these patients
are those most at risk of dying from their asthma (over 1,000 deaths per year in the UK) and they account for
up to half of all healthcare resource costs for asthma. They often remain symptomatic despite treatment
including oral steroids (which can produce serious side effects including osteoporosis, diabetes and
hypertension). This group remains ill defined and understudied and there are no current guidelines on
management of this group in the British Guidelines on Asthma. New treatments aimed at this group include
anti-IgE antibodies which represent expensive treatment with poorly defined criteria for use. Recent
descriptive studies have suggested that such patients are a diverse group with a high rate of misdiagnosis and
co-existing psychiatric disease and poor adherence with taking prescribed medication. However at least 50 per
cent of difficult to treat asthmatics seem to have resistant asthma and recent efforts have focussed on defining
an agreed investigation and management approach to inform guidelines. A British Thoracic Society working
party has been established to form a UK national network of regional centres for difficult asthma to allow
setting up of a national database for research and clinical development. Current research aims include defining
sub groups who might respond to different biological therapies such as anti-IgE, anti-IL-5 or anti-TNF or
identifying markers of inflammation (such as induced sputum eosinophil counts) that might predict (and allow
prevention) of disease exacerbations. Current research areas in this field include factorial analysis to identify
disease subgroups and mapping of phenotype with genotype and patterns of inflammatory gene expression.

10. Service Delivery Interventions

The majority of straightforward cases of allergic diseases including rhinitis, asthma and eczema, can be
managed effectively in primary care by appropriately trained staff, although there is clear need for specialist
referral pathways for many allergic conditions including drug, food and venom allergy. We have access to an
armoury of evidence-based treatments for allergic diseases, although there remain significant gaps in our
understanding of some of the fundamental clinical issues in relation to diagnosis, prevention and service
delivery that need addressing in order to ensure evidence-based care of allergy sufferers. In terms of diagnosis,
we have no proof whether identification of a specific allergen trigger using specific IgE or skin prick testing
improves the outcome of management of respiratory diseases or eczema. We have no proof which blood tests
(if any) are useful in diagnosing chronic urticaria. We do not know what proportion of patients with a history
suggestive of antibiotic allergy has measurable specific IgE to penicillin or equivalent. In terms of service
delivery, there are clear, published guidelines on the management of anaphylaxis, but we do not know how
often A/E treatment of anaphylaxis complies with best evidence, or whether patients with anaphylaxis get
followed up effectively and safely. We also do not yet know whether primary care-based allergy services
prevent hospital admissions, or understand the extent of their contribution to cost-effective disease
management.

Memorandum by European Academy of Allergology and Clinical Immunology

INTRODUCTION

Allergy is an increasingly common problem across all parts of Europe. The European Academy of Allergology
and Clinical Immunology (EAACI) is a non-profit organisation whose principal aims are to promote basic
and clinical research into allergy, to collect, assess and diffuse scientific information relating to allergy, to
courage and provide both training and continuous education for clinicians and scientists interested in
allergy and finally, to collaborate with patients and lay organisations in the area of allergology and clinical
immunology. Many of our key members are involved in research projects looking at the factors responsible
for allergy in different parts of Europe and separately, looking at treatments that may be effective in reversing
the trend and preventing the next generation from suffering from allergies.

In answer to the specific questions:

Q1. What is allergy?

Allergy is a specific immune-mediated reaction to foreign materials such as pollens, dander, food, drugs etc.
Patients with an allergy will react more or less on every exposure to the substance, even when it is only
encountered at low levels. Patients who are not allergic to that substance should not normally react to it. This
contrasts with toxic reactions where most people will react to the foreign substance if they are exposed to
enough material and intolerance reactions where people have symptoms after eating a particular food or being
exposed to perfume, newsprint etc but there is no immunological recognition of the foreign substance. The
distinction between allergy and intolerance has been blurred in the newspapers, magazines and general
popular usage. For example, everybody understands the phrase “I’m allergic to Monday mornings” but
nobody thinks you make antibodies to them!

Q2. What is and is not known about the origins and progression of allergic disease?

We know that there is a genetic risk for allergy and therefore allergies tend to run in families. However, there
has been a rapid rise in the number of people affected over the last 30 years and that rise cannot be blamed on
genetic factors alone. Rather, it seems that there is a susceptible group of the population who can develop
allergies if they are exposed to an unfavourable environment.

From clinical observations, there is a progression of allergic disease such that children may develop eczema
in childhood and then go on to develop rhinitis which may or may not be followed by asthma. This is often
called the “allergic march”.

All three conditions involve allergic sensitisation but the targets may change with food allergy being important
in infancy and inhalant allergies (pollen, dust, danders etc) becoming more important for the rhinitis and
asthma. Allergies developing during childhood often regress as the child gets older. So for example, allergies
to egg and milk are common in the first two years of life but rarely persist through into older childhood and
adulthood. An exception is peanut allergy—children with peanut allergy aged 10 have approximately 80 per
cent chance of still having it when they reach 18. People with hay fever often get their worst symptoms during
the teenage years and the third decade of life and it gradually gets less troublesome as they move towards their
40s and 50s. However recent data suggests that there may occur a second allergic march starting with hay fever
and progressing to persistent rhinitis, sinusitis and asthma in a proportion of these patients. Childhood asthma
can disappear around puberty, particularly in boys due to their differential lung growth at puberty. People
who have had asthma in childhood are at greater risk of developing asthma in later life, although it is not
always clear whether it is recurrence of the asthma or a new condition occurring in someone who is predisposed
to asthma.
In the longer term, some patients with asthma go on to develop fixed airways obstruction. This is part of the “remodelling” process that occurs in asthma, but it is not clear why some patients are more affected than others. Smoking tobacco is a major risk factor but it can occur in lifelong non-smokers. No specific preventive therapy has yet been identified.

Q3. Why is the incidence of allergy and allergic disease rising?

The precise reasons are not known but it does seem to be linked to some aspects of the more prosperous living conditions that we have enjoyed since 1960. Evidence from the United States suggests that this rise in allergies was starting to appear during the 1930s and is therefore not just due to changes that have happened since World War 2. However, dramatic increases were seen between about 1964 and 1980 with continuing increases in the presentation of allergic disease to GPs and other healthcare providers at least into the 1990s. There is some evidence that healthcare usage may be levelling off, perhaps due to changes in the way the Health Service is organised but cross sectional studies of allergic disease suggest this increase has been sustained in the UK and is continuing to be apparent in other parts of Europe. In particular, following the reunification of Germany and the increased prosperity both in East Germany and in other parts of Eastern Europe, we have seen an increase in the incidences of allergic diseases right across the former iron curtain countries. From these studies, we can tell that it is the conditions during the first few years of life that seem to matter most. For example, people born in West or East Germany before 1960 have similar rates of allergic disease, even the West Germans had much better living conditions during the 60s, 70s and 80s. However, those born in the 60s in West Germany have higher rates of allergic disease which appears to link in with the better living conditions that were present in West Germany during the 1960s. Other data from farming communities in Bavaria and Switzerland suggest that there is a critical window of exposure in the first year of life during which the child’s immune system can be influenced and their risk of allergic disease substantially reduced. Once the child passes their first birthday, the same factors that would have prevented them from becoming allergic no longer operate. This implies that any intervention to change the prevalence of allergy would have to target the very early phase of life and not be brought in at five years +.

Q4. Why does the UK have such a high prevalence of allergy?

If one allows for international differences in general levels of prosperity, then it is not so clear that the UK has substantially higher levels of allergy compared to other European or developed countries. Because the UK is relatively prosperous, there is certainly a higher cross-sectional rate of allergy but the highest rates worldwide appear to be in Australia and New Zealand. To the best of our knowledge, nobody has identified a UK-specific factor which would explain why we have a higher rate of allergy than would be expected simply from our general levels of prosperity.

In terms of the precise aspect of prosperity that may be important, many different suggestions have been made. These include changes in housing stock, changes in food technology, air pollution, vaccinations, exercise etc. It is true that modern housing and furnishing tends to increase the level of house dust mite allergens in houses. House dust mites prefer warm, damp environments which are favoured by the increased insulation of modern housing, carpeting, taking more baths etc. Reducing the level of house dust mite exposure has not been convincingly shown to reverse the trend. However, the data has often related to single interventions, such as provision of mite-proof bedding in adults and further controlled trials involving multiple interventions are needed, particularly in children who are more likely to respond to avoidance strategies. The biggest single influence on childhood immune development is food and intestinal bacteria. It is clear that there have been changes in intestinal microbial flora since the 1950s and the lack of certain gut bacteria may predispose children towards developing allergies. This is part of the “hygiene hypothesis” and is currently being tested in Scandinavia as a possible means of reducing the onset of allergy. This suggests that the change in the incidence of allergy flow from the large scale change that has taken place in food technology and our diets over the past 50 years. Other changes have been the increase in both parents working with a consequent decrease in daily shopping and rise in consumption of ready meals. Fresh foods, especially fruits and vegetables contain anti-inflammatory antioxidants which decrease on storage, those obtained from supermarkets are low in this respect.
Q5. What gaps exist in establishing the overall disease burden of allergies?

There are difficulties in obtaining precise diagnoses for these conditions, especially where they merge into normal health. Many people are sensitised to grass pollen, cat, house dust mite etc but have no definable symptoms or little difference in symptoms compared to normal healthy individuals. There is a fundamental need to understand why some “atopic” (skin test positive individuals) develop allergies (symptoms of rhinitis, asthma and eczema) whereas others do not. Many allergic conditions are handled by self-medication and do not therefore come into conventional Health Service statistics. Cross-sectional surveys are always difficult to interpret because those with the condition are more likely to respond than those without.

Q5A. What are the social and economic consequences of allergic disease?

We believe that there is substantial absence from work and school as a result of allergic disease. Importantly, allergic diseases tend to affect young people who are either in education or economically active. Both hay fever and its treatment have clear adverse effects on exam grades and school attainment.

Q6. What are the effects of current treatments on the natural history of allergic disease?

Standard drug therapy including antihistamines, inhaled steroids and beta-agonist anti-asthma medication has no real effect on the natural history of allergic disease. These are effective drugs for containing the symptoms but they do not “cure” the disease in the sense of getting rid of it. They are also more useful in preventing exacerbations rather than eliminating symptoms. We do tell patients that inhaled steroids may prevent the progression of their disease but there is little hard evidence for this.

Q8. What is the evidence base for pharmacological and non-pharmacological management strategies?

We have good evidence for symptom control with ordinary pharmacological strategies. For example, about 35 per cent of patients with hay fever report good symptom control with the combination of antihistamines and topical steroids, 45 per cent have partial control and about 20 per cent have poor control.

Non-pharmacological management includes allergen avoidance and immunological approaches such as desensitisation. The evidence for using allergen avoidance is rather mixed. There are significant criticisms of many studies in this area, particularly in terms of failure to target advice to those patients who are likely to benefit and failure to choose correct end points. Specific immunotherapy (also known as desensitisation) is effective on symptom control and has some effect on the natural history of the disease. In particular, desensitisation of children with rhinitis can prevent them from developing into asthma, and may reduce the likelihood of acquiring new sensitivities. However, desensitisation is not widely practised in the UK. This reflects concerns about safety, but elsewhere in Europe and North America, desensitisation is commonly used in patients presenting with rhinitis and asthma. Sublingual desensitization is becoming available in the UK—it is amenable to home use after the first dose. A major question is whether this can, like injection immunotherapy, prevent disease progression.

Q9. Is the level of UK research into allergy and allergic disease adequate?

Allergy represents a modern epidemic in UK and Europe and there is an urgent need for more investment in research if this trend is to be reversed. Such research requires the existence of high quality allergy services at secondary and primary care level, which can serve to expand research capacity and build research networks in which the necessary clinical research and clinical trials can be conducted.

EAACI would particularly welcome research across Europe looking at how different risk factors operate in different countries. There is quite good evidence that there are gradients of risk across Europe and these may reflect both genetic variation and environmental variations such as diet, air pollution etc. different risk factors are likely to have a variable instance in different parts of Europe. In this sense, the European countries represent a very useful laboratory in which to study the causes and management of allergy and asthma. Two UK Universities (London and Southampton) are already engaged in a EU-funded network of excellence (GA2LEN—Global Allergy & Asthma European Network), and others are involved in a food allergy research network (EUROPREVALL).
A corollary is that it is quite likely that individual risk factors may operate differently in the UK than other European countries, so interventions need testing in the UK, even if they appear to work elsewhere. This type of applied research needs more support and this may be forthcoming through the new DH R&D programme (research for patient benefit—RfBP). Current basic and mechanistic research in the UK is of a very high standard but funds are limited.

Q10. **What are the most promising areas of research into preventing or treating allergy?**

Interesting data is developing in preventing allergy through the use of probiotics and nutritional strategies in childhood. These are reviewed in detail in Tricon et al 2006 (funded as part of an EU network of excellence under the sixth framework programme). Whereas drug therapies are well established, they have no impact on the long-term course or progression of allergic diseases. In contrast, the use of allergen specific immunotherapy is promising in this regard. A study of immunotherapy in children with seasonal allergic rhinitis (hay fever) has found that about 45 per cent of children will develop asthma if they are untreated, while only 20–25 per cent develop asthma if they receive immunotherapy (Niggemann et al 2006). This benefit has been sustained for 7 years after completing treatment, so it is not simply delaying the onset of asthma. Roughly speaking you need to treat four children to prevent one from becoming asthmatic. One of the four will become asthmatic anyway, and in the other two you will have improved their hay fever but they would not have gone on to get asthma. There is also an urgent need for research into controlling the long-term downstream consequences of allergic disease, particularly in relation to asthma. Further details of research priorities in allergy are contained within the submission from the British Society for Allergy & Clinical Immunology and will not be repeated here.

Q11. **How effective has Government policy and advice been in addressing the rise in allergies?**

Current rising trends in allergic diseases argue that policies have been less than effective, although a good example of successful intervention is the reversal of asthma mortality trends following the implementation of asthma guidelines, whereas the trend for ever increasing hospital admissions for life-threatening anaphylaxis is particularly worrying, as is the less serious but none the less bothersome allergic rhinitis that now affects a quarter of the UK population and is associated with considerable impairment in work/school performance.

From the existing data, the most important single thing we could do to reduce allergy in childhood is to reduce smoking by mothers and mothers-to-be. Maternal nutrition is probably important, but we are not yet in a position to give hard evidence-based advice to pregnant mothers. Government advice on diet during pregnancy has been of questionable value, especially in relation to peanuts. It was tempting to offer advice that sounds sensible, but the evidence suggests this has not affected rates of peanut allergy and may even have increased it.

There is a separate issue regarding the way that the public view government information. We live in an age when official information is distrusted, even when its credentials are impeccable. Advice from doctors is also mistrusted and routinely rubbished in the press and other media. Patients are left wondering who to believe and often end up going to unofficial sources for information. Separately, there is an impression that Government is not particularly interested in allergy and has yet to be convinced that this is a significant Public Health problem.

Q12. **How is current knowledge about causes and management of allergic disease shared within Government?**

Recently, a UK indoor environment group has been formed which is looking at the interaction between health and the environment in terms of housing and housing design. People from social services, local government, schools, architecture and the Building Research Establishment have all come together around this, although they are interested in several other issues as well as allergy. Further evidence is really required from scientific studies before one could make definitive advice on how housing policy should be altered.

Food policy and labelling regulations are really two separate issues. There are questions about food policy that relate to the development of allergies and asthma. In particular, if the nutritional evidence is to be believed, then we should be looking at advice on dietary content and supplementation.

Food labelling regulations are more to do with risk containment in people who are sensitised. There is a major issue at the moment regarding foods that are labelled as “may contain traces of nut”. This term has caused considerable disquiet and confusion among patients and their advisors, since there is an enormous difference between foods that may occasionally contain large quantities of nut as opposed to foods that do regularly
contain small amounts. Indeed, recent anecdotal reports suggest that there is probably less nut in a food that “may contain traces of nut” than in a food that has no mention of nuts on the label. A widespread perception that food manufacturers are putting this label onto their foods in order to avoid blame for allergic reactions does not help to increase confidence amongst the general public.

**Patient and Consumer Issues**

Q13. *What impact do allergies have on the quality of life of those experiencing allergic disease and their families?*

Asthma can seriously affect patients and their families. It limits people’s life ambitions, their ability to participate in sport and in a number of occupations including the armed forces, police force, baking, car repair workshops etc. Hayfever and rhinitis have been shown to have even more impact on quality of life than allergic asthma. These are not trivial conditions, even though they do not kill very many people.

Food allergies can lead to considerable psychological trauma and difficulties for children and their families. Most schools now have sensible policies in place for managing nut allergy but in the absence of any specific treatment, the whole management strategy has to depend on containing the risk exposure. This can lead to considerable friction both between parents and child and between the family and others concerned in the child’s social activities.

Q14. *What can be done to better educate the public?*

There is a plethora of information available to the patient and public but much of it is unfiltered and can be confusing. The problem is not giving more information but making sure there is some way of encouraging people to go for high quality information. Whether this should be by offering lists of preferred internet sites or quality stamping sources of information is a difficult judgement. It is not helped by the fact that there are a wide range of views out there, held by both patients and practitioners. While these may be applicable to individual cases, they are not always applicable to all patients. Better access to NHS allergy services would be a big step forward.

Q15. *Are current regulatory arrangements for private clinics etc satisfactory?*

Many alternative and complementary therapists claim to offer allergy diagnostic tests. In some cases these are unconventional tests for diseases that are accepted by everyone to be allergic. So for example, they may offer an alternative way of testing for sensitivity to explain your asthma or your hayfever. Others are offering to look for allergy as an explanation for symptoms that we do not think are allergic. So for example, someone might offer to test for an allergic basis for fatigue, headache, weight gain etc.

We have to assume that the people offering these tests genuinely believe allergies may be responsible for this, despite the fact that there is no evidence to support this belief. Obviously if anybody offered such tests while knowing that they were false then this would be fraudulent behaviour and come under the trades descriptions act.

We believe that much of the current provision of alternative and complementary services for allergy is driven by failure of provision within the state-funded healthcare sector. Even reputable tests such as specific IgE cannot be interpreted without a detailed clinical history taken by an allergy-trained individual, thus over the counter and postal testing is open to misinterpretation unless expert opinion is available. If adequate NHS advice and information were available, then it is likely that many of these private sector clinics and over the counter allergy tests would no longer be necessary.

**References** [not printed]
Examination of Witnesses

Witnesses: Professor Stephen Durham, President, British Society for Allergy & Clinical Immunology, Professor Peter Barnes, Airway Disease Section, National Heart & Lung Institute, Imperial College London, Professor Andrew Wardlaw, Director of Institute for Lung Health, Glenfield Hospital, University of Leicester, and Professor Anthony Frew, President, European Academy of Allergology and Clinical Immunology, examined.

Q167 Chairman: Could I start by welcoming you and thanking you for coming to give us evidence today. I am Lady Finlay. I am the Chairman of this Committee. The meeting will be webcast on the internet. There is an information note for the public which declares the interests of members of the Committee, so we will not be declaring them during this session. We have a lot of questions we would like to ask you so if you are able to keep your answers as concise as possible that will allow us to get through this session. We have a lot of questions we would like to ask you so if you are able to keep your answers as concise as possible that will allow us to get through this session. Perhaps I can ask you to introduce yourselves and then we will get into the question session.

Professor Frew: I am Tony Frew. I am President of the European Academy of Allergology and Clinical Immunology, and a consultant in allergy and respiratory medicine in Brighton.

Professor Wardlaw: I am Andrew Wardlaw. I am an allergist and respiratory physician in Leicester and until recently was President of the British Society of Allergy & Clinical Immunology.

Professor Barnes: I am Peter Barnes. I am a pulmonologist, Head of Respiratory Medicine at Imperial College London.

Professor Durham: I am Stephen Durham. I am an allergist at the Royal Brompton Hospital and President of the British Society for Allergy & Clinical Immunology.

Q168 Chairman: Thank you. It has been evident from the way you have introduced yourselves that you describe yourselves as having an interest in allergy. Would you describe yourselves as allergists and I wonder if you could also outline for us the route by which people become allergists and quite what is meant by this term?

Professor Frew: I trained as a respiratory physician and a general physician and then did additional specialist training in allergy in London and also in Canada. I practise as an allergist and would describe myself as such. I do other things as well but I would certainly accept the term.

Professor Wardlaw: My route into allergy is through my academic interest. My research is into the pathogenesis of allergic mechanisms. My clinical practice is about 50 per cent allergy and 50 per cent respiratory medicine, and my training in allergy was undertaken in a fairly ad hoc fashion.

Professor Barnes: I am not an allergist; I am a pulmonologist, but I see a lot of patients with asthma and many patients with asthma are allergic. I have done no specific training in allergic diseases.

Professor Durham: I describe myself as an allergist. Looking backwards, the dilemma is that there was previously no formal training for allergists until five years ago and therefore unavoidably my training was ad hoc, so I have been grandfathered into the term “allergist” on the basis of 20 years’ experience. I think we should be looking forward, not backwards, as to the best way to train allergists, which is probably not through specialist training but through training allergists.

Q169 Chairman: As specific allergists, so allergy training as outlined by the College of Physicians?

Professor Durham: It is our priority, certainly in the British Society of Allergy & Clinical Immunology, to equip all practitioners to become aware of, recognise and treat allergy appropriately. There are different levels that one must address. There is the specialist allergist in a tertiary centre. We see it as our role to train chest physicians and other secondary specialists in allergy, and also to increase awareness in general practice, and I think we should be looking at a multi-layered approach in terms of equipping us. From the patient’s point of view I think that is an important benefit.

Q170 Lord Taverne: Is there a proper career structure for people who are allergists? There is a new system now for training them but is there a proper framework for creating posts for people as allergists, because I have heard a suggestion that this is a lack in the present set-up?

Professor Durham: I think it is a chicken and egg situation. We need regional centres to train allergists and then when the specialist trainees become allergists we need to create posts for them to practise in allergy. The way to look at this is to look at the needs of the allergy sufferer rather than individual specialist training. You are quite right to raise the issue that if we train allergists at the present time will there be posts for them to move into, but I think that is something that needs to be addressed centrally.

Professor Wardlaw: Allergy was created a specialty only five or six years ago and it has been a major effort by the BSACI to try and establish this as a viable specialty. That has been through a lot of
lobbying of the Department of Health to try and do that because we need sufficient training numbers and sufficient consultant posts at the end of it to make a viable speciality which will provide a network of allergists around the country. At the moment that struggle still goes on and it is far from being successful.

Q171 Lord Colwyn: Although it was a long time ago I seem to recall that the only sketchy medical training I had in allergy was how you dealt with emergencies. That was it.

Professor Frew: Certainly within the two medical schools I have worked in allergy has a definite place in the curriculum. It is small but it is there and we try to make sure that everybody coming through nowadays is given some basic knowledge of allergy. At the same time, as has been said, we are trying to provide retrospectively some training for people at postgraduate level so that everybody is aware of the mechanisms and clinical aspects of allergy as they relate to their chosen branch of medicine.

Q172 Earl of Selborne: I would like to follow up the concept of a viable speciality. How well co-ordinated is the process whereby new treatments for allergy and/or their various allergic conditions are assessed and approved for use given that the term “allergy” describes a generic immunological response and the effects may be manifested in a range of linked diseases?

Professor Frew: The problem is that allergy is a mechanism rather than a disease in itself and many of the treatments that come forward are looked at in terms of the organ-based speciality to which they relate, so treatments tend to be thought of in terms of treatments for eczema or treatments for asthma or treatments for rhinitis. A lot of the companies producing these compounds are relatively small compared to some of the large pharmaceutical companies dealing with, say, hypertension, and so it has been difficult to get some of the trials pushed forward. There are also some barriers in place, particularly for new approaches to this. For example, recombinant allergens, which look a very attractive way of treating people by specifically targeting the problem of that individual, come up against really quite strict regulations about individual components of the vaccines that you might want to use, which make it extremely difficult under current regulations to test and consider how you might get a product licence for them, and I think in general the co-ordination is not terribly good.

Q173 Lord Rea: What provision is there currently in the National Health Service for specifically treating allergy as opposed to the range of conditions affecting particular organs that come under the general heading of allergy? Of course, now these are largely handled in primary care or by other specialities.

Professor Wardlaw: It is very poor, is the answer. There are very few trained specialist centres or departments dealing with allergy specifically. There are perhaps half a dozen well established allergy clinics in the UK and there is a certain amount of provision from clinical immunologists treating general allergy, which in some areas is excellent and in other areas is more variable. The problem is that for a number of reasons allergy has always been a Cinderella subject and specialist allergy training, as we have heard, is very poor at undergraduate and postgraduate level. Organ-based specialists, I have to say, tend to be rather protective of their patch, as we all are a little bit, I guess, and I think they feel that their allergy training is better than we as allergists feel it is, so we feel generally that provision of NHS training is very poor in the UK now.

Q174 Lord Rea: Do you think there is a strong case for training nurses and doctors in primary care to a higher level for recognising allergy and so guiding their more appropriate treatment?

Professor Wardlaw: Absolutely. The majority of allergy is seen in primary care and a lot can be effectively treated in primary care or in the community, but the problem is that the knowledge of allergy in primary care is very poor and there is no mechanism for training primary care doctors because there is such an inadequate critical mass of people to train the GPs. What you need first, we think, as an allergist is to have a critical mass and then train the GPs, but it is very important.

Professor Frew: There is an additional issue here, which is that there are some conditions that patients have which are fairly easy to map onto the current NHS speciality map. For example, if you have asthma there is going to be somebody in your patch who will deal with it at an adult or paediatric level. If you have a food allergy it can be quite difficult to identify who in the area should be dealing with it. If you look at it from the point of view of the patient’s problem, if it maps on to the organ-based specialities it is easy to find somebody who at least ought to be able to address it, but if they have a more general problem—anaphylaxis, peanut allergy—it can be quite difficult to try and find your way through the system to get specialist advice if you cannot get that at the primary care level.

Q175 Lord Rea: What short courses are available for practitioners in primary care or in some other specialisms to get some improved skills for these things?
**Professor Durham:** If I may address that on behalf of the British Society for Allergy and Clinical Immunology, this is a very big priority for us. The way we are addressing this is that we are having a primary care day or two days dovetailed into our annual national meeting. We have organised a series of regional training days in allergy for general practitioners and nurses and we have a clinic list of NHS allergy clinics which is open and available to general practitioners and nurses so that they may attend those clinics in order to gain experience in allergy. It is really a more general approach to increase awareness of allergy, to inform general practitioners when to refer to secondary care level and also, for a smaller proportion of general practitioners, to encourage them to develop a specialist interest and support them through our NHS clinics.

**Q176 Lord Rea:** Do you think there is a good case for specialist nurses working in primary care to handle the allergy component of the workload?  
**Professor Durham:** I would emphasise that I think that is a very important component. We have the Education for Health in Warwick that has trained some nurses from some 9,000 general practices throughout the country in the management of asthma. The same group have also encouraged training in allergy, so nurses are an important component, but we must bear in mind that this is what we are dealing with in terms of the common allergic conditions. What is even more important is to encourage and make people in general practice aware of when to refer. To give examples, food allergy, drug allergy, venom allergy, latex allergy, occupational allergies, the patient with multiple problems, difficult paediatric problems are all just the sorts of problems that need to be recognised and referred on. I think it is our role also to empower general practitioners, and I believe the Government’s role to support not only increased awareness of allergy in primary but also the facilities at secondary care level to deal with the current epidemic.

**Q177 Chairman:** How much supervised clinical experience is contained within the Warwick course?  
**Professor Durham:** At the present time not a lot, but then I think the objectives of the Warwick course are to increase awareness of allergy and to empower general practitioners and nurses to recognise allergic conditions. It is very important for treatment to have a little knowledge disseminated widely to increase awareness of the subject at the first base, but you are quite right: in terms of the need to train GPs to more effectively manage allergic conditions it requires more specialist services at secondary and tertiary level.

**Q178 Chairman:** I just wonder whether such short courses are appropriate to provide GPs in particular with the skills that they would need to manage patients with complex conditions and multiple manifestations.  
**Professor Durham:** May I say that that is not at all possible. That is why we need to increase allergy awareness and training at all levels.

**Q179 Baroness Perry of Southwark:** My question follows on very much from that discussion. We were told by the Department of Health that they had proposed to NICE that they should develop guidelines for allergy, and I understand they are doing that now. What guidelines would you like to see?  
**Professor Durham:** Two obvious examples in terms of specific allergy treatment as opposed to organ-based treatments would be to look at anti-IgE therapy, which is a novel therapy, and subcutaneous and sublingual immunotherapy for those patients with IgE mediated disease and a very focused spectrum of problems. Anti-IgE and immunotherapy would be two appropriate areas.

**Q180 Baroness Perry of Southwark:** In general do you think that the treatments that are available for allergic diseases like asthma, hay fever and anaphylaxis are clear and easy for patients to understand and administer correctly?  
**Professor Barnes:** I would say that the current therapies for rhinitis and asthma are very effective for the majority of patients and relatively simple. The mainstay therapy for asthma is inhaled steroids, plus in many cases a long-acting beta agonist and these are highly effective forms of treatment for asthma. There are also effective treatments for rhinitis. Treatments for eczema are less effective, but there are patients where these simple treatments are not very effective and these patients often need specialist attention. Traditionally we would expect patients with difficult asthma to come to pulmonologists and patients with difficult eczema to be referred to dermatologists.  
**Professor Frew:** One of the issues here is that for a lot of patients who have anaphylaxis and food allergies it is about appropriate avoidance of triggers and also provision of first aid therapy. There is not in that case a treatment that you give on a routine basis. The main issue is about access to a correct diagnosis which then leads through to correct advice, so some of it is about getting the history and then coupling that to the advice that is available and using the existing medications that are available.
Q181 Baroness Perry of Southwark: Do you think there are any ways in which allergy treatments could be improved to make them safer, for example, to be used by children in school during each day?
Professor Frew: As Professor Barnes has said, the existing treatments for asthma and rhinitis are safe and easy to use. There is not really a problem with those. There is a limit on how effective they are, so there is room for further improvement. In relation to food allergy, where what you are trying to do is avoid ingestion but if they do have an accident you may have to administer injectable adrenaline, clearly what we would like to do is move forward to a situation where we can treat this and get rid of the condition rather than simply being there as a safety net in case somebody eats something they should not.

Q182 Chairman: Could you explain what the place is for anti-IgE therapy, whether it is only in severe disease or whether it could be used earlier on and should be used earlier on?
Professor Barnes: One of the problems of anti-IgE therapy is its enormous expense. It costs something like £10,000 a year to treat some patients with higher levels of IgE, so it could only really be considered for very severe asthma patients, but there is no doubt that some patients respond very well who have not been controlled by conventional therapy, so we would really only consider patients not controlled on maximum doses of inhaled therapy for asthma and, in particular, patients who need to have steroid tablets that have a lot of side effects, as potentially suitable for this therapy. If it were much cheaper it then might be applicable to a broader population of people with allergy.

Q183 Viscount Simon: Do all people with allergy have an altered IgE?
Professor Wardlaw: That is a very profound question. It depends how you define allergy. Some people define it quite narrowly as only people who have got IgE disease involving abnormal amounts of IgE. It can be defined more widely as conditions which have many manifestations that look like allergy or that I would regard as allergic but when that particular mechanism is not involved. I would say 75 per cent of allergy at least is IgE mediated. Going back to Professor Barnes, it is an excellent and fascinating treatment which has a place in a very specialist setting in a relatively small number of severe asthematics, but could be of considerable use. It is frustrating at the moment, certainly in my experience and I suspect others’, that the purchasers are not willing to purchase it very readily, which is a problem for us.

Q184 Lord Rea: I wondered if you could see the cost of anti-IgE therapy coming down. Is it a question of patents or is it something else that makes it so expensive?
Professor Frew: It really is a question of production costs and this links a little bit to volume of sales. There are certainly lots of patients that we see, who might benefit but who will not get it at the current price this is not a question of appropriateness; this is a question of price. In terms of the future, I do not think the patents are the limiting factor. I think it is genuinely expensive to produce and it is difficult to see it ever coming down to the level of cost that we have for the standard inhaler treatments for asthma.

Q185 Lord Soulsby of Swaffham Prior: Is it a monoclonal antibody?
Professor Frew: It is a monoclonal antibody which is given in quite large quantities quite frequently, and it is the combination of the frequency of administration, the production costs and associated hospital costs that make the treatment an expensive option.

Q186 Lord Taverne: We have already had your comments that we should look more at anti-IgE therapy and immunotherapy, and that there are shortcomings in the simple therapies for rhinitis and asthma, but in what other respects do you think the Government’s policies on the prevention and treatment of allergy are adequate or inadequate and, if inadequate, what else should we be doing?
Professor Wardlaw: The BSACI have had a lobbying campaign for a number of years to try and persuade the Department of Health that what is needed is better allergy provision throughout the spectrum of care in primary care and through specialist care, and that what we need is a cadre of specialists who can lead the management and treatment of allergies at a national level. Of course, you are aware that there has been a big review by the Department of Health and generally we are rather disappointed by the outcome of that review. They recognised, I think, that there was a major problem and that the NHS had not kept up with that problem in terms of service provision, but they came up with no real solutions to that problem and did tend to pass the buck in my view to the PCTs for whom it is not a priority and who will not pick up that buck. At the moment we feel that the Department of Health does not have adequate policies to address the allergy epidemic.
Professor Durham: If I may emphasise what Professor Wardlaw has said, there was a report from the Royal College of Physicians four years ago that was endorsed not only by the college but also the specialists within the college to encourage an improvement in allergy services in the UK. This went
on to the Select Committee report which reported two years ago. The Government saw fit at that stage to set up its own review, which was something of a surprise to us, but then it was a year later that we had the recommendations and, as Professor Wardlaw says, the problem is that they fully acknowledge that there is a problem, that there is a modern epidemic, that there is a lack of training and that there is a lack of resources, but provided no solutions and in my view really ignored the recommendations of the Select Committee. The only positive things that came out for allergy sufferers, who we should be focusing on, was the need for NICE to develop guidelines, as we have already discussed, and the fact that we need more trainees in allergy. This was openly acknowledged in the report but the only limp suggestion was that we contact the regional deaneries to see how this would come about with no central funding. We have gone through this consultative process, certainly within the North West Tees Deanery, and there is no money to encourage more trainees. That is my concern with the Department of Health review. I think it is a very inadequate response to a major problem that has already gone through four years of consultation.

Q187 Lord Taverne: What you say is obviously very important and disturbing but what about the advice that government gives to sufferers? We have heard that with the current state of knowledge and the aetiology of IgE it is sometimes more truthful to give advice on what is not working. With respect to my colleague, should part of government advice perhaps be to avoid alternative medicine practitioners who do not diagnose and thereby often may do considerable damage, or at least treat them with greater suspicion?

Professor Frew: It is fair to say that the knowledge base is limited at the moment. We do not know precisely what to do to advise, for example, pregnant or prospective mothers about how to reduce the chances of their children becoming allergic. We do know some things we can advise them. If they ask us about particular courses of action, we can give them the evidence that is available on whether, for example, avoiding peanuts in pregnancy might be helpful or not, but we are still short of accurate information and, of course, it is a difficult thing to do because we are making decisions at a very early stage in life with children who are healthy in order to try to prevent something happening some years downstream. These are long, complex studies which are usually beyond individual institutions or individual funding bodies to put money towards, and I think there is still a need, and it will be covered in the next session, for further research in this area to improve the advice that we can offer people to prevent it. In terms of advice on treatment, we are much closer to being able to say, “These are the things that you can and should do, and these are things that can and should be available widely across the country but currently are not available due to inequalities in provision”.

Q188 Lord Taverne: What about advice about what you should not do, again, a particular question about alternative medicine because I gather that 90 per cent of sufferers do go to alternative practitioners?

Professor Frew: I believe there are several reasons why people go to alternative therapists. Some of them are because of dissatisfaction with the availability of conventional services, some of them relate to popular views of how the body works, which differ somewhat from the way doctors see the world. Within reason, it is a free country, so people should be given balanced advice and information on alternative medicine. If they then wish to go and spend their money on these things then I do not have a problem with that.

Q189 Lord Colwyn: My flier here from Asthma UK says that 5.2 million people have asthma, they lose 12.7 million working days a year and the annual cost to the economy is £2.3 billion. We also read that patients actually cannot even afford the treatment, so no wonder they start going to other practitioners. Do you agree with that?

Professor Durham: I just want to endorse the reasoning that there is such a broad practice of allergy advice available now on the street and it is an attempt to meet the unmet need and people are forced on to the high street.

Q190 Lord Taverne: But my question is, should they be advised to be very careful about it because they can do more harm than good?

Professor Durham: They may not do harm in themselves. For example, Chinese remedies for treating eczema have been shown in five out of 12 cases to contain topical steroids in them, so so-called traditional remedies may not be as traditional as patients are led to think, but I think the real issue here is diverting patients from the care that they need. If they have acute severe asthma they need to be managed by a pulmonologist and have access to emergency facilities. If they have multi-system disease they need to see a specialist allergist at a one-stop-shop that can deal with the allergic components of all those different conditions at one visit and that is not the sort of thing that you get on the high street.

Q191 Lord Colwyn: There are only 14 in the UK.

Professor Barnes: I do agree with your concern that alternative therapies are widely used to treat allergic diseases and, of course, are promoted by the media, whereas often conventional therapies are criticised by
the media. The fact is that almost all alternative therapies, at least for asthma, that have been tested by adequate controlled trials have been shown to be completely ineffective. I think it is our duty to try and warn people that these treatments are not working because people pay money for those therapies and, as Professor Durham has said, the danger is that they may stop using conventional therapies that are effective. I think some practitioners advise people not to take conventional medicines which have quite a bad press, so I think it is an important duty to warn people about the inefficacy of alternative therapies.

Professor Wardlaw: On the specific questions about government advice, I would say that the Government should not be funding alternative remedies that are not based on good scientific evidence. That is where the Government’s work should be. Obviously, we are all very regulated now in our practice and they should also be making sure that patients are not exposed to treatments which can be harmful, and that does include, I suppose, situations where the patients would otherwise be prevented from taking beneficial treatments.

Lord Colwyn: If they are available.

Q192 Chairman: Could I go back very briefly to the workforce planning because we have heard that the Walport clinical academic trainee numbers have been increased by, I think, 11 going into allergy training. Do you think that is going to be adequate to address the need?

Professor Frew: I think it will help in terms of building the academic workforce. It is not going to help in terms of building the service workforce.

Professor Wardlaw: I think it has got no role for allergy. The Walport scheme is not, except maybe in one or two centres, suitable for allergy.

Q193 Lord Soulsby of Swaffham Prior: We are dealing with immunotherapy and you have mentioned IgE but, apart from IgE, what other immunotherapies are used?

Professor Durham: There is the treatment referred to as allergen immunotherapy. This treatment is used quite widely in Europe but less so in the United Kingdom. It is only indicated in patients with IgE mediated disease and it is effective in patients with a limited spectrum of allergies. It should be prescribed and administered by trained people in a specialist environment. The people who are most likely to benefit from immunotherapy are two groups of patients. There are patients with severe hayfever which does not respond to conventional treatment, and the second group, in whom the treatment is life-saving, is in patients with venom anaphylaxis from stinging insects, wasps and bees. The point about this treatment is that it is not like prevention treatment.

There are two points I would like to make about this treatment. First of all, in those defined circumstances it is extremely effective and it does things that conventional medications do not do: it induces long term remission after stopping the treatment. In children you can actually prevent the onset of new sensitisations by treating children earlier, and there is some evidence from randomised control trials that you may prevent progression, for example, from rhinitis to asthma, so there are very good reasons for prescribing this therapy in patients who fail to respond to the usual therapies. The drawback is that with conventional immunotherapy that is given by injection there is a risk of inducing systemic allergic reaction, and in the United Kingdom it is specifically contra-indicated in patients with chronic asthma. In previous times when there have been adverse effects they have been in patients with chronic asthma. It does have a role. It has a limited role in patients who fail to respond to usual therapy. In terms of research and development, if I may just extend that answer, we know this form of therapy is effective but if we could make it safer or develop novel strategies for immunotherapy then it may be more broadly available. In this context recently there has been developed a sublingual form of immunotherapy, not by injection but taken under the tongue, which is used for patients with severe hay fever. This treatment has been shown to be effective and has also been shown to be safe such that the patient is able to take this form of therapy in their home.

Q194 Lord Soulsby of Swaffham Prior: Why sublingual? Is there lots of tissue that can process it?

Professor Durham: I think the answer to that question is yes. If we look at animal models using the oral route, it is a very effective way of inducing immunological tolerance, and this is a natural extension of that work on animals. The evidence base has accumulated over the past 10 years that this is an effective way of inducing tolerance to selected allergens, in particular to grass pollen and also to tree pollen. Those are the two areas where this has been shown to be particularly effective. If you look at the 12 million hay fever sufferers in this country, 23 per cent of the population, 40 per cent of those would say that they currently are dissatisfied with their therapy, and this is work from Professor Frew’s group, so I am quoting work from his group. Probably 75 per cent of that group are not taking the treatment appropriately or regularly, but there is a hard core of sufferers, I would suggest between half a million and a million, who would really benefit from the sublingual form of this treatment which has been shown to be effective.
Q195 Lord Soulsby of Swaffham Prior: We understand that immunotherapy is more commonly used on the continent of Europe than in this country. Is there a reason for that? Should there be more courses?

Professor Durham: Could I defer to Professor Frew on that?

Professor Frew: I deal with allergy in different parts of Europe and am very familiar with the differences in practice there. Most of these are just historical. It is the way the services have developed in different countries. We used to do quite a lot of immunotherapy in this country but it was done at the primary care level. People from the allergen manufacturer used to go around, make the diagnosis and provide vaccines for use in general practice surgeries. There were a number of problems with this, and indeed between 1952 and 1986 there were about 27 fatalities associated with immunotherapy, almost entirely patients with severe asthma, as Professor Durham said. The CSM, the Committee on the Safety of Medicines, then put some restrictions on immunotherapy and said that it could only be done in places where they were familiar with its use and had resuscitation facilities available. Ironically, if that happened today, general practices have those facilities available to do it but in 1986 they did not and so effectively it stopped the practice of immunotherapy at a devolved level in the community. We were then thrown back on to the very small number of centres that were doing immunotherapy and it meant that for logistic reasons patients have not been able to access this. For example, in Southampton and in Bournemouth, where I was working until last year, we had very active clinics doing desensitisation but we also saw many patients who would come from some distance away to see us, but who were simply not able to make the repeated journeys to come and get the treatments done and would have to decide that they could not go through with this. The other issue is again about the organisation of the NHS, that because we are organised around organ-based specialities, many of these patients, when they were sent up from the general practice, went to see somebody who was not very allergy oriented and who thought that it was not appropriate for them to have immunotherapy. The third point is that when we have gone back to the MHRA, as it is now, to try to get product licences for some of the vaccines, the MHRA have taken a very stern line with this. It has been much more strict in terms of the regulation than other parts of Europe, so they have derogated from the mutual recognition process which would normally allow for these vaccines to be available in this country and told the companies concerned that they may be available in Sweden and Denmark and other countries but they are not going to allow them to go through on a mutual recognition process, which is the normal way by which these vaccines would have been made available in this country. We are not entirely clear why they are quite so concerned about this but there has been difficulty in getting allergist opinion, if you will, to speak to the CSM and the MHRA because there are not many allergists around, there is no allergist on the committee, and therefore sometimes the opinions that are expressed there are rather anti-immunotherapy.

Q196 Lord Soulsby of Swaffham Prior: In view of the success of the sublingual approach to immunotherapy what is the potential for treating food allergies by sublingual application with selected items of food?

Professor Durham: If I may, my Lord Chairman, I will ask Professor Frew to address the food allergy issue. In relation to hay fever, I think we should be cautious. We have phase three trials now that show that sublinguals are effective and we have good safety data from 2,000 patients. In terms of its fragmented distribution I think we would want to see good safety data from 20,000 patients. I think there has to be a cautious introduction through specialist centres. I would be concerned if this form of therapy was prescribed ad hoc at this stage by general practitioners, for example. I think to inject enthusiasm but also an element of caution to the sublingual route is important.

Q197 Lord Colwyn: The sublingual route is not new. It has been used for thousands of years. It is used when someone is having a heart attack. The first thing you do is put aspirin in sublingually.

Professor Frew: Absolutely, and many drugs are absorbed very efficiently from the mucosa in the mouth. It has the advantage that it gets into the system quickly and bypasses the liver. If you give a drug via the gut, it takes time to get there and is metabolised as it goes through the liver, so putting something under the tongue is a very efficient way of getting some drugs into the system. In the case of sublingual immunotherapy, what you are hoping to do is to present the allergen to the immune system by getting it taken up by specialised cells in the lining of the mouth. In terms of food allergy, there is a lot of interest in developing vaccines, for example, to peanut allergy. There is some very good work being done on peanut allergy in the States, mostly in terms of injection vaccines, but, if we could get a sublingual vaccine for it that would be easier for patients to administer. The problem I see at the moment is that with peanuts you are dealing with anaphylaxis and so the risk of precipitating the condition you are treating is higher than it is with hay fever, where it does not
matter if you make somebody’s nose run but it does matter if you give them anaphylaxis. Many of the patients with peanut allergy react to extremely low levels of peanut. Just touching peanut to the lip can precipitate an anaphylactic reaction. The stakes are higher in that situation in terms of the risk of causing side effects, but also the benefit to patients and particularly children would be enormous.

Q198 Lord Taverne: Is the sublingual method of treating it different from the pill that was recently referred to?
Professor Durham: No. That is the sublingual route. It can be given either in the form of drops or as fast-dissolving tablets.

Q199 Lord Taverne: The second question is that you mentioned that there were risks associated with injection, but in the paper which you submitted to us it did say that injection is highly effective and safe when performed by trained persons.
Professor Durham: Yes.

Q200 Lord Taverne: Is the risk because people are not properly trained in administering it or is there something inherently unsafe about it?
Professor Durham: No, it is two-fold. First of all people do need to be trained in the administration of the treatment and, secondly, the patient has to be in an environment where, in the unlikely event of a severe reaction occurring, that can be recognised and promptly treated. This is why it really is confined to specialist centres. Having said that, I think it is safe when prescribed in those circumstances and is highly effective and may induce long term remission in the selected group of patients that I have described for you in terms of venom, anaphylaxis and severe unresponsive hay fever.

Q201 Lord Taverne: But in the case of other desensitisation is it something that is only temporary in its effects or is it something which often leads to long term remission?
Professor Durham: The evidence for long term remission is in the context of the subcutaneous route at the present time, and there are now some six or seven studies that have shown that if you give injection treatment for hay fever or pollen allergies due to grass or trees for a period of three to four years you can induce a long term remission for at least three to four years after discontinuation. That is also true in the context of venom anaphylaxis to wasps and bees. For the sublingual route the evidence is in the phase of evolution at the present time. There are two control trials at the moment that will deliver that information within the next five years.

Q202 Lord Rea: What I wanted to ask has been addressed by that question. My question was about the durability of the immunotherapy. Is it ever completely lifelong or has it always failed? I declare an interest here because I was a patient of Professor Durham in his clinic and was successfully desensitised from wasp venom.
Professor Frew: There are difficulties in the natural history. If we take the wasp venom issue, if you look at how likely people are to have anaphylaxis, the risk gets less with time, so once you have gone 10 years after a sting your chances of having anaphylactic reaction are really quite low; they are about five per cent compared to nearly 75 per cent the month after you have had that anaphylactic reaction, so there is a natural improvement that goes on and you can bring the risk right down at the beginning by treating with immunotherapy. It is very difficult then to do 10 years’ studies to follow up placebo controlled studies to see what is going on at the end of it. In terms of hay fever, we have many patients who come and tell us that they had immunotherapy in the seventies and it cured their hay fever and they are now 20 or 30 years down the track and they do not have symptoms. We simply do not know what would have happened to them if they had not been treated because there are no controlled trials that go that sort of length.
Lord Rea: I am prepared to submit myself for further testing if required.

Q203 Baroness Platt of Writtle: How do allergists communicate with appropriate organ specialists such as chest physicians and dermatologists in improving the management of patients with allergic diseases, and should chronic severe asthma be managed by allergists or chest physicians?
Professor Durham: Certainly speaking on behalf of our national society, it is a major priority for us to empower secondary care specialists in individual specialities—dermatologists, respiratory physicians, immunologists—in how to manage allergy effectively. I think it is in the interests of allergy sufferers that the wider the knowledge of allergy management within the speciality the better, and if we just keep our eye on the ball in terms of keeping our eye on the patient, I think it is important that we continue that mission which is central to our society. In terms of chronic asthma, I think chronic asthma should be managed by chest physicians with input from allergists where appropriate. As Professor Barnes has highlighted, there is a large proportion of patients with chronic asthma who are adequately managed by currently available therapists. I think the contribution that the allergist has to make is that they identify and treat underlying causes where possible. In terms of chronic asthma I think the overall approach of an allergist to consult a patient with
chronic asthma can be very valuable. For example, I have strong links with Professor Barnes at the Brompton, and he sends me occasional patients to assess from the point of view of their allergies, for example, food allergies, which is one very good example. The presence of asthma is a major risk factor for sudden death in patients with food allergy. I think it is the allergist that should be treating here, and although it is uncommon in adults with asthma it is a life-threatening combination which needs to be recognised and appropriately treated. We have not talked much about paediatric practice but the combination of food allergy and asthma in children is a potentially lethal combination which in my view should be managed by a paediatric allergist.

Q204 Baroness Platt of Writtle: In the oral evidence we have heard that GPs are not sufficiently trained, and you have emphasised that today, in allergic diseases. What do you think needs to be done to ensure that GPs can deal with allergic disorders in an appropriate way and then refer patients to be more suitably treated by specialists?

Professor Frew: I think medicine is changing at the moment and we no longer exist as people who have a large body of information in our heads that we keep private and people come to see us. Part of our job is to put our information in the public domain, so we go out to meet people and in our various societies in Europe and in Britain we go out to the GPs and specialist societies. We are thin on the ground so we cannot go to every single meeting that happens and we know that the primary care level is very local. You have to go around small areas to do this; you cannot expect all the GPs to come together in one place, and so part of our job is to provide information via the internet with appropriate guidance on how to manage people prior to referral. There are NHS systems that do this as well, and again we try to have input from the specialists to make sure that the advice they give to general practitioners when they are not sure what to do is appropriate and helps them to manage allergies in the community. We are not in the business of just going out and touting for business. We want people to be managed in the community where possible and we want people who go to their GP asking for a referral to be able to get a hearing for that and, if it is appropriate, to get referred to somebody who can help them with the problem and has the time and expertise to do that.

Q205 Chairman: Professor Barnes, I think you wanted to come back on the previous question.

Professor Barnes: Yes. I would just like to address the issue of specialist management because I think this is really a critical issue in this discussion about the need for allergists. At the moment the way things work, which I think is very satisfactory, is that people with severe asthma get managed by chest physicians because it is important to have people who understand other lung diseases that can present with symptoms like asthma. Some patients will need critical care and, therefore, specialists would have an input into that. The allergist has a very important role as a specialist adviser because there are situations with severe asthma where you need the advice of allergists, so it is very important for allergists to be in tertiary centres but not looking after severe asthma routinely, which I think is better done by pulmonary specialists. I would say the same would apply to people with severe eczema which has to be distinguished from other skin diseases. In some patients it may be very helpful to have specialist allergy input.

Q206 Lord Taverne: Is it correct that something like 30 per cent of asthma sufferers have not been offered allergy testing?

Professor Frew: We have no idea because we do not see them. The majority of people with asthma will not get to a specialist clinic and they certainly will not get to a difficult asthma clinic, so it is difficult to get to the denominator. That information would have to come from the community, from rather more dispersed things than our patient base.

Professor Barnes: I would say that skin testing for allergies is not very helpful in the management of asthma because we treat patients with the same management whether they have allergic or non-allergic asthma, so it is not so critical for the management of asthma in general practice.

Professor Wardlaw: I was going to say that I agree with Peter, but I think that is where Peter and I would profoundly disagree. Severe and difficult asthma in particular should be managed primarily by chest physicians but the allergist has a huge role to play because it is amazing—with colleagues I probably run one of the biggest severe or difficult asthma clinics in the UK—how these very excellent physicians sometimes forget about the allergy perspective, which I think is hugely important. You cannot make any judgment about an allergic perspective unless you do some tests and one of the major problems for primary care is that they cannot diagnose allergy because they do not have access to this relatively simple but hugely important test. In difficult and severe asthma, and other forms of asthma actually but it is more important in asthma, a large proportion of patients do have an allergy mainly to their pets, their cats, dogs and rabbits, which plays a very big part in their disease but the problem is they will not get rid of their pets, and that is a separate thing. Peter and I would profoundly disagree on the role of allergy in that context.
Q207 Viscount Simon: Professor Frew, in your submission to us you mentioned intolerance reactions which from my reading means all kinds of things that can cause certain reactions and it would be difficult to establish what they are. In these circumstances would the patient be referred to a chest physician or an allergist immediately?

Professor Frew: Again, I should make the point that these things are not mutually exclusive. I am trained as a chest physician, I see lung cancer, critical care, and acute medical emergencies as well as dealing with allergies, so there are people in the community who bridge that gap and it is not necessarily two different people who would be seeing it, although you might be wearing a slightly different hat. If we are talking about intolerance reactions, the first issue really is to take a proper history. Sometimes people get into the trap of saying “I am intolerant of milk” or whatever, without defining in what way they are intolerant, so quite a lot of our time is spent sitting down trying to get the patient to tell us what is wrong with them, not in terms of what is causing it but in terms of what symptoms and problems they have. It is quite interesting that a lot of people have constructed great scaffolding around symptoms such that if they go to eat a pizza in such and such a place they will get a problem but not in other places without someone sitting down and saying “What is the problem and how consistent is this?” It is general medical skills but it is specialist practice in the sense of having enough time to sit down, to force the patient to tell you what they actually have in the way of symptoms and then try to map back and say, “When do you get these? What are the circumstances? What do you think is causing them? What is the evidence for that?” That is the approach allergists are trained to do because quite a lot of patients believe, rightly or wrongly, that allergy, particularly food allergy and intolerance, is responsible for a variety of non-specific symptoms. The term “food intolerance” was brought in because the term “allergy” was being slightly abused. We would use “food allergy” to mean when there is an immune reaction against the food which is causing the symptoms. If you eat something and it disagrees with you but there is no immune reaction, what are you going to call that? “Food intolerance” is a useful portmanteau term that says, “When you eat this food in a certain quantity you get predictable symptoms and the food disagrees with you” and it is without prejudice to the mechanism, it allows us to have a term that we can use to talk to the patients without implying that it is caused by an immune reaction to it. Professor Durham: If I may make a point that I think is extremely important. If you open any journal or magazine it will tell you that allergy is the cause of the problem and a huge role of the specialist allergist is that he is equipped to exclude allergy as the cause of problems. If you can do that at an early stage at a one-stop shop and nip the problem in the bud you will avoid the patient going off on a crusade into the high street or seeking alternative opportunities to treat what they conceive as allergies. An important role of the allergist is to exclude allergy as a cause of non-specific symptoms, including food intolerance and all the other things that come up under the guise of allergy. It is exclusion of allergy. The problem is that the general practitioner is not equipped to do that. If the patient comes in and says, “I have got an allergy”, it is very difficult for the GP to say, “No, you do not” if he is not familiar with the diagnosis and treatment of allergy. I believe the same is true at the secondary care level within specialties. Many of my referrals are, “Is allergy related to this problem?” and I can write back and say, “No, it is not” and everybody breathes a sigh of relief and the patient is happy. You need somebody who recognises the beast in order to exclude it and that is an important role of allergists.

Q208 Lord Colwyn: When my two younger daughters, who are in their mid-twenties now, were in their twos and threes they used to have the usual problem at this time of year with respiratory breathing problems and, of course, the GP suggested corticosteroids. At the time I resisted that and found it easier to stay up night and day. I must not say that, my wife used to stay up night and day. We resisted the corticosteroids and just watched them because I felt they only tackled the symptoms of the disease rather than treating the cause and the progression. Would you agree with that? Would corticosteroids make a disease worse because they are affecting the immune system and depressing that?

Professor Barnes: Corticosteroids are highly effective treatments for allergic diseases but people have been concerned about the side-effects of steroids and the reason we use inhaled steroids for asthma is to avoid the side-effects seen with steroid tablets. For most patients these treatments are extremely safe because only low doses are needed. However, they do not deal with the underlying cause of the disease because although they can completely control the disease, when the steroids are stopped usually the symptoms come back. They are the most effective treatment we have now but clearly there is a need to find treatments in the future that will switch off the disease long-term. Professor Durham has already talked about immunotherapy in that context but there may be other drugs that can be developed that are curative, or at least have long-term effects. I think inhaled steroids have had rather a bad press in the general public and in the media because of the side-effects that people know about steroids in general.
Q209 Lord Colwyn: Are you saying that, in fact, there are no side-effects from long-term use of inhaled steroids?
Professor Barnes: No important side-effects at the doses most patients need to control the disease. Only patients who need high doses may have some side-effects but usually these are not serious. They do not deal with the underlying disease problem, so for the future we need to find more curative treatments.

Q210 Lord Colwyn: Do some patients not respond to corticosteroids and how do you deal with that?
Professor Barnes: There is a condition called “steroid-resistant asthma” but it is extremely rare, we think it happens in about one in 10,000 asthmatics. There are other people with more severe asthma who are relatively resistant, which means they need high doses of steroids, and again they are relatively uncommon. We are talking about one per cent of asthma patients.

Q211 Lord Colwyn: Would they be treated systemically?
Professor Barnes: They may require systemic steroids or some other treatment like anti-IgE that we talked about earlier.

Q212 Baroness Perry of Southwark: You mentioned the difficulty that GPs do not have any facility for good diagnosis, what do you think about these over-the-counter allergy tests that are currently being offered? Are they of any value for patients at all?
Professor Frew: I would say largely no. The reason for that is any test you do in this area needs to be interpreted in the light of a history. I am not trying to make work for doctors but if you have not got the history and do a test it will be misleading. Very often the patients have gone to get the test because they have self-diagnosed the problem. There is some usefulness in tests. Those tests are mainly useful when they are negative. For example, if you were contemplating spending your money on allergen avoidance covers for your bed and you went and got a test which showed that you were not allergic to house dust mite you would have saved yourself and the health service quite a lot of money. If you came up positive there would be no guarantee that the bedding covers you were about to buy would be effective because for about half the people who have a positive test it is not important in driving their symptoms, and to work that out you need a little bit more insight and knowledge. My general advice to patients who come armed with this information, and usually they have been and had the tests before they see us, is “Can we just talk about your symptoms first before we talk about whether or not the test result is important”.

Q213 Lord Rea: What do you think of the idea that all general practitioners should have a kit rather like those because they would be able to interpret them with a bit more knowledge?
Professor Frew: We are going back to this issue of who it is in the practice who will be dealing with allergy. The majority of regular straightforward asthma is now managed by practice nurses, not by general practitioners. There is an interest in whether practice nurses could also take on the role of doing allergy diagnosis and advice. There is quite good evidence that they can do the tests perfectly well, there is not a technical problem with doing the test, but sometimes there is some over-interpretation of the results. With any test that is done you need to know its strengths and weaknesses and my view is if there is a difference between what doctors and nurses do it is that doctors are more concerned with the diagnostic aspects and we use our specialist nurses predominantly for managing the condition rather than for making the diagnosis, I do not see skin testing by nurses as a panacea. I do think, however, it would be useful to have it available and we are trialling this at the moment, in the community to see whether you can improve people’s care by doing skin tests and providing standard protocol advice for straightforward allergies. The one thing we already have is evidence that patients are very pleased about this because it is delivered close to them at home and they find the information useful.

Q214 Lord Soulsby of Swaffham Prior: Coming back to over-the-counter tests, how many of these have been looked at from the point of view of efficacy and safety in the way that you would look at non-complementary or alternative medicines?
Professor Frew: If you do an internet search—we did this earlier this year—looking for home allergy tests in the US and Europe there is a huge range, anything from a small questionnaire which is about trying to identify allergic triggers through to about £1,000 worth of blood tests. There is very little back-up advice on this, so people are encouraged to pick their own level of tests, gold, platinum or silver, and the test is done without much input from the patient. Some of these tests are standard laboratory tests that will be done in every NHS hospital; others are tests that we do not think have any value at all. It is very much like the internet, it is a wide open market. They
really ought to get some advice but tests are available and out there and if people want to pay for them then they can.

Q215 Lord Soulsby of Swaffham Prior: There is no system of kite mark or anything like that with some of these tests?
Professor Frew: Not that I am aware of.

Q216 Lord Soulsby of Swaffham Prior: I can see the problem is that some patients feel that they are relying on these things absolutely, but if they are not efficient—
Professor Frew: I think there are two separate issues there. One is the quality of the test. If the test measures what it says it measures then generally speaking that would be dealt with by quality control in the lab. There is a separate issue about whether the test tells you anything about your condition, which in turn depends on what your condition is and on the possible connection between the problem you have got and whether the test is informative. That is not kite markable because it depends on what your condition is. It is up to the buyer to either get advice from their practitioner or to know enough about it to know that this test is appropriate for that.

Q217 Viscount Simon: At the moment there are five NHS hospitals which currently offer homeopathic and other alternative medicine, two of which have special allergy clinics. Should the NHS provide alternative therapies for allergies alongside these more conventional treatments?
Professor Barnes: I think the answer is no.

Q218 Viscount Simon: The fact you say “no” does not surprise me.
Professor Frew: There are three different parts to this. The first is homeopathic and other unconventional treatment for conventionally diagnosable disease, e.g. homeopathic treatment for hay fever, if you want to you can go out and get that and it may or may not work; the evidence is it probably does not do much good. There is also quite a lot of unconventional diagnosis for conventional disease, so you have got people using very odd techniques to diagnose causes of asthma, causes of eczema etc. The third issue is unconventional tests for diseases that we do not think have anything to do with allergies at all, things like migraine or hyperactivity disorder in children. If you go along, people will do tests for you and tell you that such and such a thing is causing your disease. I think you have to separate those things off because the first one is legitimate as an option that people may choose to follow but the other two are straying into areas where we think the science is not there at all.

Professor Durham: What one has to do is evaluate the evidence. As Professor Barnes has pointed out, when any homeopathic treatment, for example for bronchial asthma, has been put under scrutiny it has not been shown to be effective. My personal view is those resources would be better invested in conventional NHS allergy centres rather than homeopathy. On the other hand, of course one has to acknowledge the fact that patients and the general population are very supportive of the concept of homeopathy. For me that is not a reason to continue this and I would support what Professor Barnes has said.

Chairman: I do just wonder whether the diagnostic step and the time taken to take a good history may be helpful and that may need to be separated out from the administration of different medicines.

Q219 Lord Colwyn: Can I just remind you that the perfect solution is the use of high dilution sublingually, which we have heard before this morning.

Professor Durham: As opposed to very high doses sublingually which are effective.

Chairman: Thank you. If there are additional points that you would like the Committee to consider please do feel free to write in. Could I particularly thank you all for the written evidence you have already submitted to us. Thank you.

Examination of Witnesses

Witnesses: Professor Tak Lee, Director, MRC-Asthma UK Centre in Allergic Mechanisms of Asthma, Dr Diana Dunstan, Director of Research Management, Medical Research Council, Mr Dave Allen, Senior Vice President in GlaxoSmithKline, Head of Respiratory Drug Discovery and Professor John Westwick, Global Head of Respiratory Diseases, Novartis Institute for Biomedical Research, examined.

Q220 Chairman: Thank you very much for coming today. I know some of you have listened in to the previous session so there may be additional points you would like to make. We do have a lot of questions we want to ask so if you could try to keep the answers short. To be quite clear, we are being web cast and the information note of declaration of interests is available to the public so, as I said before, we will not be reiterating those. I wonder if I could start off by asking you to say who you are and then we will go to questions.
**Professor Lee:** I am Tak Lee. I work at King’s College, London and I am the Director of the MRC-Asthma UK Centre in Allergic Mechanisms of Asthma.

**Dr Dunstan:** Diana Dunstan, I am Director of Research Management at the Medical Research Council.

**Mr Allen:** Good afternoon, I am Dave Allen. I am a Senior Vice President in GSK, Head of Respiratory Drug Discovery.

**Professor Westwick:** My name is John Westwick, I am the Global Head of Respiratory Diseases for Novartis Institutes for Biomedical Research.

**Q221 Chairman:** Thank you. Could I remind you that this room has a very high ceiling and an echo, so if you can speak up. Do not worry about shouting at us; clarity is all. I wonder if I could start by just asking you how the various charities and professional bodies in the UK, such as the British Society for Allergy and Clinical Immunology, Asthma UK and Research Councils UK, work together to promote research into allergic disease.

**Dr Dunstan:** The MRC and, indeed, the other research councils, work closely with charities when it is appropriate. I think perhaps the best illustration I have got of that is in the respiratory medicine area where we have been working very closely over the past two or three years with Asthma UK, the British Thoracic Society and other charities to develop respiratory medicine in the UK and, of course, a large part of that is asthma work. We have funded, together with Asthma UK, the centre that Tak Lee directs. We also support with the Wellcome Trust a number of studies jointly and one of those that might be of interest in view of your previous discussion is a longitudinal study of patients and children in the Bristol area, 14,000 children, so we are following them right through and they are now 14.

**Professor Lee:** In the last few years there have been three national consultations on strategy for asthma research sponsored by Asthma UK. The most recent one has just been published. Those consultations, which are national, involve a number of bodies. They involve the MRC, the British Thoracic Society, the Wellcome Trust, NICE, the Department of Health and industry in various capacities. There are liaisons and collaborations mostly in asthma. If you are talking about allergy in the wider context there is not much of that going on.

**Q222 Chairman:** Are there areas where you feel communication could be improved between different bodies?

**Professor Lee:** I do. I think we have a lot to gain by working in collaboration and in conjunction. As I am sure we will touch on, my view is that the way forward in allergy research in the future will depend on multi-disciplinary partnerships and on large cohort studies and multi-centre bodies, which will be very expensive. I think it is very likely that if we are going to pursue a strategy to impact on the epidemic of allergy in this country it will have to be funded through some sort of partnership arrangement.

**Q223 Earl of Selborne:** Dr Dunstan has told us something about the work of the Medical Research Council and its funding on research into allergies. I wonder if we could hear more about how the research councils determine what projects are suitable for funding. She also referred to the 14 year longitudinal study in Bristol and this is a long timescale for a research cohort and I suspect that other such research into allergies will require studies over a longer period than is normally convenient for funding lines. Could we hear something about whether there are any difficulties, therefore, in funding some of these long-term studies?

**Dr Dunstan:** Talking about the general mechanisms for funding research, people come to us in response mode and if their proposals are good enough, and they have to be pretty good actually to get funded by MRC, then they are funded. We do have other mechanisms. Recently we have had calls for proposals for experimental medicine and there have been some respiratory medicine asthma proposals funded in that call. We had a call for biomarkers and there were none. I looked before I came today and there were no proposals in that that were relevant to allergy. We fund training, so individuals apply to us for training grants. We fund PhD studentships, fellowships, senior fellows, that kind of thing, so there is a wide range of things there. As you say, we do fund long-term work. Long-term work is partly done in our units and institutes. That is largely basic work. We do quite a bit of work in relation to allergy in three of our units. Mainly the cohort studies are funded in partnership with other funders because, as you point out, they are expensive. We have mentioned the Avon ALSPAC long-term study and there is also a Southampton Women’s Survey that is relevant to diet and food intolerance. That is a long-term study following women prior to them being pregnant, through pregnancy, and the children after birth. Most of the children in that study are now three or four years old. In the long-term study area we are looking at all the cohorts that are funded now in conjunction with other research councils and other funders so that we can best fund the new sweeps needed, so we have decided to have a partnership on funding these long-term cohorts. You are quite right, they are very expensive and it is important that we have a partnership looking at the sweeps so that everything that needs to be included in a particular...
sweep is included and nothing is missed out and we can all contribute to the funding.

Q224 Earl of Selborne: Would you expect the proportion of the MRC budget on these long-term studies to increase?
Dr Dunstan: I would certainly expect them to increase over the next few years because we know two or three of them are coming up to their next sweep.

Q225 Lord Taverne: You obviously have to look at how strong the particular case is for a particular study, but do you also have an overall view about which are the most important studies to do, which are the most urgent ones? Is there a way of considering the priorities of these? As far as the expense is concerned, obviously the fact that they are long-term studies makes them expensive but how far are they somewhat disadvantaged by the fact that you also need very large numbers of cohorts for infants or whatever it is?
Dr Dunstan: Priority-wise, the boards that look after these particular subject areas have priorities in their minds. Every year they look at their portfolio and they point out areas of priority. The boards that look at the proposals that come to us and assess them for funding have priorities for their areas and they will apply those priorities when they decide on which ones are going to be funded. In the asthma area, respiratory medicine, that is a high priority for one of our boards. We have got about 15 proposals that we funded last year in response to a call and clearly they were applying the priorities in that case. Expense is always a problem but if the research is good enough and we have enough partners to contribute to the expense then I think we can cope, and that particularly applies to the cohort area.
Mr Allen: I wanted to volunteer some information from the GSK perspective. We have set up a number of long-term academic collaborations with a number of the Centres of Excellence supported by the MRC. We collaborate with the NHLI, with the Universities of Southampton, Manchester and Edinburgh. These are long-term relationships which, although they are focused around a particular area of research at any one time, tend to have a strategic nature because these are the Centres of Excellence so the long-term relationship ultimately benefits these sorts of long-term studies as well.

Q226 Lord Colwyn: I think my first question is to Mr Allen. When pharmaceutical companies are deciding where to put their research effort, do you tend to put it into allergies in totality or do you go down the route of individual disorders?
Mr Allen: The short answer is that we do both. It is very important to us to focus on application of need when we are looking for new medicines. To do that we need to understand what the patients are looking for and until we can fundamentally affect allergy then we need to treat the consequences of it. We need to treat asthma, we need to treat the bronchoconstriction, we need to treat the inflammation that follows it, we need to treat the rhinitis, the watery eye and that sort of thing in hay fever. Obviously to deliver those therapies it has got to be very different if you want to give them via an inhaler for asthma or intra-nasally for hay fever. We try and treat the consequences of the allergy in the appropriate way and we focus on understanding the consequences and treating it appropriately. To go beyond that and start to think about how we can fundamentally affect the course of these diseases, then we need to do research into the basic allergy mechanisms, we need to understand the way that T-cells and the subpopulations of T-cells start to talk to each other. That is where we collaborate a lot more with academic centres to do more fundamental research to try and
progress our understanding long before we can start to apply it in a sense that will fundamentally change the natural history of these diseases.

Q229 Baroness Perry of Southwark: So the route you go down is much more to look for collaboration with, say, MRC funded research rather than to look at what they are doing and do something different?  
Mr Allen: It is fair to say that when you look at the more basic science then the amount of work that we can bring to bear, even as a huge pharmaceutical company, is very tiny compared with the amount of basic science that goes on globally, so we look to play our part and we look to partner and we look to do that in collaboration. Where it is applying those learnings in a drug discovery sense that becomes something that we think we are quite good at, so obviously we will try and do that ourselves, but it is both parts.

Q230 Baroness Perry of Southwark: Perhaps I could ask our witnesses more broadly, given there is great disparity between the amount of money put by Government into allergy research compared with what is put in by the pharmaceutical companies collectively, do you think there is a danger that pharmaceutical companies might determine the agenda of research?  
Professor Westwick: Yes, I think that is possible.  
Dr Dunstan: I was going to answer differently actually. I am not sure what figures you have got but there is a paper that we received quite recently about asthma that suggests charities and Government together invest about the same amount as industry each year.

Q231 Baroness Perry of Southwark: In that one field.  
Dr Dunstan: In that one field, yes.

Q232 Baroness Perry of Southwark: I was talking about allergies in the broadest sense.  
Dr Dunstan: I do not think there is any chance that either of us are going to dictate the agenda. As Mr Allen says, we are going to be working together.  
Professor Lee: I agree broadly with what has been said already but there is one slight problem sometimes that arises when a therapeutic manoeuvre developed by a company is extraordinarily expensive. If the programme of work that the academic community wants answered is not necessarily within the strategic direction of the company they may not provide you with the material to study. If it becomes prohibitively expensive for academia to pursue, that is one slight issue which can arise from time to time. It does not happen very often but when it does it is awful.

Q233 Chairman: An area which concerns me is we have heard in previous evidence there are areas of rather unglamorous research which need to be done and people have a lot of difficulty in securing funding from anywhere, partly because the pharmaceutical industry has no interest in those areas particularly at the moment and because the research funding bodies have already committed all their money. I wonder if you want to comment. That is really more for Professor Lee, I think.  
Professor Lee: Obviously it happens. There is no real solution to that because if the funding is not there to do the work then the work cannot be done.  
Mr Allen: I have doubts about whether the disparity really exists. If you look at respiratory research and recognise that allergy is only a part of that, a lot of GSK’s funding, for instance, goes into chronic obstructive pulmonary disease which is likely to become one of the world’s top three killers by 2015 to 2020, there is no allergic component, but if you capture that spending under respiratory research it will be a very substantial part of it. I do not think there is a disparity, generally we partner where we have joint expertise, we invest ourselves where we have unique expertise and I think we would expect the research institutions to invest where they have unique expertise.

Q234 Baroness Perry of Southwark: Some of the research that we have been hearing about this morning into the prevention of the allergic reaction in the first place, so to speak, to de-sensitise the person, is that something that pharmaceutical companies leave to academic blue skies research or are the pharmaceutical companies involved in that as well?  
Professor Westwick: There are a number of smaller companies that are linked up with larger pharmaceutical companies. There are a large number of immune deviation trials going on right now, I am aware of at least five that are in operation. The whole purpose is to look for a long-term loss of allergic response.  
Mr Allen: There are two levels that we need to understand. To fundamentally modify the immune system has to be a very long-term goal. We should recognise that you do not mess with the immune system very lightly. It is because of that that I would fully support a strong research base in the UK that continues to tease out the role of the immune cells, the sub-populations, the way they talk to each other, the way antigen is presented in all of its complexities. Where we look at the hope in the near term, which is to re-educate the immune system not to respond to grass pollens and tree pollens, there are good clinical studies ongoing and it is an area of very active interest for all the pharmaceutical companies.
Q235 Lord Rea: How does UK funding for research into allergic disorders compare with other countries? I am talking about all the sources of funding, Government, charity and industry, how do those compare with what goes on in other countries?

Dr Dunstan: I do not have the figures for anything except respiratory work. In respiratory work, the share of the funding that we have is proportional to the share of biomedical funding that the UK has in relation to spend in other countries but in some other areas of respiratory work countries such as Australia, Finland and Sweden have a significantly greater investment relatively speaking than the UK.

Mr Allen: From a purely GSK perspective, we have the majority of our asthma and rhinitis work based in the UK which means we have a disproportionate amount of our spend internally in the UK. We do have collaborations in the US and across Europe but because our people tend to be here, we collaborate locally with the academics that are here. From a company perspective we are investing disproportionately in the UK.

Professor Lee: I tried to get some information about spend on allergy/asthma research from a number of different bodies and the information I have is incomplete, nevertheless I have some information. The NIH was very helpful and wrote back to me and their spend per annum in the financial year of 2005 was £154 million.

Q236 Lord Rea: As compared with the UK of what sort of figure?

Professor Lee: Dr Dunstan was telling us about the MRC spend. Away from the MRC, including the Wellcome Trust, Asthma UK and a little bit of information from the Department of Health, the amount of money other than Research Councils is in the order of £6 million per year.

Dr Dunstan: MRC spends a bit over £5 million a year directly on allergy research and £15 million a year on basic understanding of immunological mechanisms, some of which would be relevant to allergy.

Q237 Chairman: Dr Dunstan, could you clarify is that all allergy and of that amount how much is asthma and how much is other allergic manifestations?

Professor Lee: That is the issue. When I tried to find out information about this, including how different research organisations label their funding, it was complicated. Allergy and asthma tends to be mixed up. Looking at the portfolios, the ones that I have seen from the titles, the majority of those is asthma rather than allergy globally and more fundamental than translational. The numbers are quite startling really.

Professor Westwick: I think one of the problems when you are talking about respiratory is trying to separate how much is allergy/asthma because respiratory now includes a very large area within the pharmaceutical companies, but if you just say “respiratory” it is good to know that within the UK the three leading pharmaceutical companies worldwide have their respiratory research, which often includes their allergy/asthma research, located in the UK.

Q238 Lord Rea: Which allergic disorders receive the largest amount of research funding and do you think this is appropriate? I can foresee that you are going to say “asthma” but then we have the problem with what part of the asthma research is directed specifically towards allergy.

Professor Lee: I can only speak for Asthma UK. About 30 per cent of the Asthma UK spend is directly related to allergy.

Q239 Lord Rea: That is clear.

Dr Dunstan: I do not have those figures for MRC. I can get them for you if that would be helpful.1

Q240 Lord Taverne: I want to ask you about Sir David Cooksey’s recent review. They recommended that: “greater priority should be given to supporting medicines and therapies that tackle unmet health needs in the UK”. They recommended that the Government should set up a new Office for Strategic Co-ordination of Health Research. Do you think that this approach will overcome the difficulties which are currently experienced in allergy funding? They also recommend that the Department of Health should review the impact of diseases and illnesses to determine the health priorities. Do you think that will help to establish allergy as one of the health priorities in the UK?

Dr Dunstan: We welcome the proposals in the Cooksey report and certainly they will put a major emphasis on collaboration between the money that is spent through the health departments on R&D and the MRC. Also they will put a major emphasis on translation and exactly how that will work out I am not sure. One of the things they have asked the overarching body to do is to make sure that unmet needs are met. When UK Clinical Research Collaboration looked at areas that they have considered were under-funded in relation to morbidity, respiratory disease, of which asthma as a part was one and colitis was another, and I think there is some inflammatory work and allergy related to that, so they may well fall into the categories of unmet need that we shall have to direct more attention to.

1 Please see MRC supplementary written evidence.
Professor Lee: Let me add to that. I think it is absolutely crucial that we do try to estimate the burden of the disease and unmet need in allergy. I do not underestimate at all the real difficulty in capturing that information because at the moment in the Health Service we do not have a structure that allows us to collect that information. When you look at that burden and unmet need you have to take into consideration not only the very few people who find their way to allergy centres but we also have to take into account the other patients in dermatology clinics, respiratory clinics and so on. When trying to understand unmet need you also have to take into considerations estimates of the holistic patient, not just in that specialty. Whilst I very, very strongly support the idea that we should do this, I think collecting the information would be very, very difficult but necessary. Probably some resource will need to be put into that to allow that to happen. That is my first point. The second point is even if you have the resource to do that, methodology will have to be developed because although we have methodology for assessing asthma the suite of methodologies for assessing angio oedema, for example, and other allergic diseases away from asthma are not very well developed and they may have to be developed to really understand this problem in the wider context.

UKCRC, that has already been referred to, in respiratory medicine has been a very big driver in understanding the funding just does not match the disability, morbidity and mortality of the disease. We all suspect, and there is evidence, that allergy is in exactly the same position but allergy is not just respiratory, it is only the tip of the iceberg when you think about asthma.

Q242 Lord Taverne: Should they consider allergy as a single health issue or would it be more suitable to consider the health priorities of the various different disorders?

Professor Lee: No, I think we should consider allergy as a disease grouping because many patients with allergic problems present with multi-system disease and that, in a sense, is one of the rationales for establishing a service which allows a one-stop-shop. I agree with the previous conversation in the last session where allergists also have to contribute towards looking after severe asthma in a contributory capacity but allergy as a specialty has a very major role to play.

Q243 Baroness Platt of Writtle: There are certain areas of research which may not necessarily have a precise answer or profitable outcome but, nevertheless, are of considerable long-term importance. For example, we are still not able to provide reliable nutritional advice to pregnant women or young children to prevent allergic disorders. Where should the funding come from to research areas such as these?

Dr Dunstan: I think the research councils and the charities have a significant role to play. I guess in some of the cases you mentioned we are back to long-term studies with cohorts again. We are doing that, and we are getting partnership funding for those: ALSPAC, Southampton Women’s Survey. For environmental allergies, I suppose the UK Biobank, which is looking at a more elderly population, middle aged onwards, will also provide information. I know, for example, in Professor Lee’s centre there are studies going on about whether children at a high risk of allergies should be exposed to peanuts or whatever, and we are currently discussing with the Food Standards Agency whether we can jointly fund a study on early weaning. I think these kinds of studies should give some of the answers that your questioner needs.

Professor Lee: I very much support that view. I think, as I said already, partnership is going to be the answer in the future, but I also feel there is a role to play in some of the really big questions which will involve very large cohorts and will be very expensive to adopt a more iterative approach to arriving at protocols and arriving at a way forward. I think for very good reasons much of the funding strategy is a competitive one and you do obtain very, very good applications of exceptional quality because of that. We all have to go through that system. There are major opportunities in the future to work together in partnership in long-term studies on major questions which will impact on healthcare where the development of a programme of work on an iterative basis may be a better way forward. Certainly from
our own perspective, a few years ago we worked very closely with MRC to develop an iterative programme to look at the safety of salbutamol in asthma. It took us a long time to arrive at that programme but we did arrive at that programme and we did the study which was very informative and was published in a very high impact journal and is often used as one of the major studies in this area. I think it can work and we should do more of it.

Q244 Chairman: How much is that iterative process involving the patient population who have the allergic manifestation?

Professor Lee: I think the answer is more and more. Certainly in one of the consultations we have just finished and published, Basic Asthma Research Strategy, and also the one on Clinical Asthma Research Strategy, lay people were involved. In fact, in February there is a conference at the Royal Society of Medicine which I am chairing for lay people. We will be discussing our Basic Asthma Research Strategy with them in depth.

Q245 Chairman: Dr Dunstan, can you tell us how much the MRC will interact with the GA² LEN centres?

Dr Dunstan: Sorry, with whom?

Q246 Chairman: With the GA² LEN centres.

Dr Dunstan: I am not sure what the GA² LEN centres are.

Professor Lee: The European framework.

Dr Dunstan: We interact with European funding quite a lot, whether we interact specifically with these or not, I do not know. We are doing quite a lot of work on quality of life across a variety of diseases on those issues.

Q247 Baroness Platt of Writtle: What about research into other lifestyle issues, such as the impact of pollution on allergic disease? Who is carrying out research into that?

Dr Dunstan: I think pollution may be one of the issues which comes out of the UK Biobank study and other long-term cohorts. It is fair to say that the research councils, NERC, ESRC and MRC, are looking again under a broad heading at what we call “environmental health” and pollution will form a part of that. It will be one of the bids which goes forward jointly from the research councils into the spending review this time.

Mr Allen: Of course environmental triggers are one of the things which attract a lot of research at a basic scientific level, things like ozone and particulate matter that will trigger asthma responses do feature very largely in academic research.

Q248 Baroness Platt of Writtle: Are your commercial companies involved in that?

Mr Allen: Insofar as we are trying to understand the response to these allergic triggers, then certainly we are, yes.

Q249 Viscount Simon: As allergic diseases involve many different genes and exhibit considerable phenotypic variation, what steps are being taken to develop more individualised treatments? Secondly, what research is being undertaken to understand the factors which determine an individual’s susceptibility to allergic disease?

Mr Allen: From a GSK perspective, we have the objective of taking, with the patient’s consent, blood samples from every single patient who is involved in a GSK research and development organised clinical trial, with the objective of genotyping (subject to clinical trial outcomes) that patient so that we can subsequently look at how that genotype has reacted to the treatment and the outcome, both from a safety and efficacy point of view. That is ultimately the goal. We have a very high percentage (60 per cent) of those samples taken now so we can go back and ask very careful questions about how certain patients have reacted to the drug that is in the clinical trial in relation to genotype. The other thing we need to recognise is there is a huge phenotypic variation within the allergic diseases. We have heard about severe asthma patients who do not respond well to steroids, who would have a difference response, and we need to understand the clinical phenotypes within each of the diseases as well as between the diseases. We can only do that by good translational medicine work, by long-term clinical studies, but also by phenotyping these patients very carefully so that we can start to understand their disease long before we can start to attempt to cure it or even modify it.

Professor Westwick: It is very similar studies that have been going on in Novartis as well. Again, we like to identify the phenotype and the genotype. Indeed, a number of papers have been published in the last four years which were thought to identify the genes responsible for asthma, but on reproduction elsewhere that does not seem to be the case. To say that we know the genetic basis of asthma right now is probably wrong but we may get to it. The second part of your question, can we modify the environment so that the allergic responses are removed, goes back to the first thing I was talking about where we and many others believe that how the specialised dendritic cells within the airways respond to the environment in the presence of a specific antigen and various T-cells is the key to regulating that. For that reason, we and others have developed agents which modify particular receptors on these dendritic cells to deviate the response away from our allergic mechanism.
Q250 Lord Colwyn: Are there any populations of individuals anywhere in this country or elsewhere who are particularly susceptible to allergic disorder through inbreeding and inter-marriage?

Professor Westwick: Indeed, that is where the genetic basis of asthma came from, from these inbred populations. The problem is when you move to wider populations it does not seem to hold true in terms of the identity of the gene which was found in those studies.

Professor Lee: This is an incredibly important area and it is also an area where I think collaborations between the universities, academia and industry should flourish because industry does so many pharmaceutical trials. They have a readout in a very detailed and well designed way of the responsiveness of individuals to certain drugs. We know that the distribution and response to drugs follow a certain pattern and some respond very well, others do not. To be able to have all the blood samples genotyped and be able to link that to treatment responsiveness is very, very powerful. That has been used, especially in the United States, to look at a number of different questions, including the efficiency and safety of beta-agonists, for example. I think the pharmacogenetics effort, which is what this is, at the NIH is probably very strong as a result of this sort of collaboration and probably more advanced than what we have in this country. This is not just an academic question because the regulatory authorities in the future will demand to have this sort of information when you are registering your drugs and that is a very powerful driver to do this sort of work.

Professor Westwick: I would agree with what Professor Tak Lee was saying, but one has to keep in mind that most of the studies in asthma and allergy have shown that these are polygenetic diseases, they are not monogenetic, like cystic fibrosis. It is a very complicated sector involving a number of genes as well as an environmental influence.

Q251 Chairman: Who is responsible for publishing negative results?

Mr Allen: The results of all clinical trials have to be published.2

Q252 Chairman: There may be some analyses though that can be done which fall outside the main trial protocol. How much freedom do researchers have to proceed and publish those when they are in a drug company funded study?

Professor Westwick: I think most academic and clinical centres worth their salt will not get into an agreement with a pharmaceutical company unless they can publish the work they are doing.

Q253 Lord Taverner: What is the panel’s view of what currently are the most important areas of research, and who is undertaking these?

Mr Allen: How long have you got?

Professor Lee: Let me start because I am going to give you an answer which will seem a little vague but, nevertheless, I want to refer you to four documents and that is really my answer because we have been through this in some detail and they have been submitted to you in written form. First of all, the most recently published document on Basic Asthma Research Strategy, which we lovingly call BARS Version II, was published only a few months ago. That sets out a number of priority areas with key questions which we feel we should answer in the asthma area. It is multi-professional involving many funding bodies in that consultation. Then about two or three years ago there was a similar consultation on Clinical Asthma Research Strategy which has already been published. Some of the issues raised within that consultation are part of the Health Technology Assessment exercise and have been funded to some extent by the Department of Health, so, again, that is already in the public domain. The third is a letter which Professor Durham wrote to you as part of his written submission on what the British Society of Allergy and Clinical Immunology believes the research priorities should be.

Q254 Lord Taverner: This is the one we have got, is it?

Professor Lee: Yes, that is the one you have.

Q255 Lord Taverner: The recent one, British Society of Allergy and Clinical Immunology?

Professor Lee: Yes, so you have that information. The fourth document I will refer you to is a document published by the Department of Health entitled, “A Review of Services for Allergy: The Epidemiology, demand for and provision of treatment and effectiveness of clinical interventions”. That review, apart from many things, covered and highlighted parts of the research evidence from the health service point of view.

Q256 Lord Taverner: Is that the document of which Professor Durham and Professor Frew said: “It gives no grounds for optimism”?
Professor Lee: That is correct, that is it. They were referring to the development of the health service framework and health service delivery, but the issues which that document raised about health services' research required to provide the information base to develop future strategy I think are very intuitive. In my answer I will refer you to those four documents, if I may.

Q257 Chairman: Can I go back slightly to the previous question. If each company has very rich data on genotype and phenotype, is there a move to produce a pooled Disease Registry so that all this information can be shared and avoid duplication and also allow further research projects to be built on the information which is held?

Mr. Allen: I have to be careful because I am not expert in this sort of area. I do know that a very important consideration is the consent given by patients when they are involved in a clinical trial. You have to be very, very explicit about what the samples would be used for, who would have access to them, and to what purpose they would be put. Research undertaken is restricted by the scope of the written consent. It is a very important part of any governance of clinical trials. The only thing I would be cautious about is we must therefore only do with these samples exactly what we have told the patients we will do with them but, of course, the sharing of information and collaborating with all of this information is in everybody’s interest.

Q258 Chairman: Of course you cannot do anything with the samples you have got other than what the consent has permitted, but I was wondering whether there are moves to establish a pooled Disease Registry with consent in future studies then ensuring that those patients could be involved and registered on a central Disease Registry rather than each centre having its own much smaller cohort of patients?

Professor Westwick: The requirement of published clinical trials and to register that should provide that information for everyone to look at, whether it be another pharmaceutical company or not. I think you are going one stage further where all basic information that is generated, which may not be generated from clinical trials but from some sort of analysis of databases which are either in the public domain or the private domain, that comes out of that is going to be publicly shared. I do not think we are there yet.

Q259 Chairman: Professor Lee, have you got any comments?

Professor Lee: No, except that if that database was available it would be extremely useful.

Q260 Lord Taverne: What new products are being developed which could have a significant impact on the treatment of allergic diseases over the next five years?

Mr. Allen: I guess the first point is five years is a very, very short time period in drug discovery; unfortunately it is more like 15 years to turn basic research into a product and take it through all the regulatory requirements.

Q261 Lord Taverne: Which end of the last five years of the 15 year period?

Mr. Allen: I will not talk about that, I will leave that to someone else. There are some very interesting developments going on in the way that the basic immune cells talk to each other and the way they respond to different antigens because this is all about inappropriate immune response. This is not about immuno-suppression, we are not talking about suppressing the immune system, we are talking about teasing out some very subtle whispering that goes on amongst these immune cells. We know the sub-populations of immune cells which seem to be responsible for a lot of the chemical messengers and inflammatory mediators which are now associated with allergy in its broadest form and we are starting to find mechanisms to impact those in a very, very specific way. I do not think they are going to do it with medicines in the next five years, but I think over the next five years you are going to see early clinical trials on mechanisms which do talk to these very small populations of T-cells being modified in very specific ways. That really will be the next generation of therapies for allergy.

Professor Westwick: I agree with what David said. In terms of what is going on now, you have already heard about Xolair, the anti-IgE which came out from the laboratories of Genentech. There are also a lot of other antibodies out there now in clinical trial for asthma and allergy, antibodies directed against various cytokines and these are small proteins that are involved in this allergic response. They are in proof of concept or Phase II (b) studies right now, so it will be another three to four years before they will be registrable.

Q262 Lord Taverne: Is there a prospect of a successor drug to Xolair which would be cheaper because I gather it is very, very expensive?

Professor Westwick: Yes. First of all, if you look at all diseases and all pharmaceutical approach, the use of antibodies is increasing dramatically. It used to be all the small molecular weight compounds but if you go into all diseases, antibodies are increasing and particularly so within allergic mechanisms. The cost
of antibodies and the work involved in getting to the state you need is much more than it is with the low molecular weight agents. However, having said that, I think where antibodies are also being used is first of all as a proof of concept that that particular target is important. A lot of companies are following behind with some low molecular weight equivalent which can be usually much cheaper to produce and will come out two to three years later.

Chairman: I think we are at the end of our session. Could I thank you very much for coming today. Also, if there are additional points you would like to make to the Committee, we invite you to send them in writing to us. We will be sending you a transcript of the session for you to correct for accuracy. Thank you very much again and thank you also for the papers you submitted to us, particularly Professor Lee.

Supplementary memorandum by the Medical Research Council

1. Which allergic disorders receive the largest amount of research funding from MRC, and do we think this is appropriate?

Asthma is the allergic disorder that receives the largest amount of research funding from MRC. We believe this is appropriate because asthma is a major and growing health problem. Furthermore, we receive applications in response-mode, and this is the field in which there is the largest critical mass of expertise in the UK. Much of the research classified as asthma research will have potential for wider applicability to allergy (see below). Other allergies which the MRC currently supports are dermatitis and allergy to antibiotics.

2. How much does the MRC spend on asthma research, and how much of this is directed specifically towards allergy?

It is not easy to distinguish research on asthma that is unrelated to other allergies, or research on allergy that would be unrelated to asthma, especially in basic research (eg genetic predisposition, understanding immune responses etc). According to the way we have categorised our projects, for the five years 2001–02 to 2006–07:

— our total spend on asthma research was £15.7 million.
— Our total spend on general research was £13.0 million (this includes research into known cellular components of the allergic reaction, how the allergic reaction is induced, signalling pathways in the allergic reaction compared with the reaction to infection, aspects of vaccine design and stimulate allergic responses, molecular regulation of cytokines genes known to be involved in allergic reactions, the molecular structure of molecules in the IgE network, and some aspects of nutrition and allergy).
— Our total spend on other allergic diseases was £2.1 million. (this includes eczema, dermatitis and allergy to antibiotics).

These figures are mutually exclusive, but for the reasons given above should not be over-interpreted.
Letter from Professor Anthony Newman Taylor CBE, Head of National Heart and Lung Institute, Faculty of Medicine, Imperial College, London

Thank you for inviting me to submit evidence to your committee’s inquiry into Allergy.

I will focus on occupational asthma because it is the most important of the occupational allergic respiratory disease and the one in which I have most experience.

Occupational asthma, is asthma induced by an agent inhaled at work. This may occur in one of two ways:

1. The inhalation of an irritant chemical, such as chlorine or sulphur dioxide, in concentrations toxic to the lining cells of the bronchial airways. This causes an acute inflammatory reaction with local injury in the airways, which in a minority of cases is followed by the development of chronic asthma.

2. The development of a hypersensitivity reaction (allergy) to an inhaled protein or low molecular weight chemical. Proteins which may be inhaled at work and cause asthma include enzymes used in the detergent and baking industries, proteins excreted in the urine of laboratory animals—rats, mice, guinea pigs—and proteins in flour encountered in bakeries. Low molecular weight chemicals, so called “chemical sensitisers”, inhaled at work include isocyanates, used in the manufacture of polyurethane plastics and polyurethane spray paints, acid anhydride used in the manufacture of epoxy resin, plastics and paints and complex platinum salts, essential intermediates in platinum refining.

Of these two, hypersensitivity induced (or allergic) asthma occurs considerably more frequently than irritant induced asthma. Occupational asthma is the most frequent category of occupational lung disease reported by chest physicians and occupational physicians to the voluntary reporting scheme, SWORD (Surveillance of Work and Occupational Respiratory Disease). The total number of cases of occupational asthma reported by SWORD has fallen during the past decade, primarily due to a reduction in the number of cases reported by chest physicians between 1999 and 2000. The number of cases attributable to isocyanates is now less and the increase in the number of cases caused by latex allergy has decreased since the widespread use of low protein non-powdered rubber gloves. However, a similar decline has not occurred in the number of cases attributed to flour in bakery workers.

It has been estimated by a panel of the American Thoracic Society about 15 per cent of asthma in adult life (ie one in seven) is attributable to an occupational cause.

Occupational asthma is distinguished as a type of asthma by being potentially preventable and, in many cases, curable. Several studies, undertaken by different groups in the 1990s, showed that the major risk factor for developing occupational asthma, caused by allergy to an agent inhaled at work, was the level (concentration) in air of the specific agent in the place of work. This was demonstrated in studies of enzymes in the detergent industry, animal urinary proteins in the pharmaceutical industry, flour and enzymes in the baking industry and acid anhydrides in the chemical industry. Prior to this, allergic occupational asthma had been considered as a consequence primarily of individual susceptibility. The important implication of evidence for an exposure—response relationship is that the incidence of occupational asthma should be decreased by reducing the level of exposure to its causes in the workplace. This has now been demonstrated in studies of enzymes in the detergent industry, of latex in health care workers and of isocyanates in Ontario, Canada. Comparable interventions now need to be extended into other industries in order to make further impact on the overall incidence of the disease.

Because occupational asthma in the majority of cases is due to the development of an allergy to an agent inhaled at work, to provide the best opportunity for asthma to improve and in some cases resolve it is, in general, important to avoid further exposure to the responsible agent. There is consistent evidence to indicate that early diagnosis and avoidance of exposure to the cause of allergic occupational asthma provides the best
opportunity to prevent the development of chronic asthma. It is therefore important to provide services which enable an early and accurate diagnosis of occupational asthma. Of similar importance is mis-diagnosis of a case of occupational asthma, i.e., attributing asthma incorrectly to an occupational cause, which can lead to inappropriate advice to leave work often it is difficult for individuals to get back into the labour market, with important financial and social consequences.

There is therefore an important need to provide specialist services within the United Kingdom, to which possible cases of occupational asthma can be referred, in order that an accurate diagnosis and informed advice about future employment can be provided. The number of such specialist centres does not need to be great, probably no more than half a dozen throughout the United Kingdom. They are an important resource for the specialist management of a disease which requires understanding of respiratory illness and the hazards of work as well as the provision of well-informed advice about future management.

Unfortunately in many cases the only way to avoid exposure to an allergic cause of asthma is a change of job, which can mean the loss of employment. There is evidence from a number of studies that those who leave their job because of occupational asthma can remain out of work for several years; they seem less likely than other asthmatics of a similar age to obtain new employment. There is a real need to provide the means to support re-training for individuals with occupational asthma, with facilitation into new jobs. This could be a function of the Industrial Injuries Scheme, which provides compensation for occupational asthma as a prescribed disease. Unfortunately, since the withdrawal of Reduced Earnings Allowance in 1990, this opportunity is no longer available under the scheme. Review of the Industrial Injuries Scheme, with a view to reforming it, is currently under way. The introduction of a benefit which could support and enable re-training of individuals unable to continue in their current job because of a prescribed disease, such as those with occupational asthma, to enable them to remain in or return to work should be an important function of a reformed scheme.

20 November 2006

Memorandum by Professor Raymond Agius, Professor of Occupational and Environmental Medicine, and Director of the Centre for Occupational and Environmental Health, The University of Manchester

SUMMARY PREPARED IN RESPONSE TO SOME POSSIBLE QUESTIONS ON OCCUPATIONAL ALLERGY (DERMATITIS, ASTHMA AND RHINITIS)

Data from SWORD (Surveillance of Work Related and Occupational Respiratory Disease) and OPRA (Occupational Physicians’ Reporting Activity) up to 2005 inclusive shows that certain occupations present a particularly high risk to UK workers of developing occupational asthma, notably bakers, confectioners and others exposed to flour (amongst whom allergic rhinitis is also common), and vehicle spray painters exposed to isocyanates, although risks are widespread in many occupational sectors. Dermatitis in the UK as reported through EPIDERM is widespread and exhibits the highest incidence amongst hairdressers and beauticians, although in absolute numbers reports in nurses tend to be greater since they constitute a larger occupational group.

Although occupational asthma accounts for only about 15 per cent of occupational disease cases reported to the University of Manchester by respiratory physicians (SWORD) (the majority of cases still being asbestos related), the situation is reversed in reports to us from occupational physicians (OPRA) from whom occupational asthma reports account for the majority of occupational lung disease. Occupational dermatitis is by far the commonest occupational skin disease reported to us by dermatologists (EPIDERM), occupational physicians (OPRA) or GPs (in The Health and Occupation Reporting Network for GPs: THOR-GP) but differentiation between allergic and irritant cases is not always easy especially for non-specialists.

The HSE recognises that there is substantial under-reporting of ill health through RIDDOR (the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations) and 2002–03 was the last year for which RIDDOR ill health reports were compiled into its summary statistical tables. The data from SWORD, OPRA and EPIDERM up to 2005 inclusive are consistent with statistically significant reductions in reported incidence both of occupational asthma and occupational contact dermatitis. However caution has to be expressed because of potential artefacts, and also the presence of differential trends depending on causal agents or exposures. Thus for asthma there appears to have been a persuasive fall in reports of latex asthma yet for asthma caused by flour no such trend is apparent. Glutaraldehyde asthma reports also appear to have fallen; but we have concerns about sporadic reports associated with its substitutes, as well as evidence from our other research based on their chemical structure suggesting that some of these may also present an asthma hazard.
General Practitioners generally receive hardly any training regarding the recognition or prevention of occupational allergic diseases, and they probably tend to treat asthma, rhinitis and dermatitis in a similar way regardless of cause. However courses such as the Diploma in Occupational Medicine are available to them on a short course or distance learning basis. Our data mainly from ex-alumni of ours who have attended the latter suggest that these GPs, who participate in THOR-GP, refer about one quarter of the suspected new cases of occupational asthma and occupational dermatitis to specialists, mainly to chest physicians and dermatologists respectively, but occasionally to occupational physicians.

Analysis of the reports in our growing database, by industry sector and especially by temporal trends should permit us to continue to identify high risk exposures and to evaluate the effect of control strategies on trends in incidence. Moreover research such as ours relating chemical structure to allergic hazard through Quantitative Structure Activity Relationships (QSAR) can help predict novel hazards.

Acknowledgements:

EPIDERM, OPRA, SWORD and THOR-GP are constituents of THOR (The Health and Occupation Reporting Network) which encompasses the occupational surveillance and research schemes of the University of Manchester: http://www.medicine.manchester.ac.uk/coeh/thor/

Data collection through EPIDERM, SWORD and OPRA was funded by the UK HSE until 31.12.2006. Data collection through THOR-GP is funded by the HSE until November 2008.

Examination of Witnesses

Witnesses: Professor Anthony Newman Taylor, Chairman, Industrial Injuries Advisory Council, Mr Rob Miguel, Health & Safety Officer, Amicus the Union, Professor Raymond Agius, Director, Centre for Occupational & Environmental Health, University of Manchester, and Dr David Orton, Consultant Dermatologist, Amersham Hospital, Buckinghamshire, examined.

Q263 Chairman: Can I thank our witnesses for coming today. I am Lady Finlay. I am chairing this select committee inquiry. There is an information note with all the declared interests of members of the Committee so we will not be going round declaring our interests during the evidence session today, but it is available for members of the public. We are most grateful to you for coming today. Professor Agius, you have sent in a document which we have now circulated to the Committee. I wonder if you could introduce yourselves briefly.

Dr Orton: Good morning. I am Dr David Orton. I am a Consultant Dermatologist at Buckinghamshire NHS Trust with an interest in contact dermatitis and occupational dermatitis generally.

Professor Agius: My Lord Chairman, I am Raymond Agius. I am Professor of Occupational and Environmental Medicine at the University of Manchester and I am Director of the Centre of Occupational & Environmental Health there which, amongst other things, collects data on occupational and work-related disease.

Mr Miguel: My Lord Chairman, I am Rob Miguel. I am the Health & Safety Officer at Amicus, which is a trade union with 1.2 million members representing quite a few sectors in the UK. I deal with general practice and I serve on a number of government committees.

Professor Newman Taylor: I am Professor Anthony Newman Taylor. I am a Consultant Chest Physician at Brompton Hospital. I am the Head of the National Heart and Lung Institute and the Department of Occupational and Environmental Medicine there, and I am also Chairman of the Industrial Injuries Disablement Benefit Scheme.

Q264 Chairman: Thank you. Perhaps I could start with a question which I would like you all to try and answer. We have a lot of questions that we want to get through with you today so it is helpful if you can keep your answers concise so that we can get through all the topics we want to cover. Which occupations present the highest risk to workers of developing conditions such as occupational asthma, dermatitis, rhinitis and other allergic diseases?

Dr Orton: My Lord Chairman, as a dermatologist I think I had best restrict myself to dermatology but I would say that the largest groups in occupational practice that we see with skin problems are from the healthcare sector, healthcare workers and hairdressers. It really depends on how you examine the data. If you look at point-prevalence cross-sectional studies amongst certain occupations or you look at the data submitted by medical practitioners to organisations such as EPIDERM, generally speaking, fairly consistently across Europe and Australia and the United States certain groups such as healthcare workers and those in hairdressing, as well as those exposed, obviously, to sensitisers in the plastics industry and the construction industry, are going to be represented fairly consistently.

Professor Agius: I would agree entirely with what my colleague has said. I think one also has to bring the matter of denominators into account, so while I would agree with him that one tends to see more cases
reported to us from amongst healthcare workers, of course they constitute a large proportion of the working population and if we took their denominator into account then the risk amongst, say, hairdressers and beauticians is about 10 times higher than the risk amongst healthcare workers, because of course there are fewer hairdressers and beauticians. So we might see in the order of three per thousand hairdressers per annum reported to us by specialists and there is only one tenth that rate for nurses. Of course, if one looks further down the pyramid one has to bear in mind that the reports from specialists are only a proportion of the cases seen by GPs, perhaps one in four, so the pyramid then gets wider and wider at the base and it is difficult to measure at the base.

Mr Miguel: I have been looking at the figures produced by HSE, and hairdressers in relation to dermatology is the highest group followed by chemical workers, but these figures could be confusing because there are other factors to be taken into account. For example, there is an amount of screening which goes on which screens out workers who may be susceptible to asthma. There are other reasons to believe that these figures are accurate but not completely accurate. The figures I looked at came from EPIDERM for dermatitis and from SWORD for occupational asthma—moulders, core makers and die casters. I do not know if you know what those occupations are but primarily moulders and core makers are producing things like taps and boilers and they are cast in a die. Secondly on occupational asthma, if you take other figures into account spray painters come out the highest figure. If you look at things like industrial injuries’ disablement benefit information from occupational health physicians the figures come out slightly different. I will say though that there is quite significant under-reporting in dermatology and in occupational asthma. You only have to look at the example of Powertrain, where they had a massive outbreak at Longbridge. There were 101 cases reported. Eighty seven of those were of occupational asthma, 24 of alveolitis. If you look at the figures and I give you a figure per 100,000 workers of 96 for paint sprayers, if I do that calculation in Powertrain alone the incident rate per 100,000 workers would be 4,000, and you can see there is a significant difference, so there is a lot of under-reporting that goes on. However, I have sat on a board with HSE which looks at occupations and at anomalies, and they roughly came out with the same sorts of figures, so for occupational asthma it is people in engineering, paint sprayers, people in confectionery, flour, and with dermatitis it is hairdressers. Even when you look at all the anomalies, the highest occupations still come out the same. Part of the under-reporting is due to UK employment law, frustration of contract, where if a worker is deemed not to be able to do his job then he can be laid off by his/her company. This is going to account for quite a bit of under-reporting. Also, the occupational health system relies upon GPs within the system, and they do not actually feed into the reporting. I understand from HSE that they are looking at inviting GPs to become involved in the reporting system. I have some more to say but I know you want the answer to be concise so I will leave that there.

Q265 Chairman: Bring that in later.
Professor Newman Taylor: In terms of occupational asthma, the most common group is spray painters. There are then plastic workers, chemical process workers, bakers and laboratory technicians that constitute the highest incidence, as far as we are aware, of occupational asthma, and then healthcare workers. I would add to what has been said that that is based upon the reporting by consultant specialist chest physicians and occupational physicians, and so therefore, in order for us to be aware of those cases, they need to have been seen by a specialist chest physician in the case of asthma or a dermatologist in the case of dermatitis, and clearly a significant proportion of cases does not get there. In terms of occupational physicians, it is worth appreciating that it is estimated only about 12 per cent of the workforce is covered by an occupational physician; therefore the opportunity for them to report cases is going to be relatively small. We did a study trying to estimate both the numerator and the denominator for laboratory animal allergy and came to the conclusion that in relation to the SWORD data the numerator was higher and the denominator was lower and so the true incidence was higher, but these are the major causes.

Q266 Chairman: Can I just ask you how many do you estimate have got multiple allergies?
Professor Newman Taylor: When you say “multiple allergies”, multiple allergies to both agents they meet in the general way as well as at work?

Q267 Chairman: I was thinking about patients who would be going round different specialist services because their allergies manifest in different ways.
Professor Newman Taylor: I would have thought that that is a minority, because the reality is that although there are overlaps in terms of what causes dermatitis and what causes asthma, the two tend to be fairly separate.
Dr Orton: There is just one point that needs to be clarified from the outset, which is that although occupational skin disease is extremely common and may be due to contact dermatitis, there are, of course,
two sorts of contact dermatitis—irritant contact dermatitis and allergic contact dermatitis, and the majority of cases that primary care physicians, or indeed consultant dermatologists, might end up seeing will be irritant contact dermatitis, but often cases are complex and involve both irritant and allergic factors and that the diagnosis of allergy needs to be teased out in order to help with the management of that specific patient.

Q268 Lord Taverne: How has the pattern changed? In Professor Newman Taylor’s letter he mentions that there are now fewer reported cases of certain kinds of asthma, that there is no change, as far as one can see, in the case of bakery workers, and that the increase in latex allergy has decreased. What is the cause of the change?

Professor Newman Taylor: Maybe I can start with this and Professor Agius, who is particularly familiar with the data, can follow. What has happened since the reporting scheme started in the late 1980s is that there has been a fairly consistent number of cases reported and the causes of those cases have been fairly consistent. Overall there has been a decline in the number of cases reported due to isocyanates. It remains the most frequent cause, but the number of cases reported has declined. There was the epidemic caused by latex in the 1990s, particularly in healthcare workers, with a marked increase and subsequent reduction following the introduction of non-powdered low protein latex gloves. There has been an overall reduction in the number of cases which seems to have occurred in one year so that it has been about flat, come down and then been reasonably flat again. There have been changes but overall, the incidence of the disease and the causes which are being reported, with the particular exception of latex and the reduction in isocyanates, has not been that dissimilar during the period of reporting.

Professor Agius: As Professor Newman Taylor has said, the situation is rather complex. There are many factors which militate against getting the highest quality data. One is that to a great extent what we get is collected from specialist doctors reporting voluntarily. We have recently, in response to a point made by Mr Miguel, started collecting data from GPs as well. If one assumes a linear trend, and of course there are lots of reasons why that trend might not be the true one, and takes into account as far as one possibly can factors like the fact that doctors might get tired of reporting and so on, then if pushed I might say that we have found significant year-on-year reductions but the extent to which the reductions are manifest varies slightly by the reporting group. For example, amongst dermatologists reporting occupational respiratory disease we tend to see a year-on-year reduction of about 3 per cent, whereas amongst occupational physicians with skin disease it might be of the order of 10 per cent. For respiratory physicians reporting occupational asthma and occupational physicians reporting occupational asthma there are suggestions of a significant trend year-on-year to the order of seven per cent. Having said that, one has to exercise caution because even though we are using the best statistical methods to take into account possible artefacts, such as doctors getting tired of reporting and so on, it cannot be conclusively said that we have got rid of all of those. Professor Newman Taylor has said that the pattern is very patchy within the various causes, so, sadly, for occupational asthma caused by flour, which arguably, subject to correction by Professor Newman Taylor, is probably the oldest known cause of occupational asthma dating back a few hundred years, there has been no change in that. As Professor Newman Taylor has said, insofar as latex and glutaraldehyde over the last three or four years we do not get more than 10 specialist reported cases per annum and yet for some of the commoner and big causes the problem still persists.

Q269 Chairman: Are there actions that should be being taken to decrease the incidence? You cited the change in latex gloves. Are there other things we should be doing to minimise or even possibly eliminate risk in some of these groups of workers that are just not being done at the moment?

Mr Miguel: Yes, more could be done in the way of identifying sensitisers and putting in the appropriate controls, but as well what you have to remember is that in the UK the structure of the workforce is changing. I had some figures from our personal injury lawyers. We have 134 dermatitis cases and 102 occupational asthma cases and those occupations come from engineering and manufacturing. The UK is changing to service based industries so therefore you are going to find a decrease in the reported incidence.

Q270 Lord Soley of Swaffham Prior: With respect to these various conditions that are being discussed in this question, is the fundamental immunological response the same in them all, starting with sensitisation of a delayed character and then moving to an acute response, or are there differences with asthma, dermatitis, rhinitis and other allergic conditions? I am wondering if there is a unity there.

Professor Newman Taylor: If I can answer the question particularly in relation to asthma because the underlying immunological response in relation to dermatitis is different. In relation to asthma, what we can describe as allergic asthma, fulfils the criteria of a hypersensitivity response: it develops in a minority
of people who are exposed; it occurs after a latent interval, and those affected react to levels of exposure which are much less than cause problems in other people. So it fulfils the criteria of an allergic reaction. But it is only in a minority of the cases we can identify a specific immunological response in the usual way by finding IgE in the blood. We can do that for almost all of the protein causes of occupational asthma but for chemicals it is only in a minority of cases. We can do it for acid anhydrides, for complex platinum salts, and for a minority of cases of isocyanates. So for many of the causes one cannot identify evidence of a specific immunological mechanism, although the character of the disease is the same as in those in which we can.

Dr Orton: Again, with allergic responses in the skin there are two distinct processes that can result in skin problems. There is an immediate type of allergic response which is predominantly what we have seen very frequently with latex proteins in gloves, and then there is the delayed hypersensitivity reaction involving a different immunological mechanism that results in dermatitis. It is the basis of the latter which we use in the diagnosis of allergic contact dermatitis with our patch testing technique.

Q271 Lord Soulsby of Swaffham Prior: Where there is a delayed response will that always be a delayed response or will it change to an immediate response? Dr Orton: No. It usually is delayed. There is a rare exception when exposure to certain proteins can result in an immediate type of response which, after a prolonged period of time, evolve into a dermatitis and we see that certainly in certain food handlers such as sandwich makers, this is described as protein contact dermatitis.

Q272 Chairman: Professor Agius, could you confirm to me that the general practitioners’ Quality Outcomes Framework does not specify allergic occupational diseases? Professor Agius: to the best of my knowledge, my Lord Chairman, it does not.

Q273 Baroness Perry of Southwark: My question is about the role of the Health & Safety Executive. When they gave evidence to us they said that they were currently making efforts to reduce work-related allergies by raising awareness. They have got schemes such as National Hairdressers’ Day, which is aimed at raising awareness about dermatitis. Do you think schemes such as this will reduce the incidence of occupational allergic diseases and what else do you think the Government should be doing to ensure that employers, staff and health and safety personnel are aware of the number of agents known to cause occupational allergic diseases?

Professor Newman Taylor: I can try and start to answer that question. The important thing that needs to be understood is that the best evidence which we have, and it is now quite consistent in relation to a number of different causes of occupational asthma, and I am focusing now on asthma, is that the risk of developing the disease is predominantly a consequence of the level of exposure to the agent which causes it. The higher the exposure in general, the greater the risk of the disease developing. If the incidence of the disease is going to be reduced what needs to be focused on is a reduction in the level of exposure to its cause, be it urinary proteins from laboratory animals, flour and enzymes in bakery, et cetera. There have been two good examples where control measures have been taken that have made a significant difference to the incidence of the disease, virtually eliminating it. One is enzymes in the detergent industry and the second is latex. In the detergent industry, which caused major problems when powdered enzymes were added to detergents in the late 1960s, it caused problems not only in the workforce but also in consumers. The way this was got round was to encapsulate the enzymes in granules, which were too large to be suspended in the air, so they fell out of it and could not be inhaled. One has to recognise that there was a solution there which was possible, as indeed with latex because it was the powder which the protein from the rubber was absorbing that was getting into the air and being inhaled. By providing gloves with low protein content in the rubber and which were not powdered latex allergy could be virtually eliminated. That is a much more difficult thing to do in many other circumstances, but the principle is the same and we need to see how we can apply it. The principle is more difficult, for instance, with laboratory animal urine proteins because you cannot really granulate an animal, you cannot granulate its urine. We need to find ways in which we can prevent the urine deposited on the dust in the cage getting into the air and being inhaled, but it is more difficult. The second problem is that these two examples are in large employers. The enzyme detergent industry employs many people. Procter & Gamble, Unilever, many others, are big companies employing occupational health physicians and safety advisers and are able to implement on a large scale these sorts of changes. As Rob Miguel has said, the problem we have now is with an industry that increasingly is moving from manufacturing to service, with smaller workforces, smaller factories and more self-employed people. That is a much more difficult problem. Hairdressing is, generally speaking, in relatively small outlets where there are relatively few people who are working, so there is greater difficulty in finding ways to ensure they work in a safe fashion which reduces
the risk of disease developing. The answer is that the type of program the Health & Safety Executive is doing is welcome because it is raising awareness. It is also hopefully going to be backed up by informed discussion with employers about what the risks are and how they can be reduced, but the difficulty for the Health & Safety Executive in this sort of workforce is that it is very difficult to enforce regulations. It is much easier to enforce at ICI than it is in a local hairdresser and to my way of thinking this is the real problem and we need to look at means to persuade employers that it is in their interests to ensure safe working conditions. That is, I believe, what we need to look at now. There has been some recent research looking at the costs of occupational asthma, which is quite considerable in terms of people leaving the workforce, loss of productivity, benefits paid, etc. The great majority of the costs falls on the individual and on government and a relatively small proportion on the employer, so at the moment those sorts of incentive are not really there.

Mr Miguel: My Lord Chairman, I agree with everything that has been said there, especially about the fragmentation of the workforce; there are a lot of small workforces out there. These sorts of campaigns are very effective as long as they are run in combination with the workforce through trade unions and employers. One of the HSE boards, the Disease Reduction Programme Board, has been set up to get all these people together, trade unions, employers, medical people, and look at these deliveries. For example, in the Powertrain incident, and that is a major company, they did not actually know what the sensitisier was there, so consequently people were sensitised and disease occurred, so it is not just occurring in small companies; it is also occurring in large companies because they are unaware of the facts. Part of the programme, regarding these initiatives is for trade unions and others to get involved in that campaign, and to help the HSE with that campaign because they cannot achieve outcomes by themselves. Amicus and other trade unions have undertaken to help the HSE. One of the things we are doing is introducing this type of material and these initiatives into our education programme, where we ask our safety representatives to take the material that they have learned back into the workplace, because they have direct access to safety committees, especially in large companies and direct access to employers’ health and safety professionals in there. This campaign can only be effective if run together with employers and trade unions and other work/employee organisations. It is about awareness. It is okay sending a leaflet out to hairdressers so that they can have a look at it, but this needs supporting. I did make some suggestions, we ran a campaign on prostate cancer several years ago and we approached a television company to put a storyline on prostate cancer in a very popular television programme which came out on a Sunday. That had a very positive effect and I did suggest that if you are looking at hairdressers, who are very difficult to reach, and I know it sounds silly, but maybe to have a storyline in Coronation Street where they have got a hairdressing shop. That would reach more people than just sending out a couple of leaflets. This is the type of thing that needs to be done to back up these sorts of campaigns.

Q274 Chairman: Have you approached Coronation Street?

Mr Miguel: We have not yet.

Chairman: It sounds like a job for tomorrow.

Q275 Lord Soulsby of Swaffham Prior: Under the 2002 Control of Substances Hazardous to Health regulations which have recently been revised employers are required to ensure that exposure to substances that may cause asthma or dermatitis is controlled. Does this in fact work effectively? Is it a problem for employees to ensure that the workers are not exposed? Are there always additional substances that come to light that may be problematic?

Dr Orton: Only if it really happens. Education and legislation can achieve only so much. I would like to revert quickly to the last question in the sense that if you target your audience and your trainees, for example, in the hairdressing industry, evidence from Europe does suggest that you can reduce the incidence of occupational skin disease. That is mainly, I suspect, irritant contact dermatitis, but as I keep saying, with dermatitis it is often complex and there are both irritant and allergic factors playing a role in the end skin-related problem. We have great problems even investigating cases of allergic contact dermatitis, looking at the material safety data sheets that are often provided by companies because they are often incomplete and it takes a great deal of time and effort to be able to identify what the sensitisers are. Legislation is useful, obviously, and it does help, but there are changes that need to be made to make even the investigation of such cases easier for the clinicians.

Professor Agius: I certainly agree with what Dr Orton and Professor Newman Taylor have said and I would emphasise that the steps have to start at the very top following the hierarchy in the Control of Substances Hazardous to Health regulations, so every effort must be made to substitute harmful agents for ones which are less harmful and to reduce exposure. All too often we find that convenience in using certain agents is exposing workers to greater risk, so we find that people are using aerosol sprays to clean surfaces because it is quicker to use an aerosol spray and just
aim it in various directions than it is to use a gloved hand holding a hand wipe. It is those steps that have to be implemented at the highest level insofar as what manufacturers produce and what employers expect by way of work practices, and only after all those things have been done is it then possible to try and achieve, a final level through personal protection and education of the workforce. In response to the earlier question about hairdressers, I do share some of the doubts that have already been expressed by witnesses as to the extent to which education alone will help things. The proof of the pudding will be in the eating. Sadly, hairdressers have got a very high incidence especially of dermatitis, possibly to the order of one per hundred per year, and it should be possible to track and prove in due course whether or not these interventions have helped and whether the legislation has helped.

Mr Miguel: The legislation, COSHH, as it is generally known, is procedurally fine and it can transpose to allergies easily: identifying a sensitiser, calculating the risk to the person and controlling this using a hierarchy, and the hierarchy is first to eliminate the hazard in ways that have been described or using engineering controls and so on. The downfall with it is that it is too generic and in cases that are complex, such as this, identifying the hazard, identifying the sensitiser, is easier said than done. In the Powertrain incident at Longbridge the sensitiser was not identified, and there is evidence that the causative agent could have been bacteria. There is also evidence that biocides used in the metal cleaning fluid also contain endotoxins which could be a sensitiser. These are all complex issues which a major company failed to pick up, so the legislation was there, and the procedures were there, but obviously you have to identify the hazard in the first place. If there is no research, or if there is low level research or that research is not published, then the employer is not going to pick that up. In relation to data sheets, data sheets are very generic themselves, so in this instance, the data sheets said the health risk was irritation to the respiratory tract. It did not mention possible bacterial contamination of the metal fluid when it was in use, so we were just looking at the metal fluid itself, not the process, and no specific respiratory disease was mentioned. It did say that local exhaust ventilation could have been used if the mists were excessive, but did not describe “excessive”, so the information available to employers from this legislation, and data sheets, is inconsistent and it does not help employers. It helps the HSE to prosecute employers if they go wrong, but it does not on its own help employers enough. More work needs to be done in relation to COSHH. There is some new European legislation coming up called REACH which asks the supplier to identify the hazards/risks and I think a push needs to be made in relation to allergies to identify properly the sensitisers in these materials.

Q276 Lord Soulsby of Swaffham Prior: Is it legitimate to refuse employment to someone who is known to be allergic to items in the workplace? Mr Miguel: I would not say it as illegal, although the disability law has to be considered, because if you have a pre-employment check which asks those questions then the employer is not going to give that as a reason. They will just refuse employment.

Q277 Earl of Selborne: Can I ask a question with reference to REACH? This has been in the offering for an awfully long time, it seems to me, and it never seems to quite come to fulfilment and it only deals with chemicals and not with other substances to which there might be an allergic reaction. Do you have much confidence therefore that REACH is going to help?

Mr Miguel: I think REACH will help as long as it is combined with existing legislation and existing guidance because that point has come out on several committees, that REACH was going to overshadow COSHH, which includes biological hazards. That would be unacceptable because you can see from the example I gave you that there was a process, and information from suppliers did not identify the sensitisers which come from that process, it was not the original chemical, so there are going to be faults with REACH but that has to be backed up further by UK legislation.

Q278 Viscount Simon: What training do health and safety inspectors receive with regard to occupational allergic diseases and is this adequate? Do you think there are enough health and safety factory inspectors for small businesses, such as the car spraying operations that you have already mentioned?

Mr Miguel: I do a lot of work with the Health & Safety Executive so I know the answer to this. When they begin their training, they get an occupational health tutorial, which includes allergies, this includes respiratory diseases, skin sensitisation, asthmagens and COSHH, so they do get training in the beginning. This is reinforced by experts that work within the Health & Safety Executive, so inspectors can call on colleagues. When they go to sites in the first instance, if there is a specific thing, such as occupational asthma, they usually have a specialist colleague with them. If they have a specific intervention which deals with risks to skin, for example, they take a colleague with them and they get advice from that colleague, so they do have training from the beginning, which is reinforced by supervision and by experts. The HSE also have doctors and nurses and occupational hygienists. I do...
Chairman: Q279 incidence over time. Problems and education as to how to reduce their supported in terms of bringing awareness of the additional to HSE or ways in which HSE can be so therefore we need to look at other means small workforces I would think is asking a great deal, going to be able to focus at that sort of level in such hairdressers, to be able to have individuals who are the numbers are not sufficient, nor could they ever be sufficient. If we are thinking about asthma in hairdressers, to be able to have individuals who are going to be able to focus at that sort of level in such small workforces I would think is asking a great deal, so therefore we need to look at other means additional to HSE or ways in which HSE can be supported in terms of bringing awareness of the problems and education as to how to reduce their incidence over time.

Q279 Chairman: Professor Newman Taylor, could I ask you how much you think occupational asthma is compounded by smoking in the workplace or smoking overall?

Professor Newman Taylor: There is evidence that for some, particularly chemical, causes of asthma the risk of developing occupational asthma has increased. You see that clearly with platinum salts and acid anhydrides but they are relatively small contributors to the overall burden. With regard to the evidence we have in terms of the extent to which it increases the probability of getting occupational asthma, probably it does not contribute very greatly. On the other hand, if you are a cigarette smoker and you develop this disease then the consequences may be worse because you are smoking as well as having asthma due to this.

Q280 Earl of Selborne: Professor Newman Taylor in his written evidence refers to the need to provide a means to support retraining for individuals with occupational asthma for the facilitation of new jobs and presumably there is a need for other occupational allergic diseases and you refer to the review of the Industrial Injuries Scheme. Could we hear from you—and I am sure Mr Miguel will want to come in on this also—on what you would like to see as the outcome of this review of the Industrial Injuries Scheme and what new training schemes or other measures might be appropriate?

Professor Newman Taylor: If I can focus in terms of the review of the Industrial Injuries Scheme on how it impacts on this, one of the problems with the Industrial Injuries Scheme at the present time is that the way in which benefits are provided for prescribed diseases and industrial accidents is uniform. It is essentially a benefit which is provided for so-called loss of faculty, that is to say impairment, and the level of disability which is caused by that. If one thinks of someone who has occupational asthma, and dermatitis may be similar to this, if you can identify the disease sufficiently early there is the potential for it to resolve completely. Take someone who has occupational asthma due to, let us say, to being a baker working with flour. The major problem they have is that they are unable to return to work in an environment where they come into contact with flour or the enzymes that are added to flour in the baking process. What we need to put into place is a system which provides support to enable them to retrain and go into alternative employment. The problem for many cases of occupational asthma, and there have been several studies that have looked at this, is that somewhere between a third and a half of cases of occupational asthma remain unemployed three to five years later. They have had to leave their work because of the risk of progression of the disease if they remain there and of it becoming chronic and are unable to find alternative employment. What I was suggesting in that letter is that the Industrial Injuries Scheme could have a benefit which could be applied to that. There was a benefit called Reduced Earnings Allowance. Reduced Earnings Allowance was introduced originally in the late 1940s with the Industrial Injuries Scheme which enabled people who had pneumoconiosis to move into other jobs where they were less exposed to coal dust and therefore less at risk of progressing to Progressive Massive Fibrosis, so it had a very important preventive role in terms of coalworkers' pneumoconiosis. It was an earnings replacement which enabled that to occur. That was withdrawn by the Government of the day in 1990 and so that is no longer available. What I would hope in the reform of the Industrial Injuries scheme is that there will be a benefit, which could be time limited, which would be focused on providing occupational rehabilitation and retraining for people who have those conditions, of which asthma is a notable example, where continuing exposure leads to progression of the disease and the appropriate route to take is avoidance of the exposure. At the moment people may not bring their disease to attention because they are concerned they will lose their job and will not get another one, so we are in the worst of both worlds.

Dr Orton: I would agree wholeheartedly with Professor Newman Taylor's aspirations, but with regard to the skin there are a couple of complicating factors. The evidence at the moment suggests that if people with occupational skin disease change their employment it may not always result in a significant improvement in the prognosis for those individuals. There is also the condition of PPOD, or persistent post-occupational dermatitis, which is when somebody develops dermatitis in an occupational setting and you then remove them from that occupational setting and the exposure, yet their dermatitis persists. There is some evidence from
Australian large-scale studies that up to 10 per cent of the workforce within their study group developed this particular condition, so that also has to be taken into account when one is considering retraining or taking people out of various employments when they develop dermatitis.

Q281 Lord Taverne: What training do general practitioners receive about the treatment of occupational allergic diseases? It has several times been stressed, and now again by Professor Newman Taylor, that what is so important is early diagnosis. Do GPs receive sufficient training in the diagnosis?

Professor Newman Taylor: I would think it unlikely. Occupational health and occupational disease are not usually a part of the undergraduate training programme. It is not seen to be usually as important a part of a general practitioner’s training as the other conditions which they may see and so therefore their knowledge of these conditions is probably not great. Added to that, the number of cases that they will see individually is not going to be huge and so therefore their experience and the need to understand this is not as great as it might be. My answer to your question is that I think it probably is not enormous. We have run a clinic for patients with occupational lung disease, the majority of whom have occupational asthma, and we see about 250 cases a year, and of the order of 5 to 10 per cent of those patients are referred to us by general practitioners. It is a relatively small proportion of the cases that come to us. The majority come to us from occupational physicians or from other specialist physicians.

Professor Agius: By training I am a specialist in occupational medicine and I have never practised in general practice. However, I am involved in undergraduate medical education in a number of British medical schools, including my present one. Sadly, I think it is fair to say that the level of training that the average British graduate gets in the recognition of occupational allergic disease is exceedingly limited to the extent that when we set up, about 18 months ago, a scheme for recording reports of occupational allergic disease emanating from general practice, because they are, if I could use the analogy, at the base of the pyramid as compared to specialists, we felt we could not rely on the average general practitioner. We had to select from the few thousand GPs who have what is called a “Diploma in Occupational Medicine”, and even then, in my judgment, they rarely have had the sort of training which the average graduate ought to be getting but is not.

Q282 Lord Taverne: Given the importance of this, both in terms of the impact on individuals and the quality of their life and of the economy in general, are representations not being made to try to secure much greater priority for training in this for medical students?

Professor Agius: Yes, representations are being made. For example, the Centre, and the Faculty of Occupational Medicine to which I belong has yet again, and has done so in the past, embarked on initiatives to bring this to the attention of medical educators. I think what tends to happen is that there are lots of other specialities and interests, with good cause, vying for their own special features to appear in the curriculum but, given the fact that most people will present in the first instance to their GP and that such a huge burden on health could be prevented at that stage by early recognition and early steps, yes, I do believe more should be done to train GPs.

Dr Orton: I agree with my colleagues in the points they have made today. Even in dermatology the undergraduate curriculum usually consists of only two weeks’ attachment, whereas 20 per cent of all GP consultations involve some form of dermatological problem. We have to tackle it from another angle because what we need to do is improve the pathway of the patient. Obviously, the GP has to be aware that occupational allergic disease exists but it is getting that patient through to specialists as soon as possible that we have to concentrate on.

Q283 Lord Rea: How often is the subject of occupational allergic disease—asthma or dermatitis—included in postgraduate programmes organised by postgraduate deans for general practitioners, for trainee general practitioners, for registrars and principals in practice? There are these courses all the time going on. How often do they include an element of occupational health, including allergy?

Professor Newman Taylor: My answer is that I suspect it is in a minority. I do not have definite data but I am very familiar where my colleagues and I are asked to talk, and we give many talks to postgraduate meetings. It is a minority of those for general practitioners; the majority is for other specialists.

Chairman: I think it is probably a question we need to ask the GPs in relation to that.

Q284 Baroness Platt of Writtle: To which specialists do GPs refer patients suffering from occupational and allergic diseases and how often do these referrals happen?

Professor Newman Taylor: I would have thought that they would refer them particularly to respiratory chest physicians for occupational asthma and dermatologists for skin conditions. Those are probably the two most commonly referred because those are the circumstances in which the cause and effect relationship is clearest. Clearly, somebody who has occupational deafness may be being sent to an
ENT surgeon, but there is nothing to distinguish that deafness symptomatically from deafness that occurs in the population as a whole. I am unable to speak for other clinics but from my perspective, the majority of the occupational lung disease cases referred to me, come from occupational physicians, nearly two-thirds; a third from other specialists; and 5 to 10 per cent is from GPs.

**Q285 Baroness Platt of Writtle:** Then to take the two major causes, considering a number of people suffering from occupational dermatitis, are there currently enough specialists in that area and will there be a potential shortage of specialists when the present cohort of occupational asthma specialists retire?

**Professor Newman Taylor:** The situation with occupational asthma is that I think there is a need for a relatively small number of sub-specialists who have this as a particular interest. The reason there needs to be a small number—it is not something which all chest physicians can provide—is because there are particular factors which, in terms of understanding the nature of work, the relationship of work to the asthma, the investigation of the cases, which can include inhalation testing, and then the management of the case subsequently which need interaction between employers and others involved in the future management of these cases. It seems to me that it is important there should be a number of specialists in this field, not least because it is very important to identify a case because, as I said in terms of asthma, you have the chance, if not of cure, at least of improvement. I would agree with my colleague that not all cases of asthma resolve, but the majority will improve when they avoid exposure. Equally devastating is if you say to somebody, “Your asthma is caused by your work”, and it is not, “You need to change your job”, and they do so and they do not need to have done it. That, I have to say, is something which I see not infrequently because of a lack of knowledge of what is needed to make a confident diagnosis so you can give confident advice. There are six or seven specialists within the UK who have this as a particular interest and it is the case that many of us are now reaching retirement age. I think that there is a real need to ensure there will be successors, otherwise experts in the field will go. That is something which I would say at the moment is not secure.

**Dr Orton:** I would agree with all of those points. With respect to dermatitis, it is very important to have sub-specialists with a particular interest in occupational disease because that is going to provide at the end of the day the best management for the individuals who come to see them. Equally, within dermatology, many of my colleagues who have an interest specifically within occupational dermatology are also coming to retirement age and there does not seem to be the number of individuals coming through who have a particular sub-specialist interest in this area, so there is going to be a problem in the future almost certainly.

**Q286 Chairman:** Is there also a problem in terms of the number of consultant posts that are not being renewed now?

**Dr Orton:** Without getting too much into a political statement here, dermatology is a specialty under threat also, being moved from hospitals into a primary care setting and, indeed, much of dermatology now being undertaken by primary care physicians—and this of course here, relates to the previous question—they will not have received any specific training in occupational dermatology so we are entering a downward spiral here which I can only see as a future problem.

**Q287 Baroness Platt of Writtle:** Whose responsibility would it be to put this right, because for both allergies you are saying that there are retirements and this is going to be a problem? Who should be taking it up?

**Professor Newman Taylor:** I would suggest that the Department of Health needs to take responsibility with regard to this and I say that because for any individual hospital moving into the era of foundation trust status, where clearly financial viability is an extremely important issue, we are talking about two specialties where the revenue which will be received in terms of patient care is certainly not as great as, let us say, somebody who is going to need to be in an intensive care unit. If there is going to be an area where people will wonder is this in fact an area where we should continue to focus on, it must be one of the areas that a chief executive must wonder for the reasons that I have given. Occupational dermatitis and asthma will be services that will be at risk. In those circumstances, unless there is either Department of Health or, a specialist commissioning process where there are funds made available for it, which is the way it probably can best be done, I can see this as something which no individual hospitals might see as their responsibility to continue.

**Q288 Viscount Simon:** Professor Newman Taylor, you have mentioned the specialists to whom patients can be referred. Is there any particular reason why you have left out allergists?

**Professor Newman Taylor:** In the main, no, I have not really, but the reason that I am focused on respiratory physicians and dermatologists is that the majority of these sorts of patients are referred to them. If you have allergists who have a particular interest and have received training in occupational
Q289 Lord Broers: What course of action would typically be recommended for a patient suffering from occupational asthma or allergic skin conditions, and at what stage is a patient advised to give up work?

Dr Orton: First of all, within normal practice we would make a risk assessment for this individual and we would perform the necessary investigations to arrive at a diagnosis, whether it is allergic, irritant or both, and whether there are constitutional susceptibilities. As I mentioned briefly, giving up work is not always the answer because, certainly with regard to dermatitis, it does not always significantly lead to an improved prognosis. There are cut and dried cases where it is purely an allergic contact dermatitis and the patient is meeting that particular allergen only in the workplace. There are some allergens which are found not only in the workplace but also in the domestic environment and part of the management for that particular patient is teaching the patient about these exposures. However, in the clear-cut cases it is sometimes necessary for these individuals to leave work, particularly if they are volatile allergens and there is not going to be any way that they can avoid exposure in their current place of work. Obviously it is very difficult to give a generic answer to this and each case must be taken on its own merit and has distinctive features.

Professor Newman Taylor: Talking about asthma, in part it relates to the nature of the agent and in part the severity of the asthma which is occurring. One has to look at it against the background that the evidence that there is would suggest that the longer you continue to be exposed to the cause of your asthma, the greater the chances are the asthma will become irreversible, so there is a need in the individual case to avoid exposure both to prevent acute reactions and also the risk of progression. Agents such as isocyanates, which are volatile chemicals, are extremely difficult to avoid sufficiently if you become sensitised to them and to prevent the progression of asthma. In general, for people exposed to chemicals such as isocyanates, one would recommend that they should avoid exposure in some way, and to the extent that it is possible one looks to try and see if relocation is possible within the factory or workforce in which the person is involved. There are other allergens, particularly with particulate agents, such as flour or laboratory animals, where it may be possible to enable people to continue at work wearing sufficient respiratory protection. That certainly I would advise in circumstances where it provides the individual with the time to look for and obtain other employment. If you have got someone, for instance, who is a PhD student and is two years into it one would work quite hard to enable them to complete their PhD which also gives them a year in which they can look for alternative employment, let us say working with tissue rather than live animals. It is not hard and fast, but clearly the aim is to avoid exposure.

Mr Miguel: My Lord Chairman, on the employment issue, it is very difficult because a lot of these people go to their GPs and their GPs may advise them to give up work, but that does not necessarily mean the employee is going to go back into work and give their job up, they may work on. We have done some work with certain employers regarding security of employment policy, whereby they re-deploy those people in the same plants in different rolls. Rolls-Royce is a good example. Which leads to a further question, if they do have to give up work what sort of training is available to them? There was a mention of the benefits system, to clarify a point, reduced earnings benefit at the moment is being replaced by working tax credit. However, the benefits system itself does not help people to get back into work because if you have a look at the benefits system, one example, you need to be off work for about 30 weeks before you can claim for your mortgage. If you go back into the workplace, you lose that benefit and start from square one; I think they allow four weeks grace. Who in their right mind is going to go back into the workplace, or be encouraged to go back into the workplace when they are going to lose this type of benefit and they have to start from square one again? For example, they would have to wait for 30 weeks to have a mortgage payment. The benefits system is not helping at all. The diagnosis and the fear of medical confidentiality breach’s are not helping. We would like to see a proper government-led training initiative for people with allergies which involves job centres, where job centres are aware of industries where these allergies occur, and to re-train those people at the same skill level as they had before, getting the same pay because what we are trying to do now, is to say to them “You are no good for this job now, or, you can do this job where it is half the pay and we will try and top that up using tax benefits”. In fact, it does not work so I think we need to look at the benefit system quite carefully, look at the way the diagnosis is happening, and how the information is getting back to the employer, because the employer, or the job centre are not getting adequate information or using it correctly.

Q290 Lord Broers: How much do you get involved with small companies? What if it is a small paint shop where they are flagrantly ignoring safe practice? Do
you get much involved with that, if these might be organisations of only half a dozen people?

Mr Miguel: Unfortunately, trade unions are usually involved with big organisations, but I do get involved with small organisations of about 50 employees where they have this sort of problem. I do not want to name the companies here, but we do get involved, I do go on to site and give them advice because they have limited knowledge on re-deployment, on allergies, on information about what is an allergy, and what is a sensitisser but very rarely, because trade unions are more involved in major companies than smaller ones, but that is changing.

Q291 Chairman: Given the shortage of specialists that there is and the importance from the Union’s point of view of accurate diagnosis, which you highlighted earlier on, has the Union thought about developing its own service and employing an allergy specialist itself, or part-employing an allergy specialist itself?

Mr Miguel: No, that is not something we consider. We do work with employers and their occupational health departments, but we do not think that it is the trade union’s role to supply specialists, it is the employer’s role to do that.3

Q292 Lord May of Oxford: This is a question that probably reflects my ignorance. We have heard that one of the major sources of allergies was among hairdressers and I was under the misapprehension that a great proportion of hairdresser outfits were small businesses. Am I wrong, because if I am right then that means that is a really very significant problem, of this issue not being addressed because you are typically dealing with larger outfits?

Mr Miguel: I will answer that very quickly. They are small businesses yes and they have got very little occupational health advice, although the HSE is trying to bring the schemes forward, so, therefore, the campaigns which we talked about earlier are very relevant to reaching those small businesses and some of the media tactics that I mentioned, but, you are quite right, they are small businesses in need of help.

Q293 Lord May of Oxford: They sum up to a large number.

Mr Miguel: Yes.

Dr Orton: I would like to comment on that. Amongst hairdressers, in occupational skin disease, allergy is a part but irritancy is probably a greater part. In my own practice and when I am talking to other dermatologists, the days of going into a large industry and looking for large outbreaks of sensitisers causing problems are very much lower than they used to be. It is usually the smaller industry and smaller workplaces where the majority of patients now seem to be coming from.

Q294 Lord Rea: The Health and Safety Executive regularly convenes a group of occupational respiratory disease specialists with the aim of developing a document setting out standards of care for the diagnosis and management of occupational asthma to circulate throughout the medical community. What recommendations do you think should be included in this report? Am I right in thinking that this group is the same or related to SWORD? It seems to be very much covering the same area.

Professor Newman Taylor: I think it is a different group from SWORD. SWORD is the reporting scheme, which Professor Agius is now responsible for; GORDS is an informal group of respiratory physicians who have an interest in occupational disease which has been convened by the Health and Safety Executive and meets two or three times a year. One of the proposals it is currently looking at is this question of setting out standards of care for the investigation and management of patients with occupational asthma. The answer is that it must be a worthwhile endeavour because it is going to improve, or its promulgation should improve, the quality of diagnosis and management of this condition. Whether or not it will do anything to increase the number of cases that we are aware of is really another issue because that is all about individuals either at general practice level or specialist level recognising that a case may be attributable to their occupation, bringing it to attention and investigating it appropriately. I think it has the potential to improve standards of care; the extent to which it will increase awareness and, therefore, increase the number of cases I am less sure about. Just as a footnote to that, last year I chaired for the British Occupational Health Research Foundation—a committee which published guidelines on the prevention, diagnosis and management of occupational asthma. These have now been incorporated into the British Thoracic Society guidelines for the management of asthma and have been circulated to all respiratory physicians. So I would hope that at least at that specialist level that information is getting there already. For this to make an impact, it is going to have to get beyond the specialists who are currently seeing the cases.

Q295 Lord Rea: I hope so. What about a similar document being produced for occupational allergic skin disorders?

3 AMICUS has various partnerships with industry bodies, for example Electrical Contractors Association (ECA) and AMICUS form the Electrical Joint Industry Board (JIB). This and our other partnerships, have health care provisions as part of its benefits to employees.
Dr Orton: I am not aware of any current work that is being co-ordinated with the HSE for that.

Q296 Lord Rea: Do you think it would be desirable? Dr Orton: I think it would be desirable, absolutely.

Q297 Lord May of Oxford: This is a question primarily I think for Professor Agius. The University of Manchester, as I understand it, runs several schemes that collect data involving occupational and allergic diseases. What proportion of the cases reported in these schemes has an allergic basis and how has the number changed in recent years?

Professor Agius: My Lord Chairman, yes, his Lordship is correct, we do collect data from a number of schemes. Historically, the schemes in their origin were based around specialists, for example the specialists of interest today are mainly respiratory physicians, dermatologists and occupational physicians and, as I intimated earlier, they reflect very much the tip of the iceberg. The shape of the tip of the iceberg gives us very little indication of what the iceberg’s shape is like below the waterline, so we have been arguing for a few years that we should collect data closer to the base by getting information from GPs and, indeed, we did launch such a scheme 18 months ago. In very round figures because the results are preliminary, based on the information in the reports GPs give us, out of the totality of work-related disease that they see, about one in 10 relates to skin and the vast majority of that is occupational contact dermatitis. The GPs are not very well qualified to determine what proportion of that is allergic and what proportion of it is non-allergic irritant. However, based on the information that the specialists give us, and that has already been alluded to by my colleague, Dr Orton, we would expect a bit less than half of those to be allergic at least initially. Then as far as respiratory disease, about one in 20 of the cases of occupational disease that GPs report to us generally consist of respiratory disease and the vast majority of those would be either asthma or asthma-like syndromes, perhaps not yet fulfilling the full definition and not yet proven by specialists. The majority of those would have allergic features although, as my colleague, Professor Newman Taylor, said, not all of them might fulfil all the immune criteria. If we now look at the totality of the data we get, but, as I said earlier, this is very much influenced by what the specialists tell us, we get an estimated 20,000 cases of occupational disease every year, of which about 2,500 are reported cases from dermatologists and about 2,500 from occupational physicians. Of the 2,500 from dermatologists it is estimated about three-quarters of those are occupational dermatitis and 15 per cent from the 2,500 or so estimated cases from chest physicians are asthma. If we look at occupational physicians who report a large number of cases, probably an estimate of about 10,000 cases of all work related disease per year, but then in them a much higher proportion of the respiratory cases would be asthma because that tends to temporally have quite a close relationship to work exposure. Whereas chest physicians tend to proportionally report a majority of cases of non-allergic diseases related to asbestos. That is the answer in a nutshell.

Q298 Lord May of Oxford: And the trend or the time? Professor Agius: As I mentioned earlier, trend is something which is difficult to establish because there is a number of artefacts which can explain apparent trend. We are doing our best to take account of those artefacts. By “the artefacts” I mean changing denominators of the number of doctors who report, who leave the schemes, and who join them and phenomena like fatigue which doctors tend to experience when they are expected to fill in lots of forms and paperwork. Having taken account of those, we do get a linear trend assumption of a reduction of about seven per cent per annum in incidence, but that is subject to lots of caveats and we are investigating that further. Once we have data in due course from the GPs, then we might be able to be a little bit more certain, or perhaps uncertain, as to how accurate that estimate of trend is.

Q299 Lord May of Oxford: Among those caveats, as I understand it, first of all, some of the less severe cases do not present themselves through diagnosis. The scheme of reporting is voluntary and so there have been suggestions that maybe there is under-reporting, or perhaps, alternatively, biased reporting. I wonder, beyond what you have said, whether you think there is validity in those criticisms and, if so, what you are doing to try to address them?

Professor Agius: There is validity in some of those criticisms, my Lord Chairman, indeed I have conceded some of them. Having said that, the schemes are one or two orders of magnitude better than the statutory mechanism. The statutory mechanism, namely RIDDOR, the Reporting of Injuries, Diseases and Dangerous Occurrence Regulations, is, by the HSE’s own concession, at least by personal communication, “positively misleading”—I call it negatively misleading—in as much as they now no longer publish the results from that. On questioning, they say they have through RIDDOR about 40 cases of asthma per annum and 120 cases of dermatitis per annum on average over the last few years. That in itself is one-tenth, or less than one-tenth, of the specialist cases that we get, and that is in itself per annum probably one-tenth of the
Professor Agius: on that? among very young children. Do you have a comment with the need for really good data on the incidence sensibleness of the conjunction of that constraint not very prevalent. I did really wonder a bit about the I understand it, for collecting data on things that are the Paediatric Surveillance Unit has the responsibility, as Thomas’, are among younger people. The British allergy, and particularly in our visit to St V

Q300 Lord May of Oxford: I had occasion recently in a different context to meet with the British Paediatric Surveillance Unit and, first of all, many of the cases of allergy, and particularly in our visit to St Thomas’, are among younger people. The British Paediatric Surveillance Unit has the responsibility, as I understand it, for collecting data on things that are not very prevalent. I did really wonder a bit about the sensibleness of the conjunction of that constraint with the need for really good data on the incidence among very young children. Do you have a comment on that?

Professor Agius: My Lord Chairman, our remit extends to people in employment who either present themselves to their GPs, specialists or occupational physicians.

Q301 Lord May of Oxford: Yes, but setting that aside, do you feel that the question of getting good statistics on really young people is handled well, because after all you are one of the experts on these databases?

Professor Agius: We have put forward proposals for research that would involve studying cohorts of young people and some work has been done on that but perhaps not enough. There are, for example, asthma cohorts already in existence, some of which my colleague, Professor Newman Taylor, is involved with. If there were to be funding to permit those to be followed up prospectively they might give us some answer to your question. As to rare conditions, specifically we encourage our doctors to report things which are rare even if they come outside the sampling frame. If I may explain, my Lord Chairman, so as not to tire our doctors out too much we sometimes target them at specific times of the year at which at random we ask them to report and we encourage them to report rare things at other times as well. In conjunction with the research which I have already described, we also have got research trying to relate rare causes of asthma, and indeed of dermatitis, to chemical structures and so on to try and develop a strategy to be able to identify early novel causes of occupational asthma and occupational dermatitis.

Q302 Lord May of Oxford: Finally, here is a chance for you to lay down a marker, but I am curious how long the project you have in hand is going to continue, where the future funding is going to come from and, more generally, how you feel about the funding for this kind of vital factual underpinning of what we are talking about?

Professor Agius: The HSE funding for data collection from the specialist schemes ended when data collection finished at the end of last month, we are now carrying the schemes partly through reserves of funds and partly through charitable support. The HSE provided us with a commitment in principle 10 months ago to fund specialist schemes for a further five years, but they tell us that they are under severe financial constraints and so far that commitment has not been made good into a contract, which we seriously need because we have good staff leaving. In so far as the GP schemes, these are funded for data collection into November of next year. Funding in occupational allergic disease, as in all occupational disease, I think is very much a Cinderella issue. It does not engage the same sort of high profile as funding for other causes of ill-health. A lot of the funding, these days, what little there is, comes from charities like the Colt Foundation and so on. Funding from government is tiny and we are told by the HSE that it is now severely constrained compared with what it was before.

Q303 Earl of Selborne: I will follow up that point because it is clear that RIDDOR was never providing the information which was accurate it was under-reporting of ill-health, according to what Professor Agius has told us, and Health and Safety required RIDDOR, to provide itself with the information on ill-health caused through allergic diseases, yet you have not apparently expected the Health and Safety Executive to replace RIDDOR by funding the Manchester University schemes. Would you like to comment on that?

Professor Agius: We are hopeful and optimistic that we will be able to persuade the HSE to make tangible its in-principle commitment to extend the funding of these schemes for a further five years. So far that has not happened but we are hopeful that it will.

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Professor Anthony Newman Taylor, Mr Rob Miguel, Professor Raymond Agius and Dr David Orton
appreciate that they are under severe financial constraints. Having said that, we do feel that, as an area which contributes a great deal to the health burden of the nation, not just occupational allergic disease but occupational diseases in general, it is grossly underfunded and tends to fall between various stools.

Q304 Lord Soulsby of Swaffham Prior: The written evidence that we received from the Government is that there is no simple test for objectively confirming cases of work-related allergic disease. Do you think that the introduction of standard criteria for diagnosis for accepting an occupational origin would be useful in measuring the incidence of these diseases and what should be the criteria?  
Professor Newman Taylor: I will restrict my comments to asthma. In fact, there are methods which are available which can be applied that provide confidence in the diagnosis of occupational asthma. One can ask those in whom it is suspected to make regular measurements of their peak flow, which is the maximum flow of air which can be achieved at the mouth, at regular intervals over several days when they are at work and away from work and compare the two. In many of the cases you can see a real difference between the two as the asthma occurs, becomes increasingly severe at work and improves away from work. It can be that you need a period of more than a two-day weekend to see sufficient improvement, but it is certainly a useful diagnostic tool. In those cases where there is evidence for an immunological response, then one can identify that in terms of skin tests or specific Ig antibody in the blood. In the final analysis, if it is really important to know what is the cause of asthma in an individual case, it is possible to do inhalation tests, but inhalation tests are potentially hazardous and, therefore, need to be undertaken in careful conditions in specialist centres, which is the situation now. The answer is that while there is no single simple test which says yes or no, there is a number of investigations which can lead one to being confident as to whether it is present or not. I think that if one were to introduce standardised criteria in relation to each of those, that could only be helpful. With comparable diagnostic criteria it allows comparisons of disease rates at different times and different places. Whether that will enable one to better know what the incidence of the disease is I think is a different question, because that is a matter of recognition and attribution of the asthma to a specific agent and then of reporting that, which is something we have been discussing. I can see potential benefits; I would question whether it will improve knowledge of the incidence of the disease though.

Dr Orton: From the dermatitis perspective, I would have concerns and difficulties in making these criteria because the assessment of dermatitis, as I have alluded to before, is extremely complex with constitutional genetic factors, irritancy as well as allergy. Although we have a standardised test to identify if somebody is allergic to a chemical substance, those substances are not only found at work, but they are also found in people’s domestic environments and it is a very confused area and needs teasing out. Often, certainly in medico-legal cases, it is down to a degree of subjective interpretation and one’s own experience.

Q305 Lord Soulsby of Swaffham Prior: Basically you are both saying that we are not at the present stage of utilising the standard tests for evaluation.  
Professor Newman Taylor: I think there is a number of tests which are utilised in the diagnosis of asthma and that one can use standardised criteria for deciding whether or not they are likely to be positive or negative, but there is clearly an important element of individual judgment in relation to the results of those investigations which leads you to determining whether or not it is likely to be due to the particular occupational agent.  
Dr Orton: For skin, I would say that those tests are less conclusive.  
Mr Miguel: All the tests are non-conclusive and I think it is very important to remember that any poorly-validated criteria should not exclude anyone from employment and a past history of occupational asthma, asthma or dermatitis should not exclude people. I think it is a question of running an array of tests. The immunological tests are 50-50, as I understand. This has to be backed up probably by a questionnaire which is a good way of finding out and health practitioners need to ask the right questions. When they see these people, they need to be aware of sensitisers in the workplace, the type of work that person is doing and what materials they are using. The list of sensitisers used by the DSS is very limited and there is a further extensive list of sensitisers and health practitioners need to be aware of those.

Q306 Baroness Platt of Writtle: Is the prevalence of latex allergy now under control or are there any other outstanding issues in this field that need to be addressed? Is there a danger for people who work in supermarkets and shops that latex-containing packaging may produce or exacerbate contact dermatitis?  
Dr Orton: In my own experience and from looking at the evidence, certainly amongst healthcare workers you can see that the level of problems related to immediate allergic responses to latex have now plateaued out. My other colleagues might be in a
better position with regard to the reporting mechanisms to confirm that. With regard to whether there are any outstanding issues, I would like to bring something to the fore. Often either for healthcare workers or patients who are sensitised to latex, hospitals and dental practices constitute very important sources of exposure and a danger for those individuals. Currently the procurement of latex-free equipment for hospitals and dental practices is undertaken on an individual basis amongst individual trusts and this is both time-consuming and a difficult process to obtain the necessary information from manufacturers. I think it would be extremely helpful to have some form of centralisation for this so that individual trusts are not duplicating the work involved and that it becomes an overall easier process. With regard to the question of supermarkets, the wearing of latex gloves and dangers to the public, I think certainly people are trying to move away from wearing latex gloves altogether in supermarkets and the healthcare setting to try and prevent problems. In terms of the dangers for consumers from shop workers wearing latex gloves, there is very little danger of people developing sensitisation to the rubber chemicals that are added to the gloves, which are often responsible for the delayed allergic response producing dermatitis. There have been case reports of residual proteins within gloves that are thought to have become transferred onto foods causing the immediate type of allergic response in consumers and even from seals around foods. However, I think that those are a minority of cases and it would involve individuals who are extremely sensitive to the latex proteins.

**Q307 Baroness Platt of Writtle:** What about packaging?

*Dr Orton:* These recent case reports in the literature. Well, I think that one has to be aware of it and always think about that in one’s assessment of a patient, but I am not aware that it is a major problem and it probably would affect a minority of individuals.

**Q308 Lord Colwyn:** I wonder if I can make an observation on that. Having worked as a dentist for about 40 years, I suppose I wore gloves for the last 10 or 15 years of my practising life and had terrible problems when I first had to wear these gloves. I thought I had latex allergy, but in fact it turned out to be the fact that I was wearing rubber on my hands for eight or nine hours a day and the hands sweat. I think it was something to do with that rather than dermatitis, and I do not know how you tell the difference.

*Dr Orton:* Glove reactions are extremely common and just the occlusive effects of wearing the gloves, whatever the material, are probably the commonest cause of a reaction to a glove. Also one has to identify if there is an allergic component, if it is the immediate allergic response, for example to the latex proteins, or a delayed allergic response to the rubber chemicals that they add to the latex, which are usually the ones that give rise to the dermatitis developing, or a combination of both. That involves investigating people further.

**Q309 Lord Taverne:** You have told us something about the funding, or the lack of funding, for the collection of data. What about the funding for research in general? Who currently funds the majority of research into occupational allergic diseases in the United Kingdom and—I am sure the answer will be “There is not enough of it”—is there any particular section which is particularly under-funded?

*Professor Agius:* My Lord Chairman, within occupational disease I would not say there is a section which is particularly under-funded because there is serious under-funding across the board. At the moment, the situation is worse than it has been for some time because at least in the past there was a mechanism whereby one could apply for money from the Health and Safety Executive whereas now that does not exist at all. There are some charities, like the Colt Foundation and the British Occupational Health Research Foundation, which will support research in this area, but otherwise if one has a project which is of some interest perhaps to the Medical Research Council or to the Department of Health specifically we try and approach them, but by and large that is not seen as their remit, so the situation is dire across the board. I wonder whether, my Lord Chairman, my colleague, Professor Newman Taylor, might add to that.

*Professor Newman Taylor:* I think the situation is as has been described. The majority of the funding that goes into research on occupational allergic respiratory disease now comes from charitable sources, of which the Colt Foundation is a major provider of funds for research into occupational ill-health, but also specialist charities, such as the British Lung Foundation and Asthma UK, when there are areas within their interest, will also support it. I think the issue in relation to the Health and Safety Executive is a particular concern because for several years now the Health and Safety Executive has predominantly funded contract research for external individuals to apply for. What we now understand is that the Health and Safety Executive, because of the concerns which have been previously shared, is only able to fund research within occupational disease within the Health and Safety Executive and Health and Safety Laboratory. That is a situation which may change, but it is a situation which appears to be the
case at the present time. This has a number of problems: not only is it difficult to undertake research within the field, but it also provides problems in terms of retaining people in the field and attracting people to come into the field, because if there is not research funding for it then this is not an area of growth, and therefore of interest, for people who would follow in the future. Unless something is done to change the situation we risk finding ourselves in a few years without experts in this field because experts need to be doing research and research needs to be funded.

Q310 Lord Taverne: Are we in a much worse position in this country than, say, developed countries in the rest of Europe or North America? Professor Newman Taylor: I think we are in a worse position than Scandinavia, particularly, where they have invested quite heavily in occupational disease and have institutes. We are probably in a worse position than is the situation in Canada. The United States is more difficult to say, but probably there is still a higher proportion of funding that is going to this area in the United States than here, but in relation to Scandinavia and Canada we are certainly worse.

Dr Orton: Within skin, I would reiterate the same, that certainly in other parts of Europe, particularly in Scandinavia and even in Australia they have specific institutions looking into occupational skin disease. We are very much behind.

Q311 Baroness Perry of Southwark: I am disturbed by your answer to the previous question and I wonder what research is currently going on to identify those people who are at risk of developing occupational asthma? Professor Newman Taylor: There has been quite a lot of work which has been done on that over the last 20 years and there has been work which has looked at the risk to people who are several atopic, that is to say they have skin reactions to pollen, mites and moults and things, and also looking at some genetic markers, such as HLA, to see whether or not these people are at greater risk of developing occupational asthma. We have some evidence that is the case, that atotics working with laboratory animals, in bakeries or with enzymes are at greater risk. Similarly with HLA, in relation to some low molecular weight chemicals, platinum salts anhydrides as well as with laboratory animals, there is evidence that there is also an increased risk. The problem is that these factors only contribute a minority to the risk of the disease and the concern that has been expressed already, which I share, is that we are not in a position where those markers can be used to identify those people who will develop a disease and, therefore, prevent them from being exposed. The really important determinant of illness with occupational asthma is the level of exposure, and the focus needs to be really on the environment to reduce the level of exposure in order to reduce the number of those who become sensitised. We looked at some data which we had some years ago in terms of laboratory animal allergy, and asthma caused by laboratory animals occurs about five times more frequently in atopics than in non-atopics, but it will occur in only a minority of atopics and so if you are atopic the chances of you getting asthma are much less than of not getting asthma. What it meant in terms of a pre-employment screen, if one was going to use it for that purpose, was that you would need to exclude seven people to prevent one case and that, clearly, is not sufficiently discriminating to be used for that purpose. Much more important really, it seems to me, is that the focus needs to be on improving the environment in which the individual is working in order to prevent the case developing in the first place.

Q312 Baroness Perry of Southwark: Do you think there is a long-term hope of eliminating it entirely? Professor Newman Taylor: I think that it will be difficult in some circumstances. Laboratory animals is quite a good example, people have to handle animals, you pick an animal up, it is likely to urinate on you, if it urinates it will scratch you, all of these things could happen, the dust gets into the air. You could do a lot to reduce the level of exposure and, therefore, reduce the incidence. To eliminate it I think would be very difficult.

Mr Miguel: My Lord Chairman, that is interesting what my colleague is saying especially about HLA. I think it is quite worrying if we are going to go down the lines of genetic testing in terms of excluding people from employment and, as was rightly said, it is not conclusive. For example HLA B27, there is a predominance of HLA B27 in people with back problems, but only two per cent of that group has been identified as having back problems, so it is not conclusive and it is possible to screen out 98 per cent. What we are worried about, as a trade union movement, is that we are going to go down the lines of genetic testing and atopy which precludes people from employment when it should not. The facts that Professor Newman Taylor is talking about are very worrying if we are going to use that information for pre-employment screening, which I think there is a danger that could happen.

Professor Newman Taylor: To reassure Mr Miguel, that was happening 20 years ago and the research which we have undertaken demonstrating the importance of exposure has led most employers to abandon that as a means of pre-employment testing.
Professor Anthony Newman Taylor, Mr Rob Miguel,  
Professor Raymond Agius and Dr David Orton

Q313 Chairman: I suppose the other side is that you could be looking at people whose career advice at school level might be better targeted in the random or absent career advice that some youngsters get where they tend to fall into certain patterns of occupation, so there may be some benefit in the longer term of being able to steer youngsters to develop in different pathways.

Professor Newman Taylor: I think, as yet, we still probably do not have sufficient information to be able to give good advice on that basis. I agree with you, maybe someone who has asthma who is going to work in an environment where they are coming into contact with isocyanates, but on the basis of atopy, HLA testing or whatever, it is very important not to discriminate.

Mr Miguel: To make a point on the issue just raised, due to the small genetic pool that we have, you will find if you started carrying out that testing on children no-one would be in employment anywhere.

Q314 Chairman: You have painted a gloomy picture of the future really because we are not having the next generation of researchers coming up through the ranks and emerging, but if one tries to take a more optimistic view I wonder what you feel the most promising areas of research into industrial allergic skin disorders are in particular and who is co-ordinating and leading on this research?

Dr Orton: There are two areas there that need mention here. The first is work into persistent post-occupational dermatitis, which seems to affect maybe 10 per cent of the workforce, and that is being co-ordinated at the Institute of Occupational Dermatology Research and Education in Melbourne, Australia by Dr Rosemary Nixon and closer to us, in Germany, there is Professor Thomas Diepgen in Hamburg who is looking at the effect of intervention in patients with hand eczema, because primarily occupational skin disease does involve the hands. There has been some evidence produced to date about these targeted education programmes, getting individuals who are in wet work occupations to understand the function of the skin, what signs they should look out for if the skin is being damaged by exposure to irritants, or indeed allergens, and what measures they need to take to treat it. It is changing the individual’s behaviour with regard to treating the skin at an early stage which is having beneficial effects. Certainly, in hairdressers and healthcare workers there is published data which supports this. Obviously more work is being done in this field, but going back to Professor Newman Taylor’s point—reducing exposure is the key aim here.

Q315 Chairman: It is the key aim. Do members of the Committee have other questions that they wish to ask or other points that you wanted to make?

Mr Miguel: My Lord Chairman, this is not my field so I do not know much about it. I was reading some articles about desensitisation techniques. One of them—and I am sure my colleagues will put me right—was to inject people suffering from hay fever and asthma with bacteria which used to be found in kitchen sinks which no longer exists, to desensitise them for about a year. I do not know if any work is being done on that, but that sounds promising and if we are able to get a technique where we could desensitise people then that would be relevant research.

Professor Newman Taylor: The situation at the present time is that if we were looking at desensitisation with occupational allergens, potentially the most promising might be the laboratory animal urine proteins. Professor Kay and his colleagues have done a great deal of work to make this safe because in the past it was not done sufficiently safely. If I was going to promote a single area where one is looking at that as a means of switching off the disease, so to speak, it would be laboratory animal allergy where we know enough about the proteins that cause it to be able to make some progress. I wonder if I could make one other point and that is that you talked about research. It seems to me that what has been achieved in the last decade or so is that we have learned what the major causes of occupational allergic disease and occupational asthma in our community are. We have come to understand that it is more the level of exposure than personal susceptibility and where there needs to be a focus for research it is translating that knowledge of exposure response relationships into effective means of preventing the disease or reducing the incidence of the disease. As I have said, with latex and enzymes that has been achieved. We need to be looking at the means to be able to reduce disease incidence in other situations like with bakery workers and flour, supermarkets and isocyanate workers in garages, if we are going to make a further impact on this disease.

Lord May of Oxford: It is a good question and it may reassure you that the Committee has been excellently organised. We had a visit to St Thomas’ where some of this research is going on, and my personal impression, for what it is worth, is that there are still more questions than answers. There is a lot of progress occurring but we are a very long way from having a silver bullet that is universal. There is progress more on some kinds of things than others.

Q316 Chairman: Professor Agius, did you have another point?
Professor Agius: My Lord Chairman, I would have thought that the role of de-sensitisation would be exceedingly limited to some exceptional areas, although I defer to Professor Kay and Professor Newman Taylor in this respect. I think the emphasis, as Professor Newman Taylor has said, has to be in most respects to apply what is already known and to undertake the lines of research that determine the incidence of occupational asthma, occupational rhinitis and occupational dermatitis and to relate that to exposure. Historically, this country has made significant strides in those areas in the past and has led. At the moment things are slipping away through our fingers.

Q317 Chairman: Dr Orton, do you have any additional points you wish to make?
Dr Orton: I think they have really been made.
Chairman: Then could I thank you all for coming and the work that you put into giving us evidence today.

Supplementary memorandum by Professor Raymond Agius—in response to supplementary memorandum by Mr Ivan Lewis MP, Parliamentary Under Secretary of State for Care Services, Department of Health (p 320)

Yes indeed we did meet the HSE on 4 April and earlier today I e-mailed the University’s response to the HSE. Since the unresolved funding situation is such that we are having to consider seeking “commercial sponsorship” we have had to consult our stakeholders and the last meeting we had with them was on Thursday 17 May. In essence our stakeholders would rather we did not seek commercial sponsorship since we might lose some participation and perhaps even some standing, but on the other hand commercially sponsored schemes are better than no schemes at all.

The University has bent over backwards and has agreed to forego the “full Economic Costing” (fEC) basis of charging the HSE. Effectively through our own resources and some charitable support we were able to offer to do the work to the HSE at around half the true “fEC” cost.

However on 4 April HSE could only offer us about one half of this already grossly reduced latter amount (ie just over one quarter of the fEC cost). In today’s response to the HSE we suggested another means whereby, with their agreement, we could save money on extant work that we are doing for them and thus reduce our costs for the extension of the THOR schemes even further. Yet there is still a substantial gap, and we await the HSE’s further response.

Actually in relative terms these sums aren’t vast—they represent about 1–2 per cent of the money that we understand that the HSE pays every year to the Health and Safety Laboratory (which had unsuccessfully tendered competitively against us for the work in the first place).

Yes indeed we have, together with other European partners, bid for EU FP7 money. However the outcome of this bid would not be known until around the end of the year. If successful it would provide considerable added value to what we do now, such that we would have data across the EU that is comparable in its quality—and compared in terms of outcome. However EU funding would not significantly reduce the “core” UK costs for the collection of the fundamental data on occupational illness and its trends that are so important for determining and monitoring UK national policy to prevent this ill health.

In short: EU funding would amplify the basic work we do now but would not significantly “subsidise it”.
WEDNESDAY 17 JANUARY 2007

Present  Broers, L  Rea, L
Colwyn, L  Selborne, E
Finlay of Llandaff, B  Simon, V
(Chairman)  Soulsby of Swaffham Prior, L
May of Oxford, L  Taverne, L
Perry of Southwark, B

Memorandum by the Royal College of General Practitioners

1. The College welcomes the opportunity to make submissions to the House of Lords Science and Technology Select Committee’s Call for Evidence on Allergy.

2. The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. It aims to encourage and maintain the highest standards of general medical practice and to act as the “voice” of GPs on issues concerned with education, training, research, and clinical standards. Founded in 1952, the RCGP has over 24,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline.

Please find below a submission to the Committee’s Call for Evidence questions as outlined below the four topic headings:

DEFINING THE PROBLEM

What is allergy? What is the difference between allergy and intolerance?

3. The term allergy has evolved in medical usage over the last century so whereas once it referred to any type of immunological response, it typically now has a much more specific meaning referring to an immunological response to an antigen mediated by specific IgE. These reactions are also sometimes known as Type 1 or immediate hypersensitivity reactions.

4. At the same time as its meaning becoming more restrictive in medical usage, the word allergy has also penetrated lay social discourse, where it is also rapidly evolving, but in a way that sees it being used in an ever more broad sense.

5. Intolerance reactions are common and can result in significant morbidity. Although the underlying pathophysiological mechanisms are often not clearly understood, it is clear that these reactions are not specific IgE mediated. Clinically, these are far more variable in onset, less predictable and typically more transitory than allergic reactions; they are not life-threatening.

What is and what is not known about the origins and progression of allergic disease?

6. Allergic disorders can affect people of any age, both genders and all ethnic groups. There are however considerable variations in prevalence of these disorders internationally. Allergic conditions often manifest first very early on in life, often beginning with eczema/dermatitis and food allergy in the first year of life, progressing onto the development of allergic rhinitis and asthma in early childhood, and other more systemic allergic disorders such as urticaria and angioedema typically manifesting more commonly in middle-age. Anaphylaxis is the most serious manifestation of allergy and occurs in children and adults.

Why is the incidence of allergy and allergic diseases rising? Why does the UK in particular have such high prevalence of allergy?

7. The reasons underpinning these dramatic recent increases are complex and as yet poorly understood. Whilst some of the observed increases are likely to be due to a combination of better recognition, changes in disease labelling patterns and a lowering in the threshold for diagnosis, there has almost certainly also been a genuine increase in the incidence and prevalence of allergic conditions over the latter half of the last century.
in the UK and elsewhere. The UK ranks highest in the world for asthma symptoms, with a prevalence 20-fold higher than that in Indonesia, it is also near the top of the world ranking for rhinitis and eczema.\textsuperscript{4,5}

8. The narrow time window in which these increases have occurred makes it implausible that these changes are due to genetic factors—rather, they are due to environmental and gene-environmental interaction factors, which are affecting large sections of the population, particularly in very early life (foetal development and/or infancy). Numerous risk factors have been suggested as being responsible for these increases, but as yet the reason(s) underpinning these increases remain elusive. Given the number of identified risk factors, it is likely that these increases represent complex interactions between a variety of environmental factors and genetic predisposition.

9. The epidemiological picture has become even more complex in recent years with indications that there may be diverging trends in the local and systemic allergic disease trends: the prevalence of the more local allergic disorders such as eczema, hay fever and asthma appears to have stabilised in the UK and may even be declining, although there are no signs of similar declines in relation to the more systemic allergic conditions such as food allergy, urticaria, angioedema and anaphylaxis.

What gaps exist in establishing the overall disease burden for all types of allergy and what are the barriers to filling these gaps?

10. We currently have no data on Accident & Emergency consultation rates, hospital out-patient consultation rates and hospital in-patient prescribing, which makes it difficult to assess overall disease burden from the point of view of the NHS. We also have no real idea of loss of time from work or school or understanding of the impact on day-to-day life, educational impact, career prospects and social activities of those suffering from most allergic disorders which renders it difficult to assess the disease burden posed to individuals who suffer from many of these allergic problems.

Strategies to filling these gaps include:

— A more comprehensive range of disease codes and aetiological trigger factors for use in primary and secondary care (for example, there is currently no codes for peanut or kiwi allergy in ICD-10).
— Central database of out of hours contacts (NHS Direct).
— Central database of A&E consultations.
— Central database of out-patient consultations.
— Data linkage potential between different healthcare datasets to allow more meaningful analysis of overall disease burden to individuals and populations and also to allow the study of risk factors associated with disease development and exacerbations.
— In the light of such large variations, there is a need for on-going data surveillance, particularly for food allergy and anaphylaxis.
— Quality of life measures being developed for the full spectrum of allergic conditions.

In addition to the impact on the health service, what is the overall socio-economic impact of allergic diseases (for example, absence from work and schools)?

11. This is likely to be large, but cannot reliably be measured at present because of the absence of relevant data collection (see above).

TREATMENT AND MANAGEMENT

What is the effect of current treatments on the natural history of allergic disease?

12. There are currently no cures for allergic problems—rather, what we have is an array of non-pharmacological and pharmacological approaches which can, in most patients, help achieve symptom control and possibly result in some modification of the underlying disease course.

\textsuperscript{4} The International Study of Asthma and Allergies in Childhood (ISAAC) Steering Committee. Worldwide variation in prevalence of symptoms of asthma, allergic rhinoconjunctivitis and atopic eczema: ISAAC.

What is the evidence-base for pharmacological and non-pharmacological management strategies?

13. Whilst the evidence-base for pharmacological treatment approaches is on the whole good for most commonly used preparations, there is less secure evidence for allergen avoidance approaches that are commonly recommended. There is also very little evidence in relation to important health services research questions about how best to structure care.

14. The shortage of capacity in allergy treatment capacity has led the public to look outside the NHS. This has resulted in the proliferation of questionable allergy practice in the field of alternative and complementary medicine, where unproven techniques for diagnosis and treatment are used.6

Is the level of UK research into allergy and allergic disease adequate?

15. There are currently no dedicated funding streams for allergies in the UK and there are also no charitable funding streams for researchers to draw on. Much of the existing generic funding available from the Medical Research Council and the Wellcome Trust has, for example, been directed towards basic sciences and translational research and there has as a consequence been very little dedicated health services research into allergy. This problem was highlighted in the recent Department of Health and Scottish Executive reviews into allergy services and the relative lack of evidence uncovered in relation to how best to provide care. In view of the scale of the problem, what is needed is provision of programme research grants to allow meaningful progress to be made.

What are the most promising areas of research into preventing or treating allergy?

16. There is a need for a dedicated Cochrane review group for allergy to allow relevant high quality evidence in relation to disease prevention, treatment and organisation of care to be systematically collated and periodically updated. Areas of research that need investing in include studying the role of dietary exposure in pregnancy and infancy, evaluating the role of prebiotics, probiotics, anti-oxidants, pasteurised milk and vaccination based strategies, amongst others, and various combinations of these, for preventing disease onset and progression. Research is also needed into educational initiatives aimed at primary care staff and also new models of delivering care such as General Practitioners with Specialist Interests in allergy.

Government Policies

How effective have existing Government policy and advice been in addressing the rise in allergies?

17. The number of allergy specialists is totally insufficient to meet the need. Improved links are required between primary and secondary care. Increasing specialist capacity in allergy practice would improve diagnostic and treatment advice and would allow primary care teams to draw on an existing specialist knowledge base.

18. The only specific government advice that we are aware of relates to high risk mothers modifying their diets and those of their infants, but there was no proactive attempt to assess compliance with this and evaluate its effectiveness.

How is current knowledge about the causes and management of allergic disease shared within Government?

For example,

— Do housing policy and regulations governing the indoor environment pay enough attention to allergy?
— How effectively are food policy and food labelling regulations responding to the rise in food allergies?

19. Current housing policy has not really considered the issue of allergy in any serious detail. The recent EU directive about food labelling appears to have been helpful in allowing food allergy sufferers to better determine the contents of pre-packaged foods, but there has been no attempt empirically to evaluate whether food allergy sufferers have found this advice helpful or satisfactory. Furthermore, issues remain about the adequacy of current labelling approaches.

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Patient and Consumer Issues

What impact do allergies have on the quality of life of those experiencing allergic disease and their families?

20. In some patients, allergic disorders are relatively short-lived and exert only a relatively minor impact on day-to-day life. There is however ample evidence that they can also be life-threatening, and in those with particularly severe allergy or substantial co-morbidity the concern is that they can impact on all aspects of day-to-day life. For those with food allergy, the whole household can be affected and impairment in quality of life for young people can be comparable or even greater than those with diabetes. Living with the threat of possibly life-threatening reactions can be very worrying for all concerned.

What can be done to better educate the public and to improve the quality of information that is available to patients and undiagnosed sufferers?

21. A number of measures need to be taken, including:
   - Better undergraduate training for healthcare professionals which is based on an understanding of the needs of sufferers.
   - Similarly, better postgraduate training opportunities, particularly for GPs and their teams.
   - A national NHS e-library for allergy with a section also available to the public.
   - Map of Medicine for allergies which patients also have access to.
   - A dedicated patient helpline/website, linked to NHS Direct, for authoritative information being made available in a range of languages.

Are current regulatory arrangements, for example, those governing private clinics offering diagnostic and therapeutic services and the sale of over the counter allergy tests, satisfactory?

22. No, as there are a number of diagnostic tests available which do not have any sound scientific basis—these are therefore unhelpful, and potentially harmful, as they can result in considerable unnecessary restriction of diet etc. Better regulation would certainly be helpful, accompanied with far better access to scientifically sound tests in primary care.

23. I acknowledge the contribution of Professor Aziz Sheikh (Allergy & Respiratory Research Group, Chair; Professor of Primary Care Research & development, University of Edinburgh) towards the above comments; additional contributions were made by Dr Mark Levy (Clinical Research Fellow, General Practice Section, University of Edinburgh; Editor-in-Chief, Primary Care Respiratory Journal), Professor David Price (GPIAG, Professor Primary Care Respiratory Medicine, University of Aberdeen) and Dr Dermot Ryan (GPIAG, Allergy Lead; Rhinitis Guidelines Working Party; Rhinitis Guidelines Committee; Royal College of Physicians, Allergy Working Party). While contributing to this response, it cannot be assumed that all of those named necessarily agree with all of the above comments.

Memorandum by the Royal College of Paediatrics and Child Health (RCPCH)

1. Defining the Problem

1.1 Allergy and Intolerance

Hypersensitivity or intolerance is an umbrella term that refers to reproducible symptoms or signs to a defined stimulus at a dose tolerated by normal subjects. It includes non-allergic hypersensitivity, such as lactose intolerance and reactions to caffeine, and allergic diseases such as eczema, asthma, food allergies, rhinitis, drug allergy, venom and latex allergy. In addition many people have a misconceived belief their child is allergic. Such individuals also required accurate assessment in an allergy clinic.

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1 GPIAG: General Practice Airways Group.
1.2 Origins of allergic disease

A good deal is known about the immunological basis of allergy, but underlying causes of allergic conditions are more difficult to understand. Changes in prevalence over the last four to five decades cannot be readily explained, although a number of theories have been proposed and most have focussed on early-life interactions between genes and environment such as allergen exposure in pregnancy and infancy, maternal and infant feeding practices, viral and bacterial infections in infancy, environmental tobacco smoke, pollutants, pet contact, family size and rural living. Family history is clearly an important risk factor for allergy. Twin studies have suggested that as much as 75 per cent of the risk of developing allergic rhinitis may be genetic. Family studies have identified a number of genes that predispose to developing both asthma and atopy. As in other complex conditions, genes interact significantly with each other and with environmental factors to affect the risk of developing disease. Exposure to infections or allergens before and immediately after birth may be significant. Allergy is also less likely to develop in children with older siblings and in children brought up on farms or in close contact with animals. Breast feeding reduces the risk of infant wheezing and food allergy in infancy but may not reduce the chance of developing asthma or other significant allergies in later life. Maternal smoking during pregnancy and in the first few years of life increases the risk of asthma. Obesity also makes asthma more likely. The relative roles of allergen exposure and avoidance in the development of allergy are unclear and conflicting. For example, exposure to cats in infancy may induce tolerance and prevent the development of asthma and wheeze. Conversely, exposure to animals in a sensitised child may exacerbate wheezing symptoms. Similarly, prolonged breastfeeding and the use of hypoallergenic milk formulas has a transient impact on preventing the development of eczema and food allergy in infancy. It is currently unclear as to whether avoiding allergens or early exposure is the best recommendation for preventing the development of allergy.

1.3 The progression of allergic disease

The progression of allergic disease is well documented. Indeed the progression from food allergy and eczema in infancy to rhinitis and asthma in mid-childhood is often described as the allergic march. Most food-induced symptoms presenting in infancy have resolved by three years of age. Cows milk allergy affects about 5 per cent of children with a remission rate of 50 per cent per year for the first three years of life. Egg allergy affects 2.6 per cent of children with 50 per cent remission at four to five years of age. Peanut allergy affects 1 per cent of children, preschool children have an 18 per cent chance of resolution. Seafood allergy affects 0.6 per cent of children with about 4 per cent giving a history of having outgrown their allergy. 50 per cent of children with eczema will have outgrown it by six years of age and two to three will have outgrown it by 14 years of age. Most asthma has its origins in childhood. More asthma persists through adolescence than is generally believed and even in those cases that remit many recur in adulthood. The prevalence of asthma in children aged 9–11 years is double that in adults from the same country and region, as is the prevalence of bronchial hyperresponsiveness. Wheezing illness is at its most frequent in the pre-school period with 50 per cent of children experiencing wheezing before the age of six years. The prevalence of wheezing illness drops from 50 per cent at age 7 to 18 per cent at age 11 and to 10 per cent at age 16. Clinical studies report up to 80 per cent of asthmatics lose their symptoms during puberty. After puberty asthma prevalence rises again—to 27 per cent by age 33. The pattern of disease in early life dictates the way in which it evolves through childhood. Thus paediatricians are in the ideal position to modify outcomes.

1.4 The rising incidence of allergy and high UK prevalence

The reasons for the rising incidence of allergy and allergic disease are unclear, but have been associated with increasing affluence. Worldwide variation in rates of atopic disease suggest that environmental factors are critical to the development of these disorders in childhood. Within the United Kingdom, atopic disease is significantly higher in Scotland and Northern England.

1.5 Gaps in establishing the overall disease burden

In Britain, there is little reliable information at the national level about the nature and magnitude of the burden posed by allergic conditions and the costs that these incur. The ISAAC study estimated the prevalence of asthma, hayfever and atopic dermatitis in six to seven year olds and 13 to 14 year olds as part of a worldwide study. These data are limited by the validity of patient recalls of an allergy diagnosis (less so in the ISAAC study). The UK prevalence of food allergy and other allergic diseases are less well documented with no good
population-based studies of prevalence. Research studies looking at prevalence are often small and localised, making it difficult to obtain an overall picture of the disease burden in the United Kingdom. A central funding body for allergy research would help to address this. Within medical practice, allergy as a disease entity is coded as one of 17 definitions on ICD 10. Allergic disease is also often coded under the organ specific manifestation such as eczema or asthma. These are complex conditions, where disease definitions are unclear or ambiguous and there is a lack of uniform methods of data collection. Allergic conditions often occur together. Co-morbidity has been studied in a number of settings. Figures for prevalence vary, partly because problems of diagnostic variability and ascertainment are multiplied when more than one case definition is applied. At the same time the severity of the combined problems are underestimated. Allergic rhinitis is present in at least 75 per cent of people with asthma and increases the cost of their care and the burden of disease impacts exponentially on the sufferers.

PREVALENCE (%) OF COMORBIDITY FOR ASTHMA, ECZEMA AND ALLERGIC RHINITIS

<table>
<thead>
<tr>
<th>Number of diagnosed atopic conditions</th>
<th>Age (years)</th>
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<tr>
<td></td>
<td>13–14</td>
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<tr>
<td>1</td>
<td>33</td>
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<tr>
<td>2</td>
<td>15</td>
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<tr>
<td>3</td>
<td>4</td>
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<tr>
<td>At least one</td>
<td>52</td>
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1.6 The socio-economic impact of allergic disease

An assessment of the burden of healthcare costs of respiratory allergic disease has been made at over one billion pounds per year. Asthma is a leading cause of hospital admission in children. Rhinitis significantly reduces quality of life, interferes with attendance and performance at school and results in substantial NHS costs. There are additional economic implications for parents also needing to take time off from work to look after their children. Results of examinations held during the summer are significantly lower in hayfever sufferers. Children with hayfever may drop a grade as a result of their symptoms. The relationship between reduced final school grade results and reduced income generated once these children reach employment has added economic implications. Shopping for a child with nut allergy takes 39 per cent longer and increases the cost of the weekly shopping basket by about 11 per cent.

2. Treatment and Management

2.1 Current treatments—effect on natural history

The majority of treatments currently employed in the UK centre on symptom control. Effective treatment of allergic rhinitis improves symptoms of asthma and reduces emergency treatment and hospitalisation for asthma. Allergen avoidance is also important in controlling symptoms once they have developed. Cochrane reviews have demonstrated the efficacy of immunotherapy for the treatment of asthma and rhinitis. Immunotherapy is the only treatment capable of modifying the natural history of the disease. For treatment of allergic rhinitis, it induces long term remission, prevents spread of sensitisation to other allergens and prevents the progression to asthma in children. Immunotherapy cures 95 per cent of patients with bee and wasp venom allergies. When a patient presents with allergic symptoms, accurate diagnosis and assessment of other allergic conditions reduces comorbidity. For example, detection of persistent sensitisation to egg and/or aeroallergens in infants with eczema highlights a group at risk of progression to asthma, who may benefit from early intervention.

2.2 Evidence base for pharmacological and non-pharmacological strategies

There is a good evidence base for pharmacological strategies, particularly for the management of asthma and rhinitis using inhaled and nasal steroids, antihistamines, bronchodilators and leukotriene receptor antagonists. The evidence base for non-pharmacological strategies, including allergen avoidance, is less clear. A Cochrane review of House dust mite reduction measures reported an improvement in rhinitis symptoms.
This effect is more pronounced in children than in adults. The relative lack of evidence for non-pharmacological strategies may be impacted by sources of funding for allergy research. Research into non-pharmacological strategies would be enhanced by a centralised source of allergy funding, independent of the pharmaceutical industry.

2.3 UK research into allergy and allergic disease

The United Kingdom has a paradox of having excellent allergy researchers in several centres. Translating their research into clinical practice is restricted by a lack of centres for the practice of clinical allergy. As previously stated, there is no central funding body for allergy research. Investment in allergy research is therefore less than in other high cost areas. Allergy centres are therefore compelled to compete with higher profile translational research areas such as neurosciences, cardiovascular disease, obesity and ageing.

2.4 Research into the prevention and treatment of allergy

Research into the prevention and treatment of allergy needs to focus on immune modulation and treatment in early life, to reduce the burden of disease and prevent the progression of the atopic march. Allergen avoidance as a principle of primary prevention has been shown to be ineffective and allergen exposure in infancy may be protective against the development of allergy. Further work needs to be done to establish this. Vaccines, prebiotics, probiotics and reduction of allergen exposure are all promising areas; as is the effect of nutrition and potential for disease modification. The demographics of obesity mimic that of allergy. There is potential for exploring the relationship of allergy with the increase in obesity; also obesity prevention and its effect on allergy.

3. Government Policies

3.1 Effect on addressing the rise in allergies

Government policy and advice has been ineffective in preventing the rise in allergies. In 1999, the DOH recommended that pregnant mothers should avoid eating peanuts to reduce the incidence of peanut allergy. The United Kingdom was the only European country to make this recommendation. Surveys have suggested that the advice was not heeded by the target population, which indicates that the strategies employed by DOH to promote health are defective. In the event subsequent research has demonstrated that avoidance diets do not prevent antenatal allergen exposure and may, paradoxically, lead to an increase in the development of food allergy. Other allergen avoidance strategies for the primary prevention of food allergy (prolonged breastfeeding, use of hydrolysed formulas and avoidance of allergenic food) are relatively ineffective. A more secure evidence base is therefore needed before recommendations are made to the general public. Future recommendations will need to be clear and widely available. They will need active reinforcement in order to be effective.

3.2 How current knowledge is shared with the Government

Within the allergy community, knowledge about causes and management of allergic disease are shared through the British Society for Allergy and Clinical Immunology. Knowledge about allergic disease affecting children is shared through the British Paediatric Allergy, immunology and infectious diseases subgroup of the Royal College of Paediatrics and Child Health. Allergic disease is complex and management initiatives need to be considered within the full context of allergic disease. Both of these organisations should have a wider role in informing government policy. Information appears to be fed through to the government on a piecemeal basis. There is a lack of representation of the needs of allergy patients and allergy services at a government and Department of Health level.

3.3 Housing policy

Housing policy currently focuses on energy saving. This conflicts with the needs of allergy patients because indoor allergen and pollutant levels increase as air exchanges decrease. Patients with allergies need improved ventilation systems in their houses. Indoor air humidity also needs to be taken into account. The United Kingdom has a very damp climate and high humidity levels inside houses, compounded by washing and
cooking in homes with reduced ventilation lead to high levels of humidity, pollutants such as nitrogen oxides, volatile organic compounds etc, moulds and house dust mite in British homes. Both increased damp and house dust mite levels are significant risk factors for the persistence of symptoms in children with asthma. The type of building (houses vs. flats), ventilation system and presence of a basement all have major implications on respiratory symptoms, atopy and house dust mite infestation. Building construction affects both respiratory morbidity and allergic sensitisation through development of disease and worsening of symptoms.

3.4 Food policy and labelling regulations

Policy for food labelling is now directed by the European Union and is consequently relatively responsive and allergy aware. The Food Standards Agency enforces food labelling regulations and operates with allergy consumer input from the Anaphylaxis Campaign. Recent changes to the recommendations for food labelling have improved the information available to consumers, but are not patient centred and, in some cases, has increased the confusion experienced by allergy sufferers. Alternative foods for allergy sufferers are expensive and may not be readily available. 56 per cent of food items indicate that they contain traces of nuts, there are no substitutes for 18 per cent of items and 9 per cent are of poorer quality. The recent campaign for healthy eating in schools has not taken into account the needs of peanut allergic children. Recommending that nuts should be increasingly available as a healthy snack from vending machines increases the risk of allergy sufferers having an acute reaction by inadvertent exposure.

4. Patient and Consumer Issues

4.1 Impact of allergy on quality of life

Quality of life of children with peanut allergy is more impaired than in children with diabetes. Teenagers with allergic rhinoconjunctivitis experience impaired quality of life due to local and systemic symptoms, limited activity and emotional and practical problems. 7 per cent of children are affected by more than one allergic condition. The impact on quality of life of co-morbidity is difficult to study. For example, the effect of rhinitis and sleep disturbance on school performance and the impact on exam results and career attainment is not well documented. The timing of exams are important, children with summer hay fever will drop a grade when they sit their exams which are usually scheduled for the middle of the grass pollen season. Venom immunotherapy offered improved quality of life over provision of rescue medication alone in patients with severe reactions to wasp stings.

4.2 Better education of public and patients

The fundamental problem is that a patient often suspects that they have an allergy, but, because of lack of access to accurate allergy diagnostic procedures, they are unable to obtain accurate and effective advice (similar to a patient, suspecting they might have cancer, the first step would be to be referred somewhere where an accurate diagnosis can be made, before effective treatment can be given). We have effective treatments, but there is a gap in access to accurate allergy diagnosis forcing patients to access alternative, inaccurate and inappropriate advice through complementary medicine. This is compounded by misconceptions in the popular press. A programme of health promotion and health education and an increased awareness of allergy is needed within the general population, patient population and primary care. For general practitioners, there is a lack of teaching in medical schools at undergraduate and postgraduate levels resulting in a significant knowledge gap and a need for GP education programmes supported by a network of specialists. Currently, there is an information vacuum allowing pharmaceutical companies to provide promotional material inappropriately (for example, recommending the use of sedating anti-histamines for the treatment of hay fever). It also leaves appliance companies relatively unregulated in relation to claims about health benefits such as for vacuum cleaners, air filters, ionisers etc. The public tends to get an unbalanced view of allergy and the options available for treating it. There is a need for a centrally funded allergy awareness strategy, which is not commercially linked. A schools education programme would improve allergy awareness for children.
4.3 Regulation of private clinics

Legally constituted regulation is imposed on medical practitioners by the General Medical Council, whether they work in the private sector or for the National Health Service. Private medical clinics are increasingly incorporating governance standards used within NHS clinics and hospitals. Children with allergic disease are significantly more likely to seek advice from alternative medicine practitioners than children with other illnesses. This may reflect a lack of adequate service provision for these children or insufficient knowledge regarding the management of allergies in primary care. Non-medically qualified practitioners are able to freely practice subject to minor limitations. This unregulated situation has existed since the 16th century. There is considerable variation in the levels of professionalisation within the Complementary and Alternative Medicine world. Osteopathy and chiropractic are the only two complementary professions with statutory regulation. Other practitioners, such as herbalists, homeopaths, Chinese medicine practitioners and acupuncturists are regulated through voluntary professional organisations and are able to make unsubstantiated claims without challenge. Nutritionists without formal dietetic training who recommend dietary exclusion in infants based on unfounded tests are a particular problem. Unregulated peanut desensitisation has the potential for severe adverse effects. Kinesiology, vega testing and hair analysis as forms of allergy testing have no scientific rationale and are not valid diagnostic procedures.

4.4 Paediatric allergy training and service provision

Allergic disease has its basis in childhood. As a consequence the management of allergic disease requires an understanding of the developmental aspects of the child including physiology, nutrition and immunity. It is therefore regrettable that there are very few paediatric allergy specialists in the UK; nine specialists overall of whom six are based in London. Furthermore there are no established training programmes for paediatricians wishing to become specialists in allergy. The College of Paediatrics Special Advisory Committee is attempting to correct this but currently only two centres in the UK can provide the training to obtain the competencies required by a paediatric allergist. More tertiary centre based paediatric allergists are required—not only to treat the most complex cases but to provide research into the paediatric aspects of allergic disease and to provide the necessary training for future generations of paediatric allergists. While much paediatric allergy is dealt with at primary and secondary care level, tertiary specialists can fulfil a key role in providing a network for guidance and support to these clinicians.

Reference list [not printed]

10 October 2006

Memorandum by the Immunology SAC, Royal College of Pathologists

Immunologists and allergists provide specialist clinical allergy services in the UK, and are the only medical specialties with extensive training in the immunological basis of allergy and the clinical care of patients with allergic disorders affecting all organ systems. Allergists devote all their professional time to the management of Allergy, immunologists often have other responsibilities and varied job plans, but most devote substantial parts of their professional time to the provision of allergy services.

The remit of the House of Lords Sub-Committee is very wide-ranging and will require a thorough review of a vast amount of evidence. The published evidence on conventional practice, and that on complementary therapies will need to be subjected to proper scrutiny for quality, lack of methodological flaws, exclusion of placebo effect and reproducibility before being used as evidence for public policy decision-making.

1. Defining the Problem

1.1 What is allergy? What is the difference between allergy and intolerance?

1.1.1 Allergy—Immunological disease mediated by the Immune system—it has a limited number of stereotypic manifestations which are dictated by the immunological mechanisms underlying Mast cell activation. It has a genetic basis, but the expression of disease is influenced by the environment and reproducible allergen-triggered, IgE antibody-mediated disease mechanisms can be identified and give rise to clinically disease.
1.1.2 Intolerance is a catch-all term for any adverse effect experienced by an individual which is often mistakenly attributed to allergy but for which there is no reputable evidence to suggest that it is an immunological adverse reaction to foods or medicines. Some “intolerances” such as food-induced migraine are probably pharmacological actions of the food. Intolerance is therefore a state of sensitivity to a specific environmental component which manifests within an individual, objectively or subjectively, as a reproducible unpleasant reaction upon exposure to that component.

1.1.3 Detailed nomenclature can be found at http://www.eaaci.net/site/nomenclature.pdf.

1.1.4 Much information including practice parameters/position statements and expert evidence-based guidelines on the management of allergic disease can be found at the websites of allergy/Immunology professional societies such as www.BSACI.org.uk; www.aaaai.org; www.eaaci.net.

1.2 Why is the incidence of allergy and allergic diseases rising? Why does the UK in particular have such high prevalence of allergy?

1.2.1 The incidence of many forms of allergy is clearly rising and the rise does not appear to be related to better reporting and diagnosis, but the reasons are poorly understood. Epidemiological meta-analysis of the existing data has already been published as an appendix to the DH (Department of Health) report into the provision of allergy services, but caution is needed in comparison of results in different countries. The lack of systematic meta-analysis is hampered by the variable quality of the data and expert large scale epidemiological studies are required—the UK is uniquely well-placed to deliver these studies through the NHS and associated research but the lack of investment in the future training of specialists practicing allergy and immunology and the difficulties pursuing an academic medical career (likely to result from a potential reduction in overall funding associated with the Culyer report) are likely to impair this important work.

1.2.2 It is not known why the UK or anywhere else has a rising incidence of allergic disease—although there are many hypotheses all of which remain unproven. Despite their plausibility, the link is still speculative for most. The DH review highlighted the gaps in evidence at present.

1.3 What is and what is not known about the origins and progression of allergic disease?

1.3.1 There is much work still to be done on the genetic and environmental predisposition to the development of allergic disease, and strategies to prevent its development or modify its expression in individuals. In the absence of a national strategy, the failure to support and develop academic and NHS research into allergic disease may seriously impair future understanding of the issues in the UK. There is exciting and preliminary work suggesting that the “Allergic March” in children can be prevented by early immunotherapeutic intervention.

1.3.2 What is known:

— Genetic influences (some of).
— Environmental influences (some of).
— Immuno(dys)regulatory mechanisms (some of).
— Intrauterine and postpartum influences (some).
— The existence of the “allergy march”.
— Age influences on disease presentation.

1.3.3 What is not known: [Sic]

— Why predominance of different clinical presentations at different ages?
— Why does some atopy manifest as clinical disease and some remain latent?
— What factors determine mild vs. moderate vs. severe allergy.
— How to predict the severity of the next reaction in an individual in order to tailor individual treatment plans and risk-assessments.
— How to prevent allergy developing or modify its severity.
— There are many putative factors with varying levels of supporting evidence.
— Genetics.
— Hygiene hypothesis (much conflicting evidence).
— Pollution (personal and environmental).
— Lifestyle effects (homes, pets, diet etc).
— Climate—effects on home environment—eg for House dust mite.

1.4 What gaps exist in establishing the overall disease burden for all types of allergy and what are the barriers to filling these gaps?

1.4.1 Evidence has delineated a substantial and underestimated disease burden in the UK. Further work is needed to develop robust evidence base with validated measures, this is unlikely to occur if the specialities of Allergy and Immunology are not developed as part of a national strategy to improve NHS service and research provision, as well as providing the infrastructure for the proper gathering of such information.

1.4.2 There are likely to be significant gaps in robust mechanisms for workload recording/capacity in primary care and secondary/tertiary care. These will be essential for teasing out allergy workloads from workload recording of related/overlap diseases—especially in Immunology centres as opposed to pure Allergy centres. Improved coding necessary to collect this information in a sophisticated and standardised way is essential, as current ICD 10 and Payment by results codes are currently insufficiently detailed. It is hoped that NHS data collection will gradually be improved by these drivers.

1.4.3 There are many barriers which need to be overcome—recognition at local/commissioning level that allergy is a significant problem for the NHS, improved allocation/prioritisation of resource for allergy research, and successful establishment of the relevant NHS IT infrastructure to support improved data collection which is currently underway.

1.5 In addition to the impact on the health service, what is the overall socio-economic impact of allergic diseases (for example, absence from work and schools)?

1.5.1 The assessment of disease burden or socio-economic impact with any reliability is also very difficult, and difficulties in validation of presumed measures of economic impact. It is clear however from the evidence presented to the DH Review, and evidence from patients, patient support organisations, allergists, immunologists, GPs, nurses and other medical specialties, that allergy in all its forms has considerable impact on the lives of patients, disrupting schooling, work, and general quality of life, as well as the risk of death and other morbidity from more serious forms of allergy and asthma.

TREATMENT AND MANAGEMENT

2.1 What is the effect of current treatments on the natural history of allergic disease?

2.1.1 There is much published evidence for the effectiveness of interventions by allergists/immunologists (see AAAAI “Consultation and referral guidelines citing the evidence: How the allergist-immunologist can help”—on www.aaaai.org) particularly for allergen avoidance strategies, immunotherapy and treatment of asthma, hay fever and specific food allergies. A review of meta-analysis of effectiveness of treatments has been published as an appendix to the DH report. This highlighted the need for more research and gaps in the evidence. This will require the support and development of national centres of expertise, a network of regional centres of excellence in NHS service provision (primarily through allergists and immunologists and multidisciplinary team working) and improved service provision and data collection in primary care. Much of NHS treatment in all specialties is of necessity based on expert opinion and experience in the absence of randomised double-blind controlled trials in many areas. While we all strive to correct this, and NICE may be given the task of reviewing evidence to identify interventions for which there is evidence of ineffectiveness (in a limited number of interventions, not involving allergy to date). The select committee must remember that lack of evidence of effectiveness is not evidence of lack of effectiveness. The two are often conflated in policy decision-making, often erroneously.

2.1.2 Pharmacotherapeutic options currently available are unlikely to have significant effects on natural history of disease other than primarily managing symptoms. The same may well be true for allergen avoidance/ environmental modification measures.
2.2 The data on complementary interventions

2.2.1 Research into complementary interventions is inadequate and this is a highly contentious issue. While acknowledging that the evidence base for many conventional treatments is sub-optimal, this should not influence the critical scientific evaluation of the quality of evidence for complementary interventions, which is often regarded as poor by most scientific standards.

2.2.2 To our knowledge there is only one chair of Complementary Medicine in the UK (at the Peninsular Medical School in Plymouth (http://www.pms.ac.uk/compmed)).

2.2.3 “Vega” testing has recently been examined as complementary diagnostic technique without demonstrating efficacy (Lewith et al BMJ 2001;322:131-134). Intervventional studies are often flawed and difficult to interpret due to methodological biases.

2.2.4 If necessary the committee should consider clearly argued critiques of the evidence for the more esoteric complementary therapies from a “conventional” medical/scientific standpoint, as well as the counter arguments of the proponents of esoteric therapies to gain an insight into the controversial nature of these debates.

2.2.5 The committee should familiarize themselves with the position statements on complementary therapies of the RCP (Royal College of Physicians), AAAAI, BSACI (including that submitted to the DH review) and other allergy and immunology organisations for the expert consensus view of the evidence for some complementary therapies.

2.2.6 Most conventional medical practitioners and professional societies have reservations about the quality of evidence for many complimentary investigations and acknowledge the difficulty in producing interventional studies of sufficient power which are not subject to error and biases or the placebo effect (even if the placebo effect is a very important tool in making patients feel better and an important part of patient care, even in conventional medicine).

2.2.7 There is some recently published data of doubtful validity to suggest that IgG antibodies may predict food intolerances but this is controversial and is not confirmed by other studies. Interventional studies using dietary avoidance may have methodological errors that may lead to biases which make them unreliable.

2.3 Evidence base for Pharmacological and non-pharmacological Management Strategies

2.3.1 To a certain extent the evidence base has been examined in the appendices to the DH review. This is far too large an area to review in this submission but we would direct the select committee to the evidence submitted to the DH enquiry by the BSACI and others, and to the websites above, for expert consensus opinion.

2.3.2 The evidence base for most standard pharmacotherapeutic options—corticosteroids, H1blockers etc. have a significant body of evidence underpinning their beneficial use in allergy.

2.3.3 Adrenaline in anaphylaxis—Expert opinion and extrapolation from retrospective observations, including the UK Resuscitation Council Guidelines agree about the likely benefits, but objective evidence is lacking because of the obvious difficulties which preclude the studying of its efficacy in randomised controlled trials. It would be unethical not to administer adrenaline to a patient with anaphylaxis. There is also the distinction between the end-points of efficacy for prevention of fatalities and efficacy in rapidly terminating an episode and reducing morbidity which must be considered. This is a good example of lack of evidence of efficacy not being equated with evidence of lack of efficacy.

2.3.4 Anti-IgE—There is evidence of efficacy in severe asthma, and in increasing the dose tolerance of patients with food allergy, and it may have a role in other allergic disorders. Its place in routine practice in the UK is, as yet, unclear although there is much potential in other areas of allergy practice.

2.3.5 Non-pharmacological: Allergen avoidance: Once again there are difficulties in interpreting the existing evidence. Intuitively this is a “common sense” measure which ought to be highly effective, and there is data to demonstrate this in some food allergies such as peanut sensitivity. Objective evidence of efficacy in most sorts of aeroallergen allergy eg House Dust Mite Sensitivity is difficult to obtain, most likely due to a lack of comparability between different studies because of methods and patient selection.
2.4 Is the level of UK research into allergy and allergic disease adequate?

2.4.1 Clearly not, even though much excellent research is done by a small cadre of specialists—see appendices to DH Review July 2006 and comments above. More importantly, there is reason to believe that the future of such clinically-based applied/translational research is precarious in view of the small number of specialists and lack of training opportunities.

2.4.2 Both specialties lack manpower and have insufficient training posts, leading to current and future difficulty with recruitment and retention of clinical and academic specialists. A strategy is required to facilitate effective NHS research into the cost-effectiveness of different methods of service delivery and advance the treatment and understanding of allergic disease in general. These two aspects (service provision and research strategy) cannot be easily divorced in a highly specialised clinical service area with a small workforce.

2.4.3 Answers to UK specific problems will not be forthcoming without support for the retention and development of a cadre of specialist allergists/immunologists, and results from other countries may not always be relevant to a UK population.

2.5 What are the most promising areas of research into preventing or treating allergy?

2.5.1 There are many promising interventions including:

— Conventional allergen desensitization.
— New forms of immunotherapy with T cell modulating allergens, modified allergens and use of anti-IgE antibody therapy outside of asthma.
— Different routes of administration such as sublingual immunotherapy.
— Use of conventional allergen immunotherapy in children to prevent the development of asthma is promising.
— Bradykinin- and tryptase-inhibiting drugs and other potentially useful interventions are in development.
— Many of these experimental interventions have been championed by UK researchers and clinicians and the continuation of this in the future is in jeopardy without a coherent strategy to secure specialised services and consequent clinical applied research and development.

2.5.2 There is also a need for research into:

— Service delivery/deficiencies/needs/gaps issues.
— Efficacy of models of patient/profession education.
— The natural history of food allergy is poorly understood although we have some preliminary understanding. We suspect that some people with nut allergy outgrow their sensitivity with time but cannot predict who will do so. We also do not know if these people have a risk of re-sensitisation. There are more questions than answers at the present time.

3. Government Policy

3.1 How is current knowledge about the causes and management of allergic disease shared within Government?

3.1.1 We are not aware of effective sharing of knowledge or appropriate input into government policy in these areas other than the DH review and select committee report, although professional societies, patient support groups and Royal Colleges all responded to consultations and reviews when asked. This is a situation that has been of concern to the Royal College of Pathologists for some time in many areas of governmental activity, and it is clear that decision-making will be much improved with effective stakeholder and expert input. A mechanism is needed to facilitate this. There exists a body of experts in the Royal Colleges, willing and able to assist in the formulation of government policy yet often there appears to be no mechanism for ensuring that this resource is effectively and routinely tapped. The Royal College of Pathologists keen to act as a resource for identifying individuals with the appropriate expertise in any given area.
3.2 How effective have existing Government policy and advice been in addressing the rise in allergies?

3.2.1 The committee is not aware of any evidence of such action or evidence of its effectiveness. Part of the problem lies in a lack of suitable evidence in relevant areas, for example into allergen avoidance strategies for infants to potentially reduce the incidence of food sensitisation.

3.2.2 We feel that government policy to date has not been effective in addressing the needs of patients with allergy. The DH concluded that there was a considerable burden of allergic disease, that more specialists were required, and that provision of services was inadequate and geographically unequal and needed to be addressed, perhaps by networking. The report of the DH Select Committee did highlight the need for a network of allergy services throughout the UK, the need for additional training positions and the need for expert review of the effectiveness of interventions perhaps through NICE. Unfortunately to date there is no obvious mechanism or driver to achieve this.

3.2.3 One key problem in allergy is how to engage local health commissioners to prioritise the establishment of adequate local allergy services in the face of all the other centrally driven demands on their budgets, such as the Quality and Outcomes frameworks for General Practice and Cancer and Heart Diseases National service frameworks, NICE guidance and other drivers. Care and education of patients with allergic disease and continued NHS research and development of new treatments and interventions is unlikely to improve significantly in the absence of such a driver.

3.3 Do housing policy and regulations governing the indoor environment pay enough attention to allergy?

3.3.1 We are not aware of evidence that housing policy can impact on allergy development or treatment unless it is proven that a patient is sensitive to a controllable environmental allergen such as mould spores or dustmite. This may be of more relevance to work environments where we believe that protection against the development of occupational allergy is often covered by Health and Safety legislation.

3.4 How effectively are food policy and food labelling regulations responding to the rise in food allergies?

3.4.1 Food labelling is very important—some clear steps have been taken to make labelling mandatory including FSA documents but much more action needed (see http://www.food.gov.uk/safereating/allergyintol). The FSA 2002 report “Adverse reactions to food and food ingredients” has already examined some of the issues on this topic). One major difficulty is knowing what the minimum threshold for labelling should be, and how to risk-assess this—a few individuals could potentially be sensitive to trace amounts of rare allergens, others may not. This is a difficult issue requiring much careful thought. The role or risks/benefits of genetically modified foods is essentially unknown.

3.4.2 While food allergy must be taken seriously, some express concerns that an inappropriately low threshold for use of hazard warnings may be problematic. This problem impacts on patients who regularly report difficulties with selecting allergen-free foods and complicates the interpretation of supermarket labelling—where foods which are apparently very unlikely to contain an allergen are labelled as a risk, but the assessment of the level of risk is unclear. Some evidence based consistency and guidance is required.

Patient and Consumer Issues

4.1 What impact do allergies have on the quality of life of those experiencing allergic disease and their families?

4.1.1 There is much supporting evidence demonstrating that quality of life is impaired by every type of allergy from rhinitis to food-related anaphylaxis, and that allergy impacts adversely on many aspects of daily living. This may be addressed by better services support and advice in primary care, probably best supported by specialist hospital centres with extensive and up-to-date expertise. Much of this work is provided by patients support agencies and charities in the absence of easy access to expert consultations with allergist or immunologists.

4.1.2 There is preliminary evidence that management by an expert team is of benefit and improves patient outcomes but more work is required.
4.2 What can be done to better educate the public and to improve the quality of information that is available to patients and undiagnosed sufferers?

4.2.1 A lot could be done to improve availability of information and advice from professional as well as informed lay organisations, but much allergy advice requires to be individualized and the construction of appropriate local information is dependent on local medical expertise in allergy which is scarce.

4.2.2 Allergy and immunology centres provide extensive patient support. This includes information, training in the use of rescue medication and expert assessment of the patients' individual needs. A recent publication in the BMJ suggested that EpiPens™ were oversubscribed such that the putative cost of each putative life saved was 20 million pounds, however this point of view is flawed because it ignores the benefits of proper treatment plan in managing anxiety, preventing morbidity and reducing symptoms. Expert risk-assessment and research into improved prognostic markers by expert units is required in order to minimise this cost to the NHS and ensure that rescue medications and therapy are administered in a cost-effective and clinically appropriate manner. It is unlikely that we can rely on non-expert assessment in primary care without clear national evidence-based guidelines which will need to be supported through a local expert allergist/immunologist.

4.2.3 Nationally, a lead needs to be taken by allergist/immunologists, to create national service standards, create a workable network of NHS allergy services with clear referral patterns and community outreach—including support for education and training in primary care.

4.2.4 Web-based guidance and information—often including that of some patient support groups—is not quality-assured and often mix complementary approaches and conventional advice, which can lead to confusion.

4.3 Are current regulatory arrangements, for example, those governing private clinics offering diagnostic and therapeutic services and the sale of over the counter allergy tests, satisfactory?

4.3.1 Regulation of non-NHS clinics and over-the-counter treatments for allergy is not adequate—extensive evidence that it leads to direct harm to individuals is lacking, but there is clearly a legitimate concern that ineffective or misleading advice may be harmful, costly and may divert patients from effective evidence-based interventions. High street stores or private centers may offer complementary diagnostic testing with unproven techniques.

4.3.2 POCT (point-of-care-testing or near-patient testing) is a major potential problem even with conventional evidence-based assays when offered in a context of inadequate quality assurance procedures, and by staff who do not have the clinical training or expertise to properly interpret their significance. A specific IgE test which is offered without evidence-based expert assessment of the pre-test probability of allergic disease is worthless and potentially misleading. This is potentially as great a problem as that of the use of un-validated complementary tests of doubtful value. A positive test is not the same as the presence of a clinically important allergy or vice versa. We do not feel that a policy of "caveat emptor" is appropriate in health policy where there is an effective evidence-based conventional intervention, or where it may lead to harm, and feel that a proper regulatory framework is required.

4.3.3 Hospital laboratories offering diagnostic allergy tests are required to submit to a regime of inspection against quality standards in order to be able to offer NHS diagnostic services. The same must apply to other providers and the government should assemble an equivalent policy on the basis of an expert review of the evidence.

9 October 2006

Memorandum by the National Allergy Strategy Group

Introduction

1. Allergy is a national health problem. There are no class, and no material regional, differences in its distribution. The burden of need falls equally across the population, and is substantial. It therefore requires a national effort to secure fair access to appropriate services. This has not been forthcoming and there is substantial unmet need.
2. The NHS is now organized to provide its services through regional and, to a greater extent, local structures—Primary Care Trusts (PCTs) hold 85 per cent of budgets. One major problem, therefore, is how to address a national health issue which has not been addressed previously through a devolved NHS.

3. Allergy presents a problem of high need, low provision and hence a substantial service gap.

4. The consequence is that a very large number of people are being treated without a correct diagnosis or in the wrong way (for example treating symptoms rather than diagnosing the allergy and avoiding the allergic trigger).

3. The DH has conceded the problem. But the Department proposes to rely (even more than previously) on local and regional agencies to provide solutions. Yet, as DH has also conceded, PCTs know more or less nothing about allergy and most have no local expertise to call on and no information on the allergy needs of their population. Specialist allergists are needed to lead change, yet these are few in number and there is no investment in training to provide more of them for the future. How in this situation can the NHS be helped to orchestrate a national response?

5. Allergy presents today a clear and present challenge in this respect. But through time other new diseases will also require a national response from a devolved NHS. In this sense, allergy might be seen as presenting a test of how the NHS in the future could face up to future health challenges. At the very least, some way needs to be found to:
   
   (a) get more doctors (and other health care professionals) with the relevant expert training into service quickly; and
   
   (b) set up pilots or demonstration projects, showing what a model new service could deliver, from which the rest of the service can learn.

Effect of lack of service on research

6. Although this is much needed the UK produces little clinical research in allergy. Lack of NHS service results directly in absence of research capacity. Research requires a specialist service with large cohorts of well studied patients and clinicians with expertise in centres where research is a priority. This in turn requires clinical leadership in both adult and paediatric allergy. The UK has a tiny specialist workforce (there are only 26.5 whole time equivalent consultants in allergy)—for a huge burden of disease (allergy affects 20 million people of whom about seven million require specialist help).

7. For the reasons set out above, many answers to the questions posed in the Terms of Reference are going to be equivocal. NHS staffing/expertise/clinics/data systems/modes of treatment etc do not, for the most part, recognise allergy. And so, the basics are not there for the NHS to be a resource for knowledge generation about allergy. Information does exist, but in small pockets, where there are specialist allergy centres, and bodies such as the British Society for Allergy and Clinical Immunology (BSACI) have collected and analysed the published data.

Consequences for patients

8. People with allergy (or who think they or their child have allergy) are having to make their own judgments about what to do. This in turn has several consequences:
   
   — unregulated and sometimes dangerous private practice; and
   
   — failure to make an accurate allergy diagnosis.

Both false positives (labelling a problem as allergy when it is not) and false negatives (failure to recognize or even consider allergy) are common—this inaccurate diagnosis results in bad management and ongoing disease. The need for diagnosis is central. Across the NHS, allergy diagnosis is not being made, because staff in primary and secondary care are not trained to do this. Investment in expertise in allergy is required to make this possible.

9. Estimates of the numbers of patients where allergy diagnosis is required and where specialist referral is needed are available (see Nature and Extent of Allergy in the UK, BSACI 2006). The current capacity of all NHS allergy clinics is only about 2 per cent of those needing hospital referral (not allowing for the fact that many of the allergy clinics run by consultants in other specialties, deal with limited areas of allergy and do not
have the expertise or facilities, to undertake more complex investigation) (An NHS Plan for Allergy: Making a Start, NASG 2003, information prepared for the Health Minister).

10. The most serious problems occur for people with multiple allergy (allergy expressing itself in several different ways eg eczema, asthma, anaphylaxis etc)—and for severe allergy.

RESPONSES TO SPECIFIC QUESTIONS

What is allergy?

11. Allergy is described in the Royal College of Physicians (RCP) Report “Allergy the unmet need” chapter 1, p 3–6. Allergic diseases are wide ranging and cross the traditional organ based specialties within medicine.

12. It is important also to consider what is allergy practice. What does an allergy clinic deal with? This is not restricted to diseases mediated by allergic antibody (IgE), but depends more on presentations of illness, rather than the mechanism. Allergy services deal with many diseases unrelated to IgE, such as non allergic rhinitis, forms of anaphylaxis, angioedema, tongue swelling, drug “allergy” and food intolerance and have an important role in excluding allergy as a cause of disease.

13. The other aspect is the additional value offered by an allergy service. A particular disease might be appropriately dealt with in other parts of the NHS (eg asthma in primary care or by a respiratory physician where the focus is on drug treatment to control symptoms), but what an allergy service adds is the diagnosis/management of allergy. For the most part this is not taking place in the rest of the NHS. Because allergy commonly has multiple manifestations, the ‘added value’ of an allergy specialist is also in being able to deal with the whole patient in a single service, rather than picking off symptoms one by one and requiring referral to a series of specialists.

What gaps exist in establishing the overall disease burden for all types of allergy and what are the barriers to filling these gaps?

14. An assessment of the burden of allergic disease in the UK was undertaken by BSACI in 2005 for the DH review of Allergy services, 2006 (“Nature and Extent of Allergy in the UK”). This was evidence-based using published data on epidemiology for each disorder where allergy might be involved, and severity, complexity and co-morbidity (several conditions occurring together in an individual).

15. From these data, service implications could be calculated: first, the number which could be treated by self care or in primary care with symptomatic treatment without need for a formal allergy diagnosis and the number where an allergy diagnosis was needed; and second, the number which could be managed in primary care (assuming the conditions required to improve allergy knowledge were met) [13 million people] and the number where referral to an allergy specialist was required [up to seven million].

16. Despite the gaps in information, therefore, a count can be made of the amount of allergy. BSACI data shows that there are >47 million disease episodes or >20 million people who have a disorder where allergy may be involved.

17. Gaps were evident for:

(i) Prevalence of urticaria, angioedema, drug allergy and latex allergy and there was incomplete data for anaphylaxis of any cause.

(ii) It is also not known how many people falsely believe they have allergy and act, or are encouraged to act, as if they do so. Or their doctor takes action without a proper diagnosis. Important areas here are drug and food allergy, with medical and cost implications from incorrect diagnosis. The number wrongly labelled is likely to be in excess of seven million people for food allergy and several million for penicillin allergy alone.

(iii) In a proportion of these, investigation to exclude allergy needs to be undertaken, so that appropriate management can be put in place. No estimate is available.

(iv) There is also insufficient information to suggest estimates of the numbers of people in the country who have an illness with an allergic cause which has been left undiagnosed.

(v) Whilst there is considerable data on aspects of co-morbidity taken from the perspective of a single disorder (especially for rhinitis/asthma/eczema), there was no data in other areas. Documentation of the extent of multiple allergy (the number of diseases in the same patient) is not available.
(vi) There are several newly emerging allergies, and absence of data capture on these, for example, sesame and fruit allergy. There is now data on peanut allergy, the epidemic of the 1990s, but little information on other nut allergies.

(vii) NHS statistics on allergy are lacking.

(a) This is partly due to the failure to “code” allergy work. An allergy code was introduced in 2005 but has only been adopted in the few specialist allergy centres, and even there only applies to day case work.

(b) This is also due to failure to recognise allergy across most of the NHS. And, even when recognised, recording of allergy is not mandatory in GP data systems.

(c) NHS statistics on hospital admissions are available for a few conditions (with the caveat of under-recording, so failure to make the allergy diagnosis). Anaphylaxis admissions have risen seven fold in 10 years (Gupta et al 2004) but the absolute numbers give no indication of the real extent of the burden, as most anaphylaxis is treated in A&E, and does not appear in NHS admission statistics.

(viii) Effects on Quality of Life. There are data, but most of this is anecdotal although compelling, from the patient organisations, Anaphylaxis Campaign and Allergy UK, who receive thousands of calls to their help lines which reveal effects on quality of life from (i) failure to get medical help and (ii) coping with the disease.

(ix) Effects on cost to NHS from failure of allergy diagnosis hence appropriate management. Estimate of direct/visible costs of NHS care can be made. The effects on patients and on the cost of failure to diagnose are of an order of magnitude greater. Avoidance of the allergic trigger can ameliorate further acute disease episodes, well documented for food or drug allergy (see BSACI paper, Effectiveness of allergy interventions, 2006).

18. The major reason for these gaps in data is the lack of NHS specialist services in allergy, combined with lack of knowledge and awareness of allergy in primary care. Without a service base—particularly given the way Government research priorities are so closely aligned to clinical emphasis—there is no effective research and data base from which to build.

In addition to the impact on the health service, what is the overall socio-economic impact of allergic diseases (for example, absence from work and schools)?

19. The same issues apply as above: one needs a service to make a diagnosis before impact can be measured scientifically. Some data is available for certain disorders eg nut allergy, venom allergy. Nut allergy causes more stress for families than a diagnosis of diabetes (Avery et al 2003). Bee or wasp venom allergy can cause life threatening anaphylaxis, a common symptom of which is a feeling that the patient is going to die. This fear is reduced by allergen immunotherapy (Oude-Elberink et al 2003), a treatment which is highly effective, “switching o” the allergy, yet it is hardly available to UK patients.

However, Allergy UK and Anaphylaxis Campaign, can give extensive qualitative data on this, from their help lines. Allergy leads to huge stress and anxiety, unnecessary illness and loss of time from work or school, and is exacerbated by the failure of the NHS.

Is the level of UK research into allergy and allergic disease adequate?

Basic and clinical research

20. The major problem with allergy research in the UK is that it lacks a clinical or human resource base. Basic research relies on a few talented individuals. Clinical research requires clinic capacity, excellent clinical practice and clinicians whose main focus is on allergy, enabled to investigate well worked up patients in sufficient volume for expertise in patient management to be built up.

21. Basic research. There is excellent basic research into allergy in UK, where we are world leaders, but this is limited to a few centres, and dependent on a small number of senior academic staff. Its continuation is not guaranteed and the situation is fragile. The loss or retirement of one or two research leaders will greatly diminish our research base.

22. Clinical research. There is a serious lack of clinical research—even fewer centres, than academic centres in allergy related research—and need for substantial expansion here.
23. Examples follow: At what might appear to be a very basic level, information on the value and interpretation of diagnostic tests is needed. Most doctors do not know how to interpret these tests; thinking, incorrectly, that a positive equals an allergy diagnosis. Clinical research is necessary to throw light on this eg in nut allergy, a “grey area” has been identified in the so called “positive” range, where 50 per cent of patients are allergic but 50 per cent are tolerant (Clark & Ewan 2003). Another development is to identify the level in a test result above which nearly all patients will have allergy (Sporik et al 2000; Hill et al 2000). There are other examples eg studies on how best to manage nut allergy with evidence on efficacy (Ewan & Clark 2001; Ewan & Clark 2005). Such evidence can then be rolled out into clinical practice across the NHS.

24. This type of work requires specialist clinics with well studied patients, and clinicians with research facilities. In the UK there are only six such clinical services. The two substantially largest clinics see about 5,000 allergy patients each per year.

25. The role of allergy in asthma deaths. Deaths provide a clear end point. Unfortunately, the recording of asthma and allergy deaths has become compounded and asthma tends to be recorded to the exclusion of allergy (usually because of misdiagnosis) (Pumphrey 2004). Allergic asthma appears to be an important cause of sudden death, yet there has been virtually no study of this. New data is beginning to emerge from the Eastern Region confidential enquiry into asthma deaths—the first such enquiry with any allergy input—but there has been great difficulty obtaining funding for such work. This has important implications—for most of these deaths were in patients on standard asthma medication (ie apparently appropriate management), but the mistake was that allergy had not been considered.

26. Clinical guidelines are much needed. The lack of specialist clinical leadership in allergy in the UK (and very little NHS funding for allergy) makes clinical allergy research—and its translation to guidelines for practice etc—vestigial. It is not commensurate with the size of the problem and burden to the NHS. 20 million people have allergy at some time and about seven million need a specialist service (ie could not be expertly and safely diagnosed and managed in primary care). The direct cost for managing allergic problems has been estimated at £1 billion pa (Gupta et al 2004) but the reality is that much of the cost is invisible and incalculable because patients are undiagnosed. More capacity is needed. The essential first step is to increase the number of consultant allergists: there are only 26.5 wte consultants in the UK; and the limiting factor to expansion is the very small number of trainee places—only eight for the UK (not enough even to replace expected retirements—DH workforce data). This is a vital step, identified in previous allergy enquiries.

27. As research priorities are so closely linked to national clinical priorities, it is not easy to obtain research funding for a discipline with no priority. There is therefore a “double whammy”.

How effective have existing Government policy and advice been in addressing the rise in allergies?

28. On Policy For Service Development In Allergy Healthcare

(i) The problem allergy presents to government is how to make a start to address a national problem with a devolved health service.

(ii) The Royal College of Physicians gave unequivocal advice on how to do this three years ago: the first step is to get more specialists in allergy into the system. This would begin to create critical mass and improve the geographic distribution of allergy expertise. From these centres, support for other providers of allergy care and enhancement of services across primary and secondary care would flow. Normal processes could then take over.

(iii) The House of Commons Select Health Committee (2004) endorsed the RCP Report and said that there should be an increase of 20 adult and 20 paediatric allergy training posts for doctors, and a commitment to create consultant posts for them to move into.

(iv) The DH has implicitly rejected these recommendations as too centralist (2006).

(v) The DH recognise the need to increase the specialist workforce in allergy but say this is a problem for Strategic Health Authorities and Deaneries to deal with. However the DH advice carries no requirement for action.

(vi) The DH propose to leave the rest of service development to PCT commissioners. But it is known that PCTs lack the input and conditions to do this.

(vii) Policy is needed to enable some action and move forward from this position. One way PCTs might be helped is by example, from a pilot scheme. What are needed are model services, which are working on the ground. These might be studied, used to train more specialists to seed out to new centres, work
with primary care and inform on the most efficient way of developing services. DH might be asked to consider a national challenge fund for locally programmed developments, from which others can learn within the devolved NHS. This could provide an engine for major service development outside central priorities.

29. On specific policies—Government advice to tackle rise in allergies: little advice has been forthcoming. But there is a lack of evidence on what to do. For example, the DH advice on prevention of nut allergy (1998) was not evidence based, because of lack of evidence.

What can be done to better educate the public and to improve the quality of information that is available to patients and undiagnosed sufferers?

30. The first problem is inability to get an allergy diagnosis. This is widespread because of serious deficiencies in primary and secondary care allergy services. Education resources will have most impact once the correct diagnosis is made.

31. Some of the advice available direct to patients is of poor quality and highly misleading. Support for the work of the patient support groups, Anaphylaxis Campaign and Allergy UK, is required.

Are current regulatory arrangements, for example, those governing private clinics offering diagnostic and therapeutic services and the sale of over the counter allergy tests, satisfactory?

32. Unorthodox and unsubstantiated practices including methods of diagnosis abound in the private sector (tests of no value are described in the RCP Report p 76–77). This is in part driven by absence of NHS allergy services. Many patients get the wrong diagnosis. This sometimes leads to medical harm; or financial problems for the patient; and wastes NHS funding—unproven private treatment is being paid for by some PCTs.

33. Even the established tests (specific IgE antibody)—without interpretation—can be misleading. Thus sales of these direct to the public eg supermarket, high street or through the media are harmful. Patients are diagnosed allergic when they are not and inappropriate management follows. Furthermore, there is a lack of quality control and tests in these laboratories can be positive when the same test in a CPA accredited laboratory is negative.

Documents and References [not printed]

Papers [not printed]

October 2006

Examination of Witnesses

Witnesses: DR MARK LEVY, University of Edinburgh Clinical Research Fellow and GP with special interest in respiratory disease and allergy, Royal College of General Practitioners, DR SUSAN LEECH, Allergy Representative, Royal College of Paediatrics and Child Health, DR WILLIAM EGNER, Chair, Immunology Speciality Advisory Committee, Royal College of Pathologists, and DR PAMELA EWAN, Co-Chair, National Allergy Strategy Group, examined.

Q318 Chairman: Could I thank you for coming today. Perhaps I could just remind you that this session is webcast, so that it is out in the public domain. Members of the Committee have prepared their interests on a paper available to the public, so those declarations of interest will not occur during this session. Any over and above will be recorded. Perhaps it is worth just recording now that Viscount Simon has encountered Dr Ewan in a professional capacity, so that we have that recorded and declared. Could I ask you at the beginning of this fifth public hearing of our inquiry into allergy if you could introduce yourselves. I am Lady Finlay and I am chairing this inquiry and the other members of the Committee will be introduced as we go through the questions. Perhaps, Dr Ewan, you would like to start.

Dr Ewan: I am Pamela Ewan. I am a consultant allergist working in Cambridge, running a very large allergy service. I am also Co-Chair of the National Allergy Strategy Group, which is a group which has tried to drive forward the need for allergy services. Dr Egner: I am William Egner. I am a Consultant Immunologist working in Sheffield. I am also Chair of the Standing Advisory Committee of the Royal College of Pathologists for Immunology and I am a practising immunologist who also provides an allergy service from my unit in Sheffield.
Dr Leech: I am Susan Leech. I am a Paediatric Allergy Consultant working at King’s College Hospital. I am the allergy representative on the College Specialist Advisory Committee for Allergy, Immunology and Infectious Diseases of the Royal College of Paediatrics and Child Health and the allergy representative of the British Paediatric Allergy, Immunology and Infectious Diseases Group of the same organisation.

Dr Levy: Good morning. I am a general practitioner in Harrow. I have had a specialist interest in respiratory disease for nearly 30 years, including allergy, asthma and chronic obstructive pulmonary disease. I edit the Primary Care Respiratory Journal, which is a PubMed listed primary care journal. I am also a part-time academic at Edinburgh University. I am a clinical research fellow at Edinburgh, and I am representing the Royal College of General Practitioners at this Committee.

Q319 Chairman: Thank you. Perhaps I could start by asking you how the Royal Colleges work together to maintain standards in allergy training and developing the allergy curricula.

Dr Ewan: The Royal College of Physicians, through the Joint Committee on Higher Medical Training, has devised an allergy curriculum which is a very detailed curriculum, setting out what trainees should do. They have a log book in which the trainees record their experience during the duration of a five-year training period. That is controlled by the college. The college also have a system in place where they can review training posts, both where there are centres suitable to have trainees and, also, once trainees are in post there is a system to review trainees as they go through. I think it is perhaps important to point out that there are certain requirements for training, in that you have to have appropriate consultants to provide the training—usually two consultants in the speciality—and you have to have an appropriate clinical practice or experience for the trainees to provide the training required—mostly at the main centre but some trainees might rotate to other centres. It is well regulated from the college point of view.

Dr Egner: Yes, that is correct. The same committee oversees the immunology and the allergy curricula. It receives input from both the SAC of the Royal College of Pathology with regard to immunologists’ views of how the curricula should develop, and the Joint Committee for Immunology and Allergy, which is an intercollegiate Committee of the College of Physicians and the College of Pathologists, which provides input and liaison between immunologists and allergists and provides input into the JCHMT and they balance the different views there are regarding the curriculum.

Dr Leech: The College of Paediatrics and Child Health has a similar structure, both for supervising and training, and there is an allergy curriculum which was developed based on the allergy curricula of the European Union of Medical Specialists who have a curriculum for paediatric allergology. We have developed an allergy training curriculum based on that with input from the adult allergy curriculum as well. Paediatric allergy training for paediatricians comprises of two years of what we call “higher specialist training” — which is SPR training which all paediatricians do—followed by three years’ subspecialty training in paediatric allergy. There is a college specialist advisory committee which monitors training centres and approves training centres. It devises the curriculum and it also supervises training.

Dr Levy: The Royal College of General Practitioners has developed a curriculum and within the respiratory extension of the curriculum it is probably fair to say that allergy is mentioned not in very much detail. I do not believe that the Royal College of General Practitioners oversees the quality of training. The problem for GPs is really access to good quality training.

Q320 Chairman: Thank you. Is there a separate curriculum anywhere—and it sounds from what you have said, Dr Levy, that there is not—for GPs who want to develop a special interest in allergy or for those people coming up through other specialties, such as chest medicine, who want to develop a specialist interest in allergy?

Dr Levy: At the moment, it depends very much on personal interest and personal drive, with GPs cobbling together different courses and educational facilities that are available. For example, if a general practitioner wanted to learn about allergy or specialise in allergy, they would have to do various courses and then find clinical attachments, which are quite difficult to find. They might get some theoretical training but the clinical part is very difficult to access.

Dr Ewan: Talking about the other medical specialties, allergy is mentioned in their training curricula. It is mentioned in the respiratory medicine one, it is mentioned in the dermatology one, but it is really a very minor part of these and most people training in those other specialties would go through their training with virtually little or no exposure to allergy. It is possible, of course, for people through their own personal interest to gain more training. A small number have indeed done that and have become competent in allergy, but that is very much self-driven rather than available. I suppose the exception is respiratory medicine, in that, in allergy, we do have a tradition of having been linked to respiratory medicine. However, this is centre-driven rather than curriculum-driven and there are some
centres of excellence. Most of the allergy major centres have strong links and a strong background in respiratory training.

Q321 Lord Taverne: You have told us what you are doing separately but how far do you cooperate? Is there any overview by any one establishment?  
Dr Ewan: Not really, in that these committees operate relatively independently. The difficulty is that the integration might come at practice level rather than training level. I think, where one tries to network services. A major part of what is done through allergy centres is networking with GPs in their area and other consultants who have an interest in their area, but this is not at the training curriculum level, this is in practice.

Q322 Lord Taverne: Is there any point in having more cooperation and some more coordinating effort? Or does it not matter? Is all that matters that people should cooperate in practice?  
Dr Ewan: I think it matters a lot that they cooperate in practice. That probably enables a larger number of people to become involved. But there is certainly a very major need in primary care for more training and for all GPs to receive some training in allergy. Currently GPs can go through their training with really no exposure to allergy.

Q323 Lord Taverne: That is the worst gap, is it?  
Dr Ewan: It is a huge gap and it comes about because there are very few consultant allergists in teaching hospitals, so it is possible to be a medical student and have one or two lectures on basic principles that might relate to allergy and that is it. No clinical exposure at all because there are no doctors to provide that training.

Dr Egner: I think it is important to clarify that the immunology and the allergy curricula are devised and established by the same committee in collaboration, balancing the needs of the different specialists about what each of those curricula should contain with regard to immunology components and allergy components. For those two curricula there is a balancing mechanism with regard to their content but there is not, as far as I am aware, any interaction between the Joint Committee on Higher Medical Training that oversees immunology and allergy and that which oversees respiratory training or dermatology training and so on. Furthermore, we are in a period of rapid change with regard to medical training and modernising medical careers, and the perhaps unintended adverse consequence of that is that you can no longer train jointly in a specialty.

You have to be on the specialist register for a single specialty. The irony of that is that a lot of practising allergists in major allergy centres have strong links and perhaps have even come through respiratory medicine or other curricula training. With respiratory medicine in the past, there was a curriculum which allowed you to train jointly in respiratory and allergy but that has now gone. Ironically, you can now no longer train jointly in immunology and allergy, which one would have thought was both logical and a way of introducing flexibility into the system. All of these things are introducing difficulties.

Q324 Chairman: What is going to happen in the future to the person who then develops a specific interest as a clinician in an area with patients, who has been trained, for example, only in immunology without being trained in allergy?  
Dr Egner: The immunologist's view would be that the immunology curriculum contains a large component of allergy. If one looks at European practice, there is not a standard model. Some are joint training programmes, where you do immunology and allergy; others are stand-alone allergists; some have stand-alone immunologists; and a few countries lack one or the other. We do not know what the best model is. It is now up to Trusts to appoint the people that they wish to appoint to perform a function. It is up to that individual and the Trust to be clear that that person is re-validatable, maintains professional development and is fit to practise in that speciality and it is up to each individual doctor to know the limits of their competence and to refer on. One of the major problems is there is no formalised structure, no referral guidelines, no mechanism for referring on and no access to the service because both immunology and allergy are rare breed specialties.

Q325 Lord Rea: Dr Ewan, you mentioned the intercollegiate committee. How does that operate in coordinating the activities and curriculum development between different colleges?  
Dr Ewan: There is a joint committee, an immunology and allergy committee, which controls those two curricula, with representatives of each speciality on it, but, beyond that, the other committees are separate. One could perhaps have some input into them but in reality they operate as distinct entities.

Q326 Viscount Simon: My question overlaps the first question but goes a bit further than that, in that paediatricians and other specialists, such as dermatologists, chest physicians and ENT surgeons, have to deal with allergic diseases within those fields. Is the training of these specialists in allergic diseases sufficient?  
Dr Ewan: No, it is not. The reality is that they mostly treat these diseases symptomatically without considering allergy. For example, asthma or eczema...
can be adequately treated with medicines without considering allergy. Diagnosing means identifying the trigger for the disease and hopefully avoiding that or reducing it and so reducing disease episodes. In many children, eczema will be driven by food allergy. If you can identify the food and avoid it, the eczema can disappear. The alternative approach which would be taken by a dermatologist would be to treat it with creams or other drugs. For the most part these other specialists lack allergy training and have their own approach to the disease. That is perfectly acceptable for a considerable chunk of patients with asthma and patients with eczema. From the allergy point of view, we would not be arguing all these diseases should be seen by an allergist—certainly not—but there have been efforts to calculate the percentage of those people with these diseases where an allergy opinion is important. That still is a considerable number, although it is a minority of the total. That is where allergy comes in. Whilst it would be helpful to have some allergy training for dermatology and respiratory medicine, it is still going to be a small part of their whole remit. The other point to be made is that much of allergy is multi-system and another advantage of an allergist, assuming you need an allergy opinion, is that you sort out food allergy, drug allergy, asthma, eczema, rhinitis in a single consultation, so not only do you give the allergy diagnosis and management but you also save sequential referrals and therefore you reduce the burden on these other specialities, all of whom have their own waiting list problems.

Dr Levy: This is further compounded by the problem from the general practice aspect, where the GP refers a patient with eczema to a dermatologist and does not recognise that this patient may also have food allergy aggravating their asthma. That referral will result in a dermatological opinion, the patient comes back to general practice and we need to re-refer the patient on to another organ-based specialist. Where the general practitioner is not trained in allergy, they might not recognise the need for multiple opinions, so the referral letter might not actually describe the problem very thoroughly. I agree with Dr Ewan 100 per cent that there is clearly a need for more allergy specialists or more widespread training of the generalists in allergy.

Dr Leech: I would like to speak to that on behalf of paediatrics. I think it has to do with the quality of the consultation that is offered to the patient. A general paediatrician who sees a patient with allergies will usually manage the patient in a very superficial way; whereas in an allergy consultation you go a lot deeper into the patient’s history and you address more than one of the patient’s problems. It is a qualitative difference rather than a quantitative difference. That is not always appreciated by a lot of paediatricians who see patients with allergies. Part of the general paediatric training would cover things like respiratory medicine and gastroenterology and part of that would include allergy, but they do not go into allergy in any great depth and as a consequence of that there are fairly fundamental misunderstandings amongst paediatricians about allergy; for example, the use of the terminology is slightly incorrect and can cause confusion. Therefore, even within paediatricians there is a lack of proper understanding of what constitutes allergy.

Dr Egner: This is perhaps reflected in the guidelines written by professional organisations regarding the management of organ-specific diseases. If you look at guidelines, such as SIGN guidelines for management of asthma or other respiratory diseases, the allergy component and how to select those patients who would benefit from additional investigation and how to go about that is often not there. I think that this is one of the problems that may reflect this lack of awareness.

Q327 Lord Broers: Could you give us an overview of the training courses that are available in allergy and tell us who attends them, please.

Dr Ewan: Are you talking about training now outside of the allergy curriculum for specialists?

Q328 Lord Broers: All courses.

Dr Ewan: If we start at the top, there would be the allergy specialist training, which is a five-year training. That is an excellent training but we have very few people undertaking that because there is a limited number of places funded nationally. Eight places only.

Q329 Lord Broers: Eight places a year?

Dr Ewan: Eight places in total, not a year. It takes five years to go through the programme, so every five years these places become available.

Q330 Lord Broers: We produce 1.6 places per year!

Dr Ewan: That is the full specialist. Then we have paediatric allergy specialists with their similar courses and then immunologists will do some allergy in their training. We have talked about dermatologists and the respiratory physicians having virtually none. Apart from that, there are courses which people could undertake at the post-graduate level. The biggest is run by Education for Health (which used to be called the National Respiratory Training Centre). It puts on allergy courses. They are primarily distance learning. They have a few sessions at the centre. They are theoretical, with a little bit of practical when they go into the centre. They are mostly taken up by nurses, especially nurses from primary care, but there are some nurses from the
hospital sector. A small number of doctors go on these, mainly GPs, but it is very heavily nursing. These are good value but they lack the clinical experience and so often these nurses want to have some sort of clinical attachment so they can put their theory into context and have a better understanding. I think the other difficulty is that these nurses then go back into primary care and they are isolated. They might try to start putting something into practice but, because they have no doctor to communicate with or colleagues to communicate with, it is very hard for them to maintain what they have learned or really properly put it into context. There are some other courses around. There are some MSc courses.

Q331 Lord Broers: What is the impact of these courses on the allergy services? Inadequate?

Dr Ewan: Yes. It is better than nothing, clearly, to have them but we lack a sufficient network. GPs and practice nurses can be very well maintained in an area if you have specialist centres. If you have adult and paediatric allergy in a major centre, it is known that where these exist the GPs and practice nurses in the penumbra can be better supported and can be enabled to do more.

Q332 Lord Colwyn: I imagine there must be a terrific delay between seeing a patient at the primary care level and seeing a specialist. Also, if there is a delay, surely the treatment might have already started, in which case it is difficult for a specialist to make an informed diagnosis.

Dr Ewan: Yes.

Dr Levy: We published a survey of general practitioners throughout the country and we sent invitations to 500 GPs to respond, of whom 50 per cent did. The delay in access to allergy consultations ranged from three to six months. The overall delay, if you looked at the extremes, was much longer. There were a few other points that came out of that survey, one of which was that about 50 per cent of these GPs had had some sort of training in allergy. We do not have much on the detail of what training they received but more than 50 per cent of them felt that their partners needed additional training. The worrying thing was that although they had not had much training in aspects of allergy, like, for example, food allergy which could be life-threatening, they felt competent in dealing with these conditions.

Dr Leech: We have two training centres for paediatric allergy. We recruit an average of one trainee a year: one into one centre and then, the following year, one into the other centre, and it is a two-year programme for them. There is an allergy MSc which is run out of Southampton which is very good, and a number of people go on that. I think what is needed are a lot of local initiatives to support this requirement for increased knowledge in primary care. We find that areas where there are paediatric allergy centres or places where there are groups of people practising paediatric allergy can then develop local initiatives to increase the knowledge of their local general paediatricians about allergy in general.

Dr Egner: The two major issues are that there is actually quite a lot of ad hoc training in allergy available through web-based modules, through drug company sponsored roadshows, through college activities, through professional societies, but not a lot of it is practically based with regard to clinical management. Much of it is theoretical and virtually none of it is quality-assured in any way. The other issue is that immunology and allergy centres where people have an interest in allergy and a large service will often provide local educational activities out of their own initiative, but, again, there is no standardisation of this. For example, in my centre I lecture to local general practitioners, both by invitation and through their GP training scheme. We have taught nurses. We teach colleagues. All of these are very important activities but, again, they are fragmented. They are only available if someone locally has the interest, because there is virtually never any time to do it routinely. It is all a question of making the time and seeing the need. There is no funding.

Q333 Lord Taverne: In 2003 the Royal College of Physicians recommended that there should be clinical allergy training courses as part of the undergraduate medical curriculum. Has no progress been made on that at all?

Dr Egner: I do not have the data but I could guess that very little has happened. We do know that the pathology component of undergraduate training has diminished over years and there is some data to show that and immunology will be part of that. It has been a concern that basic immunology (which obviously underpins allergy), as well as autoimmunity, primary immunodeficiency and other diseases which involve disease of the immune system is therefore not being recognised because it is simply not being brought to their attention and does not form part of the thought processes of trainees because they have not really grasped or been taught the basic science.

Q334 Lord Soulsby of Swaffham Prior: In view of the difficulties that you are all identifying, is there a case for videoconferencing? I know in dermatology in the Royal Society of Medicine this was a very popular form of postgraduate education. It seems to me that many of the problems in allergy lend themselves visually to a videoconference up and down the country and in fact elsewhere than within the United Kingdom. Has much attention been paid to this?
Dr Egner: I do not think videoconferencing has been used in the same sort of way as it is used in radiology work, where people can sit around and look at something; or perhaps in dermatology look at a rash and have a case-based discussion about the diagnosis. There are web-based modules provided by all sorts of providers, including the European Academy of Allergology and Clinical Immunology and the American Academy and so on and so forth, which invariably do this by presenting either videos or still pictures together with additional information that people can evaluate. But they are of variable quality. They operate in different modules. There was an e-learning initiative by the Royal College of Radiologists sponsored by the Department of Health. I know the College of Pathologists is very keen to be involved in the next round of that, which may well address some of the basic science and undergraduate issues, but we are unlikely to have the resource to turn that into a clinical module in the way that you can get off some of the commercial websites that target medical practitioners.

Q335 Lord Broers: Dr Ewan, do the eight candidates taking this full course have clinical attachments during that course?

Dr Ewan: Yes, it is almost exclusively clinical. They are in clinical practice all the time. Just to augment the answer to the last point, all these courses are fine but there are two key problems. One is the lack of specialists/lack of trainees to generate the future consultants. Another problem is doing something fundamental in primary care—not just having courses but including allergy as a key component of all GPs’ education.

Q336 Lord Taverne: My next question has been largely answered, which was whether GPs do receive any basic training in allergy. It seems that the answer is no. However, in so far as they do get training, who is likely to provide it and at what stage in their career?

Dr Levy: There is some undergraduate training. The only evidence we know is from Edinburgh University, where about 26 per cent of the 46 modules include an aspect of allergy, but it is the theoretical aspects and not focusing on diagnosis and investigation. Where the GPs get their training is determined by self-interest and self-drive. If you are lucky enough, you can spend some time with a specialist in their clinic but most of the training is theoretically based, like the Education for Health and the courses that Dr Ewan has mentioned.

Q337 Lord Soulsby of Swaffham Prior: There is a deficiency amongst general practitioners, I suspect, from what you say, but what are the incentives for GPs to undergo specialist training in allergy diagnosis and management?

Dr Levy: There is virtually none. If we look at central drivers from the Department of Health or the Quality and Outcomes Framework, it includes asthma, which could include an aspect of allergy, depending on the expertise of the GP looking after the patient, but invariably asthma management would not focus on allergy. Local incentives are driven by the primary care organisations and based very much on savings at the moment. Allergy does not feature at all. A patient with cardiovascular disease or diabetes would get a lot of attention but not someone with allergy. As far as I know, there was only one general practitioner with a special interest in allergy in the whole country—and that was myself—employed by a primary care trust and that was for only nine months on an experimental basis. Despite demonstrating benefit for the patients and savings, allergy is not one of the primary care trust priorities and the clinic closed down.

Q338 Lord Soulsby of Swaffham Prior: Could the postgraduate medical centres with the postgraduate deans stimulate an interest amongst GPs?

Dr Levy: Obviously GPs will try to provide the best care for their patients, so if there is a talk or a lecture on allergy and they do not know much about it they will attend, but the key driver at the moment is work and availability of work. If you want to do general practitioner special interest work, a lot of GPs will focus on areas where there is work; that is, dermatology and cardiology.

Dr Egner: I am sure there will be many general practitioners who would want to update. Adding an additional specialty to your practice provides professional interest and clinical development. I have two general practitioners who work for me. Just to illustrate that these posts are few and far between but entirely dependent on local initiatives: they work as clinical assistants because I do not have access to any formal programme for the development of GPs with specialist interest—and nor does any allergist or immunologist have access to that, although they are established in dermatology and rheumatology. One of those has done the Southampton MSc course, as a result of which she had to undertake 18 hours, I think, of practical training in a clinic and that is how she came to me, and stayed, and has developed expertise in allergy. The other is probably about to do that on one of the other courses and again is developing expertise. But there is no formal basis for this. They will not achieve a qualification for this, there is no mechanism to give them one, but they will and have already gained specialist expertise which no doubt will be of use to the service in the future.
Q339 Lord Soulsby of Swaffham Prior: Is allergy, as opposed to asthma, part of the Quality and Outcomes Framework for GPs? If it is not, should it be?
Dr Levy: It should be. Those of us who made proposals for the last Quality and Outcomes Framework did recommend that allergy was included. It was not accepted, unfortunately.

Q340 Lord Soulsby of Swaffham Prior: If we were to make a recommendation—
Dr Levy: That would be a key driver to stimulate GPs to know more about allergy. It would drive courses; it would drive increase in quality of care; and I think it would generate a lot of savings in the Health Service. It will reduce referrals and benefit patients and general practice generally.

Q341 Lord Rea: Are there easily identifiable criteria on which you could allocate the points that form part of the Quality and Outcomes Framework with regard to allergy? Have these been worked out, as to how you would assess whether the doctor qualified for a point if it were included in the Quality and Outcomes Framework?
Dr Levy: There are various ways of addressing this. One of the ways that we suggested was quality of clinical care. For example, patients with asthma who also have food allergy are at very great risk, the risk of dying, from allergic crises. GPs were asked to record the proportion of patients who had asthma and food allergy as being assessed. That could generate a useful indicator of quality of care. Unfortunately a lot of the Quality and Outcomes Framework points are derived by ticking boxes and there is very little evidence that quality care lies behind that. There is some research going on in Manchester at the moment which will hopefully enlighten us.

Q342 Lord Rea: Do you think it would be a help for allergy to be included in the Quality and Outcomes Framework, even though the measurement of useful activity in that field is difficult to measure?
Dr Levy: If diagnosis confirmed by investigations was one of those criteria, you would need to provide evidence that investigations were done and that could be a useful example of a good outcome. There are numerous steps that could be provided. The key thing is to get the word “allergy” into the Quality outcome Framework.

Q343 Earl of Selborne: Could you tell us what strategies, if any, are in place to monitor allergy training at the primary care level.
Dr Levy: Unfortunately, none.

Earl of Selborne: I think we know the answer.
Chairman: Yes, we have heard that loud and clear. Thank you for confirming it to us.

Q344 Lord Taverne: The picture we have is of terrible mess. Is it right to say that this is probably the weakest aspect of medical training in this country?
Dr Ewan: Yes, I should think it is. You have to put it in context in relation to the clinical need. What is quite shocking about allergy is that we have this very small service on the specialist side, we have virtually no knowledge in primary care, and yet we have a huge patient burden. It is almost as if this has caught up and the NHS has been caught on the hop and has not realised what is happening. There has, indeed, been a big change in allergy in terms of patient need, not only in numbers, which have increased very substantially, but also in severity and complexity. There is this major need and patients are really being very poorly served by the Health Service. We are back in the Middle Ages trying to think about it. We have had a series of inquiries about it, nothing much happens, and unfortunately now the whole process has got caught up in the financial problems of the NHS and it is difficult to see local PCTs having any hope of sorting this out.

Dr Leech: Allergy was not recognised as a sub-specialty by the College of Paediatrics and Child Health until 2000 and it affects 20 per cent of the population.

Q345 Countess of Mar: How often is it that your patients come to you and say, “I think I have an allergy and it is this”? Is it more frequent than the training you get?
Dr Levy: Most of the time the patient gives guidance to the GP on where the problem lies. We are taught at a very young age: If you want to know what is wrong with somebody, you listen very carefully to what they tell you.

Q346 Lord Colwyn: I remember some of my training—it was a long time ago now, in the sixties—and the allergy part of the training was related to dealing with emergency procedures and reactions to drugs and various things, particularly as a dentist, that you inject into people or do to people. Would you consider that a part of the training?
Dr Levy: Anaphylaxis is certainly—

Q347 Lord Colwyn: Not necessarily anaphylaxis but even less serious reactions.
Dr Ewan: Yes, drug allergy is a very big part of allergy now. It is mostly processed in the specialist centres. Unravelling drug allergy is very complex and difficult and it is an increasing problem.
**Lord Colwyn:** If you inject some local anaesthetic into a patient and they pass out, you have to know what to do about it.

**Q348 Baroness Perry of Southwark:** I am turning to the training of consultants now. Given that you have eight coming out every five years, how has the number of allergy consultants changed overall in recent years?

**Dr Ewan:** There has been an increase, although it is a small increase in a small total. In the last five years we have had about five additional consultants, which is not very much but there is some growth. Part of that has been by recruiting doctors from overseas and some of it has been generated from our own trainees.

Another change which is perhaps beneficial is that, of these recently appointed consultants, most have been NHS funded—which is a change. Of the existing number—we have 34 consultants in allergy—a considerable proportion are academically funded. Whilst that is excellent in one way, in another it means the service may not continue beyond the life of the head of department. Recently there was a big problem at Southampton when the Professor of Paediatric Allergy left and it was not sure if the service would fold. So far it has managed to limp along, and it may survive in fact. Having some NHS funding in the system is good. I think we have had more growth in paediatric allergy than adult allergy.

**Dr Leech:** We have eight consultants in paediatric allergy. Two of those were appointed prior to 2000. Six of those have been appointed post 2001. Of those six appointments, three of them are academic appointments. Two that pre-dated 2000 are also academic appointments.

**Q349 Baroness Perry of Southwark:** Are those figures UK wide or England?

**Dr Leech:** This is England. And we have had one paediatric allergist who has emigrated to Ireland.

**Dr Egner:** Yes, I totally endorse the fact that, in terms of appointments of allergists, whole time allergists specifically, there has been a shameful lack of posts created. We need to address that. We should not forget, however, that immunologists do practice allergy as a core part of their practice and there have been 23 of those appointed in the last 10 years—on a small base as well, because there is only a total of 61 according to the RCP census in 2005. Most of the trainees would look to practise allergy in some way, some as specialists, involving most of their clinical activity, and others as a smaller part of their general activity. Knitting those into the picture of allergy service provision and getting a network that enables appropriate referral pathways, care pathways and guidance, is critical to making a better use of what we have got, whilst also supporting the development of pure allergists as a specialty and paediatric allergists particularly.

**Q350 Baroness Perry of Southwark:** What is the evidence that it is an attractive specialism? Do you have difficulty attracting people into the course? If there were more training places provided, would it be easy to recruit people?

**Dr Ewan:** So far it has not been difficult to recruit people but we have had a small number of places. I think one of the difficulties is the small number of consultant posts and really what is needed is a planned, coordinated development, creating more training posts but also with a promise of more consultant posts for them to move into. Equally, there are problems. For example, I have funding for an additional consultant post and I cannot see a suitable trainee to take it because there is nobody coming out at the moment. It is very difficult to balance this when you have a small specialty. You are trying to argue the case for funding for a new post and getting trainees to come through. One thing perhaps we should add to this discussion about the numbers is that the way you get more people is having champions for the cause. You only get more money—because money is short everywhere—by having somebody there who is pressing for the case, and we have too few of these. So it is a slow growth.

**Q351 Baroness Perry of Southwark:** Are the consultants spread widely across the country or do you have a concentration in a few centres?

**Dr Ewan:** With the allergists, they are concentrated in a relatively small number of centres. There is not a geographical spread, so patients are therefore disadvantaged.

**Dr Leech:** The paediatric allergists are concentrated in four centres in Britain.

**Q352 Lord May of Oxford:** Do you think the NHS monitors sufficiently and thinks as carefully as it ought to about the cost-effectiveness of consultant-led allergy services against other forms of service delivery? I also have a couple of follow-up questions on alternatives. One is turning to services, as it were, out in the community and the other is turning to the academic basis of understanding immunology.

**Dr Ewan:** No, I do not think they monitor what is going on. One of the problems is that the NHS centrally has not had allergy on its radar until quite recently. They do not record properly what is going on with allergy in the NHS because it is a Cinderella subject, it is a new speciality. There is now an allergy code, which was introduced into the NHS in 2005, but that has only been implemented by the specialist centres. They are now recording their work, and it could be pulled out centrally by the Department of...
Health as numbers of allergy patients seen, but, for much of the rest of allergy, which is diffused through other areas, there is no proper recoding of what goes on. The department does not have a good handle on even what is happening in allergy. In terms of cost-effectiveness, no, I do not think they have begun to be able to address this.

Dr Egner: I do not think there is any good data at the moment. I think it is going to be very difficult to generate good data until we have standards of care, agreed referral guidelines and care pathways and an effective and equitable network of services which allow local access to people in a geographically equitable distribution around the country. For example, we have heard how the adult allergists and the paediatric allergists are very much concentrated in the South East, whereas the immunologists are spread out over the North and South West and Wales. That all needs to knit together and we need to standardise care before we can look at the different models that are out there, before we can compare them and know what is cost-effective. The other thing is that many of us who are attempting to demonstrate leadership are trying new models of service. I am a single-handed immunologist—I will not be for much longer, thank goodness, but have been for the last five years—yet we have managed to develop services using multidisciplinary teams, nurse specialists, clinical assistants, and those are all strategies that need to be modelled and costed as a way of improving services for patients.

Lord May of Oxford: Are there any community care programmes which monitor the patients that have been referred to specialist services, so that you get an idea of what is going on in different parts?

Q353 Chairman: Dr Levy, did you want to say something on the previous question?

Dr Levy: The problem relates to diagnosis and then coding of the diagnosis. When general practitioners refer the patients, most of them are using computer-based systems and coding was one of the issues communicated to this Committee by the College of Child Practitioners’ report. If we refer patients into secondary care or, for example, a patient with allergic rhinitis to an ENT specialist, the code will be “ENT consultation” not “allergy consultation” so the information is not really there.

Dr Egner: We have forgotten how the Health Service is funded—or I had—until this question came up of tariffs. We cannot generate a tariff until you have some reasonable model of care and care pathways that are roughly similar throughout the country; otherwise you are going to end up with a cost in one centre that does not reflect the cost of the service in another and that will cause all sorts of problems.

Q354 Lord May of Oxford: It seems to me that this is much more broadly an area, like so many in medicine, where one is looking at the balance among the basic academic advances, the clinical application of them and somehow the specialist things like immunological training programmes to deal with it. I am really struck in this inquiry more generally at the contrast between this and HIV (which is something I know quite a bit about). I can understand why there is such an emphasis on understanding the dynamics of the immune system and the interaction and what is going on because of the magnitude of the global problem, but, if you were actually to do some weighted sum of the impact on health in the UK, you would probably find there ought to be more on allergy, and yet, compared to the sophistication of the understanding at the molecular level and not at the pathogenesis of HIV that we have and the number of ace people working on it, I am struck by the rudimentary nature still in our understanding of the immunological dynamics of much of allergies. Do you think this is just intellectual fashion? Do you think it is because there are things in other areas of immunology that lend themselves to more prestige or more to the solution? Why is it that this is so much more rudimentary than other areas? Or am I wrong in my impression?

Dr Ewan: I would have to disagree with you. We have excellent science and understanding of the basic immunology and mechanisms of allergy but we have—

Q355 Lord May of Oxford: It is still not generally agreed that peanut allergy comes from not being exposed to it younger. That is a pretty fundamental question.

Dr Ewan: Yes. We have very good basic science about the mechanisms and understand the allergic process. We lack, downstream of that, the clinical side. There are big gaps in clinical research. You have highlighted one very fundamental question. The other gap is clinical service. We do not have enough people who are looking at the clinical side, either research aspects or providing clinical service—and the two are interlinked—but we have international leaders in basic allergy research in this country.

Q356 Lord Taverne: I thought there was still a lot of contradictory evidence and uncertainty about the causes of certain allergies.

Dr Egner: The immunologist tends to have a finger in many pies but we are supposed to have mastery of the basic science of the immunological components of lots of diseases, from autoimmunity, through to allergy, through to primary immunodeficiency. There have been massive advances in the understanding of allergy but, without wishing to
and that is much more difficult to unravel. The other problem, as Dr Ewan points out, is that we do not have the network of services working in a standardised way in order to enable us to do the applied and translational research and service delivery research and cost-effectiveness research that we ought to be able to do very well in this country but we do not have the resources.

Dr Leech: I have one slightly cynical comment. I would ask how much of that HIV research is driven by pharmaceutical funding.

Q357 Lord May of Oxford: I would like to amplify what I said earlier, in the sense that I think your answer to me said that it is a mixture of the fashion at the academic end, in wanting to do clean questions rather than messy questions, as distinct from important. My impression would be that the community of academic/clinical people working on HIV internationally would be three orders of magnitude more than in allergy research. That seems to me out of whack. I personally think it is fashion, in a sense, but understandable fashion.

Dr Leech: I think a lot of allergy research is around the basic science research but then the areas of uncertainty are around causes of allergies, particularly early life events and allergen exposure. I think the teams that are working on those research areas find it very difficult to find funding for those types of research projects.

Q358 Lord May of Oxford: And not just for pharmaceutical things, it seems, but in the medical research category, it is the same people who like the neat questions rather than messy questions.

Dr Egner: In many ways the recent Cooksey report on the future of funding of research in the NHS addressed this question. It basically said that applied research was under-funded. You are only as good as your last research grant and the outcome of that. In a competitive research environment, it is a brave person who goes into a messy area with no clear outcome because they have to justify their subsequent academic funding.

Lord May of Oxford: There is a discussion this evening at the Royal Society which you probably know of.

Chairman: I wonder too whether there has been a huge drive through general public pressure. Whereas diseases such as cancer and HIV are seen to be life-threatening primarily, diseases related to allergy are viewed much more in the public eye as being some kind of inconvenience rather than life-threatening and therefore they have taken a low priority in the political pressure for research funding to go into those areas.

Q359 Lord May of Oxford: There is this concept of the disability-adjusted life years which is more and more used as a measure of medical impact rather than just looking at mortality. Has anybody looked into the impact of allergies by that kind of measure that is more conventionally used in the developing world, in terms of the disability-adjusted life year impact compared to just asking mortality?

Dr Egner: I am not sure about disability-adjusted but various other measures of quality of life indexes and so on have been used for allergic rhinitis, showing that it may not kill you but it can make a lot of people miserable and therefore is a considerable health burden. This applies to various other allergic diseases. And of course the fear of thinking you might die if you were to accidentally ingest a bit of peanut is awful. That is a major component of giving advice; trying to give people ways of coping with this and trying to reassure them, as far as we can, that they have appropriate treatment is a very important function.

Dr Leech: There is also good evidence that rhinitis can affect children’s performance in school. That aspect of quality of life has been investigated quite thoroughly.

Q360 Chairman: How much have things like the dermatology life-quality index been picked up in general practice research in relation to eczema?

Dr Levy: It is not on the Quality and Outcomes Framework so it is unlikely to be picked up as routine data.

Q361 Countess of Mar: I recall about 15 or 20 years ago there was a rush of papers which put a stigma on allergy, saying that it was “all in the mind”. Are you suffering from the tailback of that in relation to these multi-symptomatic, multi-system diseases?

Dr Leech: Yes. I think that has been a big problem in Britain. If you compare the development of allergy services in Britain with those in Europe and the United States, Britain has been in the backwater for the last 20 years, possibly as a result of papers you have described. In Europe and in the United States,
allergy has continued to grow and we feel we are just starting to catch up with what has been happening elsewhere in the world.

Q362 Lord Rea: In 2004 the House of Commons Health Select Committee produced a report and recommendations on allergy training posts and the specialist allergy workforce to which there was a Government/Department of Health response. Are the Royal Colleges satisfied with that response?

**Dr Ewan:** No, they are not, they are extremely dissatisfied. The Department of Health’s initial response to the Commons Committee was that on most of the key questions they evaded a direct response and said they would hold their own review. Those key recommendations from the Commons Select Committee were to increase allergy trainees and to increase allergy consultants and to improve training in primary care. When the Department of Health eventually did hold their review, which was a year-long review, at the end of it they produced a report which still did not address the Commons’ recommendations so they really remain unanswered. I think they completely evaded the main points. One of the difficulties is that at least the Department of Health in their review recognised and agreed with the problem, so they have accepted that there is a problem and the size of the problem and that there is a need to do something but they have not really addressed how one would go about solving it. They suggested in their report that this should be up to primary care trusts and to strategic health authorities so they have failed to take on any central responsibility for putting any pressure to actually bring about change. I think the difficulty now is primary care trusts have huge financial problems and so they have two roles really, firstly, to serve the health needs of their populations and, secondly, to balance their books and these two roles are incompatible and at the moment balancing their books is the priority, so to expect primary care trusts to be able to do anything for a new speciality or a growing speciality just will not happen; it is unrealistic.

Q363 Lord Rea: Are there any possible plans for maybe when this crisis is over—if it ever is—to encourage or endorse the creation of additional consultant posts for trainees to move into?

**Dr Ewan:** I think the first problem is that we need more trainee posts and we need more funding for them. There is no way the primary care trusts would be prepared to fund these at the moment. Although we are getting a few more consultant posts that is not primarily coming from PCT initiative; it is coming from the driver of local champions who have been pushing the service. I think the whole thing is extremely disappointing and speaking on behalf of the Royal College of Physicians, they are extremely disappointed with the outcome.

**Dr Egner:** The College of Pathologists are also disappointed with the outcome. If there were any positives that came out of the review, I suppose at least the intention to consider options for commissioning NICE guidelines is some form of progress and to work with the Royal Colleges on development of guidelines and referral and care pathways is a potentially positive development. It is good to see that the review recognised the multidisciplinary contribution to allergy services and a lot of good work and leadership that is already going on out there. What it did not do was give us any tools or any drivers which would help local champions, or individuals who were interested in setting up and running networks, or putting in place a governance structure and standardisation of care to work with and that was very disappointing. They left it to local commissioning, so deaneries were to decide whether or not they needed trainees in allergy—“to consider the options” I think was the wording—and commissioners were to consider whether allergy services were needed, but yet the whole thrust of the report was that allergy services are needed and are dreadfully under-resourced and they are inequitably distributed around the country and the training network could be better, so I am afraid overall a very disappointing outcome.

**Dr Leech:** The Royal College of Paediatrics and Child Health has similar problems. One of the additional problems is that there are so few paediatric allergy specialists and there are huge areas of the country where there is nobody to champion paediatric allergy services and those issues are therefore just not dealt with.

Q364 Chairman: We heard from the Department of Health that their plans are that a lot will be devolved out to general practitioners. Who is going to do the education of those GPs?

**Dr Leech:** That is the problem, there are not the people to do that.

**Dr Levy:** Without coding systems which identify the actual burden of allergy, GPs will not be aware of the need for training.

**Dr Egner:** I think we need to understand the context here. If all future developments are going to rely on persuading local commissioners and PCTs that they require local services, you have to be able to justify your existence by producing some data to show that you are a fit-for-purpose service that can meet national standards, but we do not have those national standards yet. You have to demonstrate that you provide value for money. You have to compete with 57 other medical specialities who are all...
producing cases that their services are under-resourced and you are doing this on the basis that you have a specialist workforce which is tiny and already over-stretched and the reality is that is going to make life very difficult. It is incumbent on us to try and do it, but it took a very long time for immunology to establish itself as a specialty and this is going to set allergy back quite some time.

**Q365 Lord Colwyn:** I think your evidence today and in fact all the evidence we have heard since this inquiry started, has made it quite clear that the paediatric and adult specialist workforce is totally inadequate. You mentioned earlier that there had been an increase of five consultant posts and six in paediatrics. Can you make any recommendation about how many consultant posts there should be in paediatrics. Can you make any recommendation about how many consultant posts there should be in the ideal world to deal with this increasing problem?

**Dr Leech:** The figure that was quoted in *Allergy: The Unmet Need* was 20 paediatric allergy consultants and 20 adult allergy consultants, and that was to provide one in each region of the country. I think that will probably just be a start. I think you would also need allergy consultants in each hospital.

**Q366 Lord Colwyn:** Our briefing from the Royal College of Physicians talks about one in 3,500 members of the public having some anaphylactic reaction and drug allergy responses are responsible for five per cent of hospital admissions. What are the estimates of the number of patients who have multi-system allergic disease or allergic problems?

**Dr Ewan:** This has been worked out very carefully and was produced in a paper by the British Society for Allergy and Clinical Immunology and submitted to the Department of Health review and a lot of work went into trying to calculate this. They tried to come up with some fairly conservative numbers because there is missing data over quite a number of these areas, but at a conservative estimate it was felt that about seven million patients had severe or complex or multi-system disease which warranted referral to a specialist. This still leaves an enormous number, many millions, a much larger number for primary care. There is no way that the sort of diseases in this seven million could be dealt with in primary care. There is not the time, the competence, it would be risky, there are more complex procedures required, so there is a huge burden. As Dr Leech has said, the Royal College of Physicians recommended this start-up of 20 extra adult and 20 extra paediatric consultants which was simply to try and get a centre in every area of the country so one had at least a focus to develop the services locally. At the same time the Royal College of Physicians Workforce Department calculated the true need and this was done in 2003 on the data at that time, which has probably increased a little since, and they calculated the ideal need, which of course no-one was expecting or asking for, would be 520 consultants. This is combining adult and paediatric allergy, so that puts it into context. It seems a ridiculously large number so asking for 20 and 20 was a start-up but it was thought important because that would begin to turn around the service. Even if it just doubled in size and one had this geographical spread it would be a very important focus to network with immunologists, to network with primary care and to grow the service.

**Q367 Lord Colwyn:** Is there a nationally agreed definition of “complex allergic disorder”?

**Dr Ewan:** It is all set out in this paper in detail.

**Dr Levy:** I wanted to just add that while I agree we need more specialists, it would be impossible for all of the patients with allergies to be treated by specialists, and while we are increasing the specialist contingency we need to focus quite a lot on primary care expertise. For example, access to tests and investigation. Very few primary care practices provide allergy testing. It is less than four per cent in fact who do skin-prick testing and access to specialised blood tests is variable throughout the country. In some areas we can get access to IgE tests but in most areas we cannot get access to specific IgE tests because of the cost.

**Dr Egner:** I think the consultant workforce and the GP workforce and the training issues and manpower issues related to those are all critical and key in terms of underpinning the structure but if there is such a big need we need to think creatively about how we can deliver these services effectively and nearer to the patient, which is the direction in which the Health Service is going. We should not forget nurse specialists, we should not forget GP clinics or GP with specialist interests and other mechanisms for delivering care closer to the patient, all of which we do not have models for at the moment nor any evidence for cost-effectiveness. I think all of these things need to be considered in the round.

**Q368 Viscount Simon:** Having heard how close immunology is to allergy, would there be any advantages in combining the Certificate of Completion of Training in Immunology with that for Allergy?

**Dr Egner:** I think that has been tried in the past and was not successful. It is a model that applies in other countries but I think we need a UK solution that best fits UK needs. I personally am in favour of it, others are completely opposed to it, and there are arguments and pros and cons on both sides. My worry about the future direction of consultant staffing in the NHS is that we need to retain flexibility. It is a core concept in the new medical world that people’s competences need to be configured for local needs and in many
Dr Ewan: we do not really know where we are going yet.

Chairman: Coming back to Viscount Simon’s question, one of the disadvantages of combining those two CCTs is that immunologists have many roles other than allergy. Allergy is one thing they do but they have an important role in providing a diagnostic laboratory service and looking after patients with immunodeficiency—some of them look after rheumatological problems or vasculitis—so they have a wide remit and allergy is part of that, in some cases a small part and for other immunologists a larger part depending on personal interest, whereas allergy is focused 100 per cent on allergy. In terms of need, the need is the allergy patient, so if you come at it from the patient perspective, it is less efficient to train people up to do a lot of other things where there is not an increased need whereas the allergy need is the important aspect. So that would be a disadvantage of combining the training because you would have to spend all these years doing training that immunologists do which allergists do not require to do.

Q369 Lord Colwyn: Do allergists get on well with immunologists?
Dr Egner: On a personal level, yes. It is quite normal, in fact it would probably be abnormal, if we did not have different views on how services should be constructed and in fact even on the allergy content of the curricula. What is important is whether patients are going to get the service they deserve? Specialist allergists are going to be extremely important and a key provider of allergy services, so how can we support them because they are in the situation that immunologists were in the 1970s. They have a very small (almost no) critical mass of specialists and minor changes to training, to recruitment and to the availability of jobs (which we need to look at as well because there is no point training people if no-one will employ them) can have disastrous effects on small specialities, which is why in many ways the situation with immunology and allergy and other specialists with a small workforce actually requires more nurturing and support from government policy and more drivers. Losing a few haematologists would cause major problems as they are already understaffed but it would not cause the whole service’s future to be in doubt, which could very easily happen with either of these specialties, and I think they both need to be valued and to be nurtured.

Q370 Chairman: Given the shortages that you have described and the uneven distribution of services, how do you see the resource of the immunologists, which seem to be a resource better spread geographically, certainly across the UK, being harnessed to meet clinical needs? How do you think that the shortage that you have outlined could be addressed in the short term by more collaborative working between the two groups in adult and also, possibly, with paediatric allergy as well?
Dr Egner: I think the paediatricians are an exemplar in this in that they work together completely; paediatric training is organised in a different way from adult training. We do already. The idea that we do not, I think, is incorrect. We have a joint committee of immunology and allergy; we have the BSACI, we have the new immunology society under the aegis of the BSI, all of which have an interest in promoting and developing the standardisation of services, networking and promotion of clinical guidelines. The Department of Health has made a statement saying that it is keen to facilitate that, and the Royal Colleges will have an interest in that. All of this can do nothing but strengthen our hand by allowing us to provide the evidence which the Department of Health review indicated was not there, in terms of what are the best models for service delivery, what is the most cost-effective way of service delivery and how can we improve training and education. In many ways, of course, it is back to us, is it not, to try and lead this? Immunologists and others work together very well in doing this. Some centres have both; some centres only have one—who knows what the right model is. It may be different in different places.

Dr Leech: The story for paediatrics is completely different. When you train as a paediatric allergist your fundamental training is within paediatrics—it is the same for immunology and it is the same for a paediatric infectious diseases consultant. The CCST that you get following completion of training is paediatrics, and then in brackets there is a recognition of your sub-speciality training. There are not separate sub-specialties for allergy, immunology and infectious diseases, so the sub-speciality you are awarded at the end of your, for example, mainly...
Q371 Baroness Perry of Southwark: Is allergy research a necessary part of allergy clinical training, and is it currently included in the curriculum?

Dr Ewan: It is a part, yes. Of the five-year training, one year is devoted to research, and it is an important part because it provides an important understanding of research and enables people to be able to independently conduct research in the future. It is also a very important part of learning, but there is a one-year component, which might be clinical or more basic research in the training curriculum.

Dr Leech: The way it works in paediatrics is that, again, we have got one year which is accredited for research but the trainee can do a research programme that lasts three years, but one year of that would be accredited towards their five-year training programme.

Dr Ewan: Immunology shares most of those features. Trainees are encouraged to do research because the skills and the critical thinking skills which are generated by participating in peer-reviewed research, either within programme or out of programme, doing an MSc or a PhD or a DPhil, is regarded as being useful in what are, basically, cutting-edge specialties with complex science that require you to keep abreast of the literature and to somehow translate that, eventually, into something which can be used in the clinic. That is equally true for paediatric and adult allergy and adult immunology, but it is not mandatory; you do not have to. As Dr Ewan alluded to before, the good news, but also the bad news, is that most new posts are being based on service commitment. They are NHS posts, and what PCTs are interested in is how many patients can be seen and given appropriate care and advice most effectively.

Finding time for research and development within those heavy and increasing commitments is an increasing difficulty for both trainees and existing consultants, as historically that has always been an important role of immunologists and now it is to generate new applied research. Most of them are based in academic centres, but there is a separate pathway now for people who wish to specialise in academic careers, who are expected to slot into this at a very early stage in their career before they have taken any other training. There are worries about how that will affect our ability to deliver research and development, and the future role of the specialities in that, but we do not know how that is going to pan out. I should point out that the research someone chooses to do depends on local opportunities and interest. For example, at least two of the immunology trainees in post at the moment are doing PhDs and DPhils in allergic conditions or immunotherapy. I do not know about the allergy trainees.

Dr Levy: We have had a number of questions related to evaluating quality of care, and in primary care while research training is not essential as part of clinical training it would certainly help if it was incorporated within primary care training, both to understand the literature that is coming out and, also, politically, to defend oneself against the claims of ‘evidence-based’ decisions by managers. A lot of our services are determined by primary care organisations, and very much on the basis of evidence, which the managers have interpreted, and I think it would be helpful to be able to have a clearer understanding in general practice.

Q372 Baroness Perry of Southwark: I was going to ask a supplementary, but it might chime with what you were going to say. I just wondered if the Walport process, with the additional fellowships and the 11
new training posts, is going to make a substantial difference.

Dr Egner: It might if we bid, but I have not been involved.

Dr Ewan: It would depend on whether any of them were allocated to allergy.

Q373 Chairman: We had heard from Professor Sally Davies when she gave evidence to us that there were 11 being allocated specifically to allergy. That was in our first evidence session.

Dr Egner: It is good news we are not aware of!8

Dr Leech: 9

Q374 Lord May of Oxford: How do the curriculum for allergy training and the number of allergy training posts in the UK compare with other OECD countries, like the US or Australia and, most particularly, with other countries in Europe?

Dr Ewan: I am a representative for Allergy in Europe, and the Union of European Medical Specialties has an allergy section, and they have recently developed an allergy curriculum for Europe, trying to bring together the various countries in the EU. The curriculum is quite similar to the UK curriculum and they partly used the UK curriculum when developing the European curriculum. There have had to be some variations in terms of duration of training, because there are a lot of differences between individual countries as to how they practice. In some countries of Europe allergy is a full speciality and in others it is a sub-speciality. For example, in Germany it is heavily linked to dermatology, so there are variations between individual countries.

Q375 Lord Colwyn: In each?

Dr Ewan: Each.

Dr Egner: Just to emphasise their heterogeneity; in a EUMS survey of 23 European countries, which I think was presented at the European Congress of Immunology in 2006, there were 16 European countries with training programmes in immunology, five of whom were joint with allergy and include allergy within that training programme; seven had stand-alone allergy programmes and six had stand-alone laboratory immunology programmes (which would not be a runner in this country). In Australasia they have two programmes, a three-year training programme, which effectively produces a physician immunologist and allergist who can see patients with any spectrum of immunological or allergic disease, and a four-year programme which includes laboratory training which also qualifies that individual to supervise the laboratory, which is core to, certainly, the UK immunology training programme, because that is a core competency.

Q376 Lord May of Oxford: Is that actually co-ordinated in Australia and New Zealand?

Dr Egner: Yes, it is. It covers both and it is a model I particularly like.

Q377 Lord May of Oxford: How about the US? Is that that too varied to be able to give an answer? I do realise the written thing you were given just said “Europe” and I am not quite sure why.

Dr Egner: There are laboratory immunologists who do have little in the way of clinical practice in the USA, and most of their physician practice is dedicated to serving allergy.

Dr Ewan: I do not know the numbers in the States but they are very large. However, allergy in the States will be either in hospitals and often linked to academic centres, and then there is a huge amount of private
practice. I do not know the numbers, but it is enormous.

**Dr Levy:** There are probably a lot of hidden allergists in Europe. For example, in Germany a lot of primary care doctors are trained in allergy and they would not be counted amongst the consultants. Certainly in Scandinavia a lot of general practitioners provide allergy services. It is an area where we do need more information. Can I just ask, if it is not too big an imposition, if maybe some follow-up note could be sent about that. It would be really helpful.

**Chairman:** Yes, it would be helpful and it would help us understand the details which would fit with Lord Taverne’s request as well.

**Q378 Earl of Selborne:** I wanted to ask about the Global Asthma and Allergy European Network which offers training and educational activities. Do we take full advantage of these activities and do we adopt the standards and resource utilisation signalled by the Network?

**Dr Leech:** I spoke to John Warner yesterday who has a large part in GA²LEN within paediatrics. Their educational activities are that there is a sort of spring school in Davos for postdocs and doctoral scientists and then there is a summer school which is a clinical allergy school which they hold once a year. His response was really that they are preaching to the converted. These are people who are already interested in allergy and already committed to a significant part of their allergy service which, when you go on these courses, you can get knowledge from. It does not really filter down to the grassroots which is what I think we have identified as being needed here.

**Q379 Earl of Selborne:** Do you know whether any allergy treatment centre in the United Kingdom has ever been certified by this Network either at certificate level one or two?

**Dr Ewan:** No, they have not yet. This is a very recently introduced scheme. There are three centres in the UK which might be possible to be accredited at level two which is Guy’s and King’s, and the Brompton and Cambridge might be possible centres, but no one has yet made an application. It seems a very complex and quite bureaucratic process just submitting the application, but these centres are considering this at the moment. Another thing perhaps to mention in relation to GA²LEN is that they do produce guidelines on management of allergy, so they have a number of educational initiatives in addition to their training courses. Of course we do in the UK have guidelines on allergy, but we are perhaps behind Europe in the number we produce, but the British Society of Allergy and Clinical Immunology produce guidelines on the management of certain disorders and this is a relatively new initiative that has only been going for the last three years, so that is in progress, but there are GA²LEN guidelines which are quite helpful within education.

**Dr Egner:** A very important initiative, although whether it will have practical implications for the practice and management of allergy patients in the UK remains to be seen because in the UK-based guidelines, practice differs—and not only within the UK, but within Europe and America—so there are many guidelines which are freely available from the American Academy of Clinical Allergy, Asthma and Clinical Immunology, but they cannot be directly translated into service-based guidelines here. There are lots of local initiatives that we need to network and share. For example, locally we organise our allergy practice using standardised guidelines, protocols and care pathways which are modelled on those immunologists use in immunodeficiency. There is a national network of all UK PIN clinics and you are required, in order to be accredited, to have a quality manual, a quality statement, document-controlled guidelines which cover your nursing, your doctor-led activities, your dietician activities and care pathways for individual patients, and I think that is a very useful model and some centres are already sharing this. For example, we are doing that within Trent to see if we can standardise care within the immunology and hopefully the allergy centres there. I think sharing good practice is something we could do a lot better and we could do much to facilitate networking. I think the GA²LEN guidelines and international guidelines may inform this, but they will not replace them.

**Q380 Chairman:** I just wondered, to wind up, if I could ask each of you if you in turn could identify what you think is the single most important issue to address to drive up, and improve, allergy education and thereby also help the service needs.

**Dr Ewan:** I would like to see more funded training posts in allergy.

**Dr Egner:** I would like to see that, but first I would like to see standards, a network, and models of care in place as well.

**Dr Leech:** I would like to see many ways of increasing allergy awareness for the people who are responsible for delivering care to the patients who are, in our service, general paediatricians and general practitioners as well. I think that needs a bottom-up and a top-down approach.

**Dr Levy:** I think including allergy or aspects of allergy in a quality outcomes framework would be key.
Chairman: Thank you very much. Could I thank you all for coming for this session and for having helped us explore these difficult issues. If there are things which come to mind when you leave here, please do submit them in writing to us and they will supplement the evidence we have had from you today. You will be sent a copy of the transcript for you to look at and correct for accuracy in case anything has been taken down inaccurately. I believe, Dr Ewan, we will have the pleasure of coming to see your unit, so there may be other aspects which you would like to share with us then. May I finish by thanking you very much indeed for being here today.
Memorandum submitted by the Food Standards Agency

INTRODUCTION

The Role of the Food Standards Agency

Responses to questions posed by the Committee that are relevant to the work of the Food Standards Agency

Defining the problem

What is allergy? What is the difference between allergy and intolerance?

What is and what is not known about the origins and progression of allergic disease? Why is the incidence of allergy and allergic diseases rising?

Why does the UK in particular have such a high prevalence of allergy?

Treatment and management

Is the level of UK research into allergy and allergic disease adequate?

What are the most promising areas of research into preventing or treating allergy?

Government policies

How effectively are food policy and food labelling regulations responding to the rise in food allergies?

Patient and consumer issues

What impact do allergies have on the quality of life of those experiencing allergic disease and their families?

What can be done to better educate the public and to improve the quality of information that is available to patients and undiagnosed sufferers?

Are current regulatory arrangements, for example, those governing private clinics offering diagnostic and therapeutic services and the sale of over the counter allergy tests, satisfactory?

INTRODUCTION

The role of the Food Standards Agency

The statutory objective of the Food Standards Agency (the Agency) is to protect the health of the public and the other interests of consumers in relation to food and drink. The Agency was set up in April 2000 as a separate Government department, at arm's length from the political process (although accountable to the Westminster Parliament and to devolved equivalents through Health Ministers) and with a clear objective. The independence of the Agency is given effect both by its formal status as a non-Ministerial UK Government Department, led by a Board appointed by UK Ministers to act in the public interest and by its powers to publish the information and advice that it issues, including advice to Ministers.
Our role in relation to food allergy and intolerance is to develop policies that allow consumers to make informed choices about their diet. We do this by negotiating and implementing legislation to improve statutory control on labelling of food allergens, and also by providing best practice guidance for industry and enforcement bodies to encourage greater awareness and control of food allergens through the food supply chain. We also provide advice about food allergy and intolerance for consumers so that they understand and can use the information provided to them by food businesses. We do this via our website and through published materials to help consumers make informed food choices that will ensure their safety, whilst not unduly restricting the choices available to them. We also commission scientific and consumer research on food allergy and intolerance to ensure that policies are based on robust evidence.

Food labelling is an area of EU competence and therefore national legislation in this area implements the relevant EU legislation. We negotiate on behalf of the UK to ensure that EU legislation in this area addresses the needs of UK consumers and industry. However we also produce best practice guidance to advise industry and enforcement bodies in areas not currently covered by EU legislation and also help to ensure appropriate training is provided.

We have responsibility for food policy and therefore this submission concentrates on food allergy and intolerance. However, the symptoms seen in many people exhibiting allergic reactions to foods include those associated with other non-food types of allergy (such as respiratory and dermal reactions), as well as gastrointestinal symptoms and possibly anaphylactic shock. Proper diagnosis and appropriate dietary avoidance strategies may help to reduce the incidence of respiratory and dermal allergic reactions. There is evidence (Pumphrey, unpublished data) to show that a significant proportion of fatal asthma attacks are triggered by allergic responses to foods that exacerbate existing, poorly controlled asthma. Furthermore, sulphites used in many foods as a preservative are also known to trigger attacks in a proportion of asthmatics. In addition, egg and milk allergies are associated with eczema in young children.

**Responses to Questions Posed by the Committee**

The Agency welcomes the opportunity to provide evidence to this inquiry. We have structured the main part of our evidence around those questions posed by the Committee in its call for evidence that are relevant to our remit.

1. **Defining the Problem**

   **What is allergy? What is the difference between allergy and intolerance?**

   1.1 Although food allergy and food intolerance are both types of food sensitivity, they are different conditions. The main differences between them are that food allergy involves the immune system, and specifically the production of IgE antibodies against the food protein in question, whereas food intolerance generally does not involve the immune system. Other differences include the length of time it takes for symptoms to appear and the type of symptoms involved. When someone has a food allergy, their immune system reacts to a particular food as if it is not safe. This causes immediate symptoms, which generally include itchiness, rashes and swelling, but can also include more severe respiratory and gastrointestinal symptoms. Sometimes this reaction is so severe that people can experience life-threatening anaphylactic reactions, which affects the whole body, often within minutes of eating the food, although this can take longer.

   1.2 The foods that most commonly cause allergic reactions in the UK are peanuts, tree nuts (such as almond, hazel nut, walnuts, and Brazil nuts), milk, eggs, fish and shellfish but many other foods are also capable of inducing allergic reactions in some individuals.

   1.3 Food intolerance generally does not involve the immune system, although gluten intolerance (coeliac disease) is an auto-immune disease. Some food intolerance reactions are caused by an inability to digest a particular food, for example because of a lack of a specific enzyme (such as lactase in people with lactose intolerance), but often the mechanism of the reaction is unknown. Usually symptoms are not immediate although there are some preservatives and flavour enhancers that can cause flushing or wheezing in asthmatics soon after eating. The symptoms can be unpleasant and severe in some cases and they can affect long-term health, but they are generally not life-threatening.

   1.4 People with a food allergy need to avoid all forms and traces of that food, however small the amount. However, people with food intolerances can often tolerate small amounts of the food without noticeable symptoms, although the amounts that can be eaten without symptoms will vary.
1.5 There are many foods that people can be intolerant to, but the most common food intolerances are to milk (cows’ milk protein intolerance) and lactose (milk sugar), gluten (a protein found in cereals such as wheat, barley and rye), wheat, food preservatives, and naturally occurring compounds in foods, such as caffeine and some amines.

What is and what is not known about the origins and progression of allergic disease?

1.6 We know the basic immunological mechanisms of food allergy and how reactions occur. Allergic diseases normally develop in two phases. First exposure to the inducing allergen results in a primary immune response (sensitisation) which primes the immune system for subsequent exposure to that allergen. When the sensitised person is subsequently exposed to the same (or a cross-reactive) allergen, there is an accelerated and more aggressive immune response that results in an inflammatory reaction and the clinical manifestation of allergy. The reaction is usually caused by specific IgE antibodies that are reactive with the food protein. These IgE antibodies attach to certain cells in the immune system and bind to the allergen. When they bind to the allergen, there is a resulting cascade of reactions that cause the clinical symptoms of an allergic reaction.

1.7 There are a number of other factors that help to determine whether an individual is likely to develop an allergic condition, including genetics and the ways in which they are exposed to an allergen (route, age and amount). Further details on these factors can be found in Annex I.

1.8 It is difficult to estimate the proportion of people with food allergy who will experience severe, possibly fatal, reactions. However, the most common identifiable causes of anaphylaxis are foods, medications, insect stings and allergen immunotherapy injections, with anaphylaxis to peanut and tree nuts being of particular concern because of its life-threatening potential. It is reported that one in two children with peanut allergy experience life-threatening symptoms with subsequent reactions. In 2004–05 there were 829 hospital admissions in England caused by anaphylactic reactions to food and a recent analysis of trends in admissions to hospital for food allergy has shown an increase of 500 per cent since 1990, with some evidence for an increase in the prevalence of peanut allergy in children. People vary considerably in their sensitivity to particular food allergens, and there is also considerable variability within an individual on different occasions, depending on factors such as the amount of the allergen consumed, the food matrix in which it is present, the underlying health of the individual and other as yet unknown factors. There is evidence to show that allergic reactions to foods can be significantly more severe in people with asthma.

1.9 However areas of uncertainty remain where further research is needed, including the role and importance of other (non-IgE) immunological factors on the regulation of the allergic response and the determination of whether an individual becomes allergic or tolerant to a particular allergen. Other emerging areas of interest include the role of T lymphocytes, including T regulatory cells, in determining immune status, the roles of other classes of antibody, such as IgG, in the food allergic response and an understanding of why proteins differ in their ability to cause food allergy.

Why is the incidence of allergy and allergic diseases rising? Why does the UK in particular have such a high prevalence of allergy?

1.10 Although there are a variety of existing hypotheses to explain the rise in the prevalence of atopic (a tendency to produce an IgE antibody response to a range of allergens) allergy and allergic diseases (see Annex I), there is no single agreed cause at the current time. Whilst the UK may have a higher incidence of some food allergies than some other countries, these countries may have a higher incidence of different food allergies. For example, there is a higher incidence of fish allergy in Scandinavia and a higher incidence of rice allergy in the Far East than in the UK. Differences in dietary habits and practices are thought to have a major impact on the incidence of particular food allergies in different countries but this is unlikely to be the only causative factor and research is ongoing to look at other possible reasons for observed differences. Further evidence on the prevalence of food allergies in the UK is given in Annex I.
2. **TREATMENT AND MANAGEMENT**

*Is the level of UK research into allergy and allergic disease adequate?*

2.1 We cannot comment on the adequacy of research into allergy in general. However we have a food allergy and intolerance research programme, which was established in 1994 by the then Ministry of Agriculture, Fisheries and Food and taken over by the Agency, when it was established in April 2000. The main aims of this programme (designated T07) have been to characterise factors that influence the pathogenesis of these conditions, focussing initially on peanut and tree nut allergy and on the later stages of allergic disease, when allergy has already developed. More recently the programme has been investigating what the prevalence of food allergy in the UK is and whether it is increasing, the factors that govern inter-individual differences in susceptibility to food allergy and whether it is possible to identify those at risk of developing food allergy. The programme has also included work on thresholds for sensitivity to gluten in order to better control the composition of foods for coeliac patients that are described as “gluten-free”, the characteristics of kiwi fruit allergy and the possible effects of some food additives on behaviour in children.

2.2 In 2000, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment published a report on adverse reactions to foods and food ingredients, which included a number of recommendations for research. Whilst some of these recommendations were directed at clinicians, academia and the Department of Health, others have been addressed within the Agency’s T07 programme. The outcomes from the T07 programme have been summarised in Annex II, but a number of other studies are still in progress. These address a range of important issues, including further investigations on the role of pre- and post natal exposure to allergens in the development of allergy or tolerance to food proteins, and the role of T cell responses in the development of allergic sensitivity or tolerance, the possible effects of additives on the behaviour of children and thresholds for tolerance to gluten. A list of the projects within the programme can be found in Annex II, and further details about the individual projects can be found on our website\(^{12}\).

2.3 This T07 programme was reviewed by independent experts in 2003 as part of a 5-yearly review cycle. The reviewers were complimentary regarding the outputs from the programme which increased understanding of the prevalence and mechanisms of food allergy and also resulted in specific information that led to improvements in the advice available to those affected. The review report,\(^{13}\) which was published on the Agency’s website, noted the need for the Agency to work with other funding bodies, both to improve the robustness of the research that is commissioned and to provide better value for money when the funding for such research is limited.

**What are the most promising areas of research into preventing or treating allergy?**

2.4 It should be noted that, at present, the only treatment for food allergy is avoidance of the food(s) in question. Although desensitisation treatments exist for some allergic diseases, such as hay fever, such approaches are not yet available for food allergies. Medication only deals with symptoms of a reaction once it is happening and medication, such as adrenaline injections, may not be effective if given too late after the reaction starts. There have been recent reports of work to produce recombinant versions of some of the allergenic proteins from foods that have been modified to reduce their allergenicity, which could then be used to desensitise the body’s immune system (immunotherapy), although actual treatments are still some years away.

2.5 The Agency considers that key areas for research are to determine:

- appropriate weaning practices for children, both those with and those without atopic backgrounds, with respect to the timing of introduction of the main allergenic foods, and the frequency and amounts to be given, so as to reduce the risk of allergy developing and promote the development of tolerance; and
- thresholds for allergens that can be used by the food industry to inform labelling decisions.

The Agency issued a call for research proposals to address these questions in March 2006 and is currently considering possible projects for funding.

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\(^{13}\) [http://www.food.gov.uk/multimedia/pdfs/t07review.PDF](http://www.food.gov.uk/multimedia/pdfs/t07review.PDF)
3. Government Policies

How effectively are food policy and food labelling regulations responding to the rise in food allergies?

3.1 One of the key aims of the Agency is to enable consumers to make informed choices about the foods they eat. In response to the apparent increase in the prevalence of food allergy and intolerance in the UK, we set out in our Strategic Plan for 2005–1014, that we would work to ensure that people with these conditions have the right information to ensure their safety and to prevent their choices from being unnecessarily restricted.

3.2 The Board of the Agency first discussed food allergy and intolerance at its open Board meeting in February 2003,15 in relation to a need for clear labelling and information, and agreed at that time to develop an Allergy Action Plan. Such a plan was agreed at a further open Board meeting in September of that year16 and updates on progress have been discussed by the Board subsequently in September 200417 and April 2006.18

3.3 The Agency’s Allergy Action Plan incorporates a number of elements, including improving food labelling (both statutory and voluntary), raising awareness of food allergy issues, particularly amongst caterers, and improving training, both for those working in all sectors of the food industry and for Local Authority enforcement officers. The Plan also encompasses improving the information available to consumers so that they can understand and use the labelling on the foods they buy. The Board will continue to review the progress of these initiatives and the Action Plan will evolve in response to changing needs. Further details regarding food allergen labelling, both statutory and voluntary, are given in Annex III.

3.4 Enforcement of allergen labelling legislation rests with Local Authorities but investigating incidents to ensure food safety is protected and food is correctly described is a key part of the Agency’s work. If an allergen present in a food is not correctly labelled, the affected food may be withdrawn or recalled and information is provided to enforcement bodies, and is also published on the Agency’s website. In addition, the Agency works to ensure that consumers with food allergies or intolerances are also informed of such incidents via their consumer support organisations. Food premises, including catering businesses, are inspected and assessed by Local Authority enforcement officers, and recent guidance to catering businesses on the implementation of safe catering practices included a section on good allergen control.

4. Patient and Consumer Issues

What impact do allergies have on the quality of life of those experiencing allergic disease and their families?

4.1 People with food allergies and intolerances face a range of dietary and social restrictions, depending on the numbers and types of foods to which they react. There is evidence to show that 9–10 year old children with peanut allergy have a significantly poorer quality of life than children of a similar age with insulin-dependent diabetes mellitus. Peanut allergic children reported more fear of an adverse reaction and more anxiety about eating, especially away from home. They also felt more threatened by potential hazards in their environment and more restricted concerning their physical activities.

4.2 Currently the choice of foods for allergic consumers can be limited and the financial costs for allergic consumers are higher than those who are not on a special diet. An FSA study in 2002 on “May Contain Labelling—The Consumer Perspective” found that nut allergic consumers took an average of 39 per cent longer to shop and paid 11 per cent more for food.

4.3 Consumer research conducted by the Agency in 2005 into the information needs of teenagers with food allergies and intolerances showed effects on social and inter-personal life, difficulties in fitting in with peer groups and dietary restrictions. Given that many social interactions in this age group are centred on eating and drinking, such conditions significantly impair their quality of life. There is evidence that a significant proportion of adolescents and young adults admit to risk taking behaviours (such as eating foods that carry ‘May Contain’ labelling, a reluctance to ask questions about the allergen content of foods, especially in restaurants, and not carrying their medication), partly in response to a desire to avoid social isolation.

4.4 In addition to providing information for consumers, the Agency also raises awareness of food allergy issues with food businesses and Local Authority enforcement bodies, by providing best practice guidance and helping to ensure that appropriate training is available (see Annex III).

17 http://www.food.gov.uk/aboutus/ourboard/boardmeetings/boardmeetins090904/boardminutes090904
18 http://www.food.gov.uk/news/newsarchive/2006/apr/openboard0406
What can be done to better educate the public and to improve the quality of information that is available to patients and undiagnosed sufferers?

4.5 Ewan and Clark demonstrated that the adoption of good management plans by food allergic patients (including detailed advice on avoidance strategies, treatment plans and prescription of medication for self-administration) reduced the rate of adverse reactions from about 50 per cent to 15 per cent.

4.6 The Agency has produced a fact sheet for those with food allergies and intolerances to help them successfully avoid the foods to which they know they react, including information on understanding food labels and advice for when eating away from home. This was made available on the Agency’s website in December 2004 and was subsequently publicised to health professionals via the GP and Chief Nursing Officer Bulletins issued by the Department of Health. Following feedback from dieticians, the Agency has recently updated this fact sheet, separating the information into two separate documents, one covering food allergies and the other food intolerances. This update was conducted in partnership with the British Dietetic Association and is being publicised to their members via their website.

4.7 The Agency has a consumer-facing website that contains a section on food allergy and intolerance issues, including background information on these conditions, and the foods likely to provoke such reactions, as well as advice on buying foods both in retail and catering settings. In addition, there is an ‘Ask an Expert’ function that allows consumers to pose questions which are replied to individually and some of the points raised are incorporated in a Q&A section on the website. Furthermore, the Agency provides information on its website explaining food labelling, including allergen labelling and information is also provided in the form of leaflets.

Are current regulatory arrangements, for example, those governing private clinics offering diagnostic and therapeutic services and the sale of over the counter allergy tests, satisfactory?

4.8 We cannot comment on the regulation of diagnostic and therapeutic services. However we receive many requests from consumers who have used over-the-counter allergy tests (many of which have not been formally validated for diagnosing food allergy), seeking advice to help them comply with the recommendations they have been given as a consequence of using these tests, to remove many basic foods, such as wheat and dairy products from their diets. We are concerned that many people follow such recommendations and restrict their diets unnecessarily without receiving proper clinical and dietetic support, which could lead to nutritional problems. We provide advice on our website and in response to correspondence that people should always seek advice from health professionals and dieticians before making major changes to their diet. The issue of un-validated tests was also addressed by the Royal College of Pathologists, who concluded that commercial allergy tests were not recommended and that some were of dubious scientific value. They also concluded that testing for allergy without first knowing a patient’s medical history was poor practice and likely to be unhelpful or misleading.

Annex I

Factors that Influence the Likelihood that an Individual Will Develop an Allergic Condition

1. There is a subgroup of the population with a predisposition towards mounting IgE antibody responses to allergens (atopic individuals). In addition, children whose parents and/or siblings have allergic diseases have a higher risk of themselves developing allergic diseases, although the form that the allergic disease takes may vary, depending on interactions with environmental factors and the nature and timing of exposure to potentially sensitising proteins.

2. One factor that influences the acquisition of atopy is programming of the developing immune system in the young infant. There is some evidence that increased protection of infants from pathogens and environmental non-pathogenic micro-organisms is associated with an increased prevalence of atopy (the so-called hygiene hypothesis). However, there is no unifying hypothesis concerning the exposure to overt viral and bacterial infection, the significance of environmental exposure to microbial compounds and the responses of the innate and adaptive immune processes. A recent review of evidence points to the view that fundamental changes in lifestyle that have led to decreased exposure to certain microbial or other species, such as helminths, rather

20 www.eatwell.gov.uk
21 http://www.food.gov.uk/asksam
than infection with pathogenic organisms or changes in domestic hygiene are important for the development of immunoregulatory mechanisms. Food safety measures are generally targeted at pathogens and do not aim to produce a sterile environment.

3. We do not know definitively why the prevalence of atopic allergic disease has risen in recent years but other possible causes include changes in diets and the introduction of “new” foods (e.g., peanuts in the 1940’s and kiwi fruit in 1970’s) may have led to an increase in the prevalence of some food allergies. Peanuts are now commonly eaten roasted rather than raw, and roasted peanut is known to be more allergenic than raw peanut.

4. Some individuals have been reported to react on their first known exposure to peanut, generating the hypothesis that maternal transfer of the allergen or immunological components may be an important factor in the development of food allergy. It is recognised that intrauterine immunological sensitisation can occur and that transmission of food allergens to infants via breast milk in an un-degraded form may be a route of neonatal sensitisation. Research on the influence of maternal diet during pregnancy and the development of food allergy in the offspring is still inconclusive and the Agency is currently funding research in this area. Peanut allergy is highly associated with a family history of allergic disease, and it is currently not possible to discount the possibility of a link between consumption of peanut by the mother during pregnancy and lactation and the incidence of peanut allergy in the offspring. Therefore the Government issued precautionary advice to mothers in 1998 to avoid eating peanuts and peanut products during pregnancy and breastfeeding if their child had a family history of allergic disease.

5. Other factors that may be important in the development of food allergy include the age of first exposure to the allergenic food and the route of exposure. Weaning practices have changed significantly over the last 50 years, with evidence suggesting a trend towards the later introduction of solid foods, including commonly allergenic foods. There is currently a lack of evidence on the optimum times to introduce the common allergenic foods into the weaning diet, either in children from atopic or non-atopic backgrounds. Given that there is currently no cure for food allergy, it is important that evidence-based advice on the introduction of allergenic foods into the weaning diet is developed so as to minimise, where possible, the number of children that develop food allergy. The Agency called for research proposals to address this question in March 2006 and is currently considering possible projects for funding.

6. Recent research has demonstrated that dermal exposure may be an alternative route of sensitisation for food allergens (especially peanut), perhaps through use of creams/oils or through general low level environmental exposure if others in the household are eating peanut. Such low level dermal exposure, especially to broken skin, is associated with sensitisation and clinical allergy whereas high level oral exposure may lead to tolerance.

7. Furthermore there may also be an increase in occupational exposure to allergens, such as latex, which is known to cross react with a number of fruit allergens associated with oral allergy syndrome. In addition exposure via inhalation may be important in some situations, for example those preparing and cooking fish may react to the vapours produced.

Prevalence of Food Allergies

8. It appears that there has been an increase in the incidence of at least some food allergies in recent years, which is in line with the general increase in the prevalence of atopic allergic diseases. An increase in clinical peanut allergy in early childhood from 0.6 per cent in 1989 to 1.5 per cent in 1994–96 has been reported in the UK, with rates of sensitisation increasing from 1.1 per cent to 3.3 per cent over the same period. Peanut allergy is reported to be presenting earlier in childhood and is more common in siblings of people with peanut allergy. There is a similar situation in the US where the prevalence of peanut allergy was found to have doubled in American children under five years of age over a five year period.

9. Definitive figures for the prevalence of individual nut allergies in the UK are currently lacking. Peanut allergy is the most common cause of severe (fatal and near fatal) allergic reaction to foods. The Agency is funding projects to determine the current prevalence and incidence of specific food allergies in the UK and whether food allergy has increased in the last 20 years, including studies to investigate the effect on the incidence of peanut allergy of the issuing of the Government advice on the avoidance of peanut during pregnancy and lactation by mothers whose child has an atopic family background. One of these projects is

22 http://www.food.gov.uk/multimedis/pdfs/rrd21
part of a large European wide study (Europrevall\textsuperscript{23}) funded by the European Commission’s 6th Framework Programme. This will provide definitive data on the current incidence of a number of food allergies amongst children and adults across Europe (nuts will be included). The project is due to end in 2010 and the Agency is funding the UK birth cohort from this study.

\textit{Annex II}

\textbf{Food Standards Agency Research Programme}

1. This programme has extended and deepened knowledge and understanding of the prevalence and mechanisms of food allergy, and has revealed new information about different food allergies, and their causes and mechanisms, which has led to improvements in the advice the Agency provides. In particular the programme has:

- Provided evidence that dermal exposure to allergens such as peanut, especially on broken skin, is a risk factor for the development of peanut allergy. Such exposure includes the topical application of creams containing peanut oil and possibly also low level environmental exposure to peanut allergens in the home if peanut products are consumed by other family members.

- Investigated the role of maternal diets in the initiation of allergic disease. Early studies indicated that the majority of peanut allergic individuals react to their first known exposure to peanut and that it is not possible to rule out a link between consumption of peanut by the mother during pregnancy and lactation and the incidence of peanut allergy in the offspring. The Government therefore issued precautionary advice in 1998 for pregnant and breast feeding mothers whose children had a family history of allergic diseases to avoid consuming peanuts. However, subsequent studies have failed to demonstrate a conclusive link between the development of peanut allergy in children and the levels of circulating peanut antibody in the mothers’ blood or breast milk. Other studies have failed so far to demonstrate a link between maternal exposure to allergen and the development of food allergy in their offspring. However the Agency is funding a further study on egg allergy to follow up preliminary data suggesting that the level of exposure to the allergen might be critical in determining any effect. These studies have also demonstrated the difficulties faced by mothers who try to completely avoid common allergens such as egg or milk. Studies have also investigated the impact of the Government advice on peanut avoidance during pregnancy and lactation and the subsequent prevalence of peanut allergy in children and these are expected to be published shortly.

- Investigated sensitivity in the same subjects to peanuts and tree nuts, showing that multiple sensitivity occurs via sequential sensitisation rather than being due to immunological cross-reactivity. In general, children have been shown to develop sensitisation to peanuts first and then go on to develop sensitivity to one or more tree nuts. This has important clinical and policy implications and the advice for children sensitised to one type of nut is now to avoid ingestion of all types of nut. Children with nut allergy should be periodically monitored for the development of multiple nut allergies.

- Investigated the roles of T lymphocytes and IgG antibodies in the development of tolerance to food allergens. Many children with egg or milk allergy in early life lose their allergy by age 5 years but allergy to peanut is often life-long. Several current Agency-funded studies are investigating the mechanisms involved in the development of tolerance.

- Characterised kiwi fruit allergy as a new food allergy in the UK. We commissioned work to investigate this emerging food allergen which confirmed that kiwi fruit should be considered a significant food allergen capable of causing severe, life-threatening reactions. Furthermore, in the UK, children are more likely to experience severe symptoms to kiwi fruit than adults, possibly because of the age at which they were first exposed to this allergen. The information has been published in the scientific press so that clinicians will be better aware of kiwi fruit allergy (as a relatively new allergy), its characteristics and how to recognise and diagnose the allergy, which will in turn improve consumer safety. Information for consumers is also published on our website.

\textsuperscript{23} http://www.europrevall.org/
Areas for Future Research

2. Nutritional status in early life has been associated with general respiratory health in childhood. It is possible that nutritional factors may modify immune function and the susceptibility to develop atopic disease, such as asthma. The Agency is currently in contract negotiations to commission research on the influence of nutrition on respiratory health and asthma in childhood. The aim of the study will be to determine how maternal, infant and childhood diet influences respiratory health in the first seven years of life. It is expected that the results of the study will be available from mid 2010.

3. There is some evidence that early introduction of significant amounts of a food allergen as part of a weaning diet may help to promote the development of tolerance to food allergens but definitive evidence to support this, and an understanding of the optimal ages is lacking. We issued a call for research to address this issue in March 2006 and are currently considering possible projects for funding. Opportunities for joint funding are being investigated.

4. There is at present, a lack of data on individual clinical thresholds for the main food allergens. There is also a lack of agreement on threshold levels of allergens present in foods that should be used for deciding whether or not allergen labelling is appropriate. This information is urgently needed to inform both advisory labelling to warn consumers of possible allergen cross-contamination (“May Contain” labels) and the criteria needed to be able to designate a food as “free from” a particular allergen. In addition, information on levels of allergens for use as a basis for decisions on labelling will help to ensure that foods are not unnecessarily labelled when only a very low level of the allergen is present, which would restrict consumer choice. There needs to be international agreement of both the threshold levels of allergens in foods above which they need to be labelled, in order to protect allergic consumers, and on how these levels should be derived, given the significant inter and intra-individual variations that exist. We have issued a call for research proposals to address this issue and are currently considering how to take this forward.

5. There is also a need for validated detection methods for the main food allergens and for standard reference materials to calibrate such methods, and some work on this is being undertaken by the EU. The European Committee for Standardisation (CEN) is currently working on the development of standards to harmonise the development and validation of methods for the detection and quantification of food allergens. In addition, the European Commission’s Joint Research Commission has been working on the evaluation and comparison of allergen methods currently on the market and the development of certified reference materials to improve the performance of existing and future methods.

List of Projects from the T07 Research Programme

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**Food Labelling—Statutory and Voluntary**

1. The UK has been pressing the EU for improved labelling of allergenic ingredients in food for a number of years. In 2003, an EU Directive was agreed that required the labelling of 12 specified allergenic foods and their derivatives, whenever they are used in pre-packed foods, regardless of the level of use. A key element of this new legislation was the removal of the exemption in the previous labelling Directive, whereby the ingredients of a compound food ingredient (such as a sponge finger in a trifle, or slices of sausage on top of a pizza) did not have to be declared if the compound ingredient made up less than 25 per cent of the final food product.
2. This list of allergenic foods was based on advice from the European Food Safety Authority (EFSA) about the foods that are of the greatest public health concern across the European Union countries. This list currently includes the following allergenic foods and any ingredients derived from them:

- Cereals containing gluten
- Crustaceans
- Fish
- Eggs
- Peanuts
- Soybeans
- Milk
- Nuts
- Celery
- Mustard
- Sesame seeds
- Sulphur dioxides and sulphites at levels above 10mg/kg or 10mg/ml, expressed as SO₂

3. This European Directive (2003/89/EC) came into force in November 2004 and products not complying with its requirements were prohibited from November 2005. A further Directive (2005/26/EC) was agreed in March 2005 that exempted certain ingredients derived from these allergenic foods from these labelling requirements, on the basis of evidence that they were no longer allergenic.

4. The European Commission has recently agreed that this list of allergenic foods should be extended to include molluscs and lupin, as there is advice from EFSA that these also present a public health concern. The national implementing legislation will be amended in due course once the EU Directive has been published in the Official Journal, which is expected to be before the end of 2006.

5. The statutory legislation described above does not cover unintentional cross contamination of a food with an allergenic food at some point during production. Many food manufacturers voluntarily provide information on such a possibility with advisory labels using phrases such as “May Contain Nuts”. The Agency has conducted consumer research, which demonstrated that many consumers find the variety of phrases used for such labelling confusing, and are concerned that they are overused, and many therefore ignore such warnings. The Agency was also approached by food industry trade bodies asking for advice in this area.

6. The Agency has worked with all the relevant stakeholders to produce best practice advice on allergen management and consumer information, and this was published in July 2006. This guidance helps businesses assess the risk of possible allergen cross-contamination of prepacked foods and also advises them on how such risks can be reduced or eliminated, so that advisory labelling is only used when there is a real risk of cross-contamination that cannot be controlled. The guidance also advises on the phrases to use if such warnings are appropriate, as research has shown that consumers were confused by the wide range of advisory labels currently in use.

7. Foods that are not prepacked (that is foods that are sold prepacked for direct sale or those sold loose, including foods sold in catering establishments) are also exempt from most food labelling legislation, including the allergenic ingredients labelling legislation described above. There is clinical evidence to indicate that foods sold in this way are more likely to be the cause of adverse reactions to foods than foods sold prepacked. In addition, responses to public consultations have indicated that there is strong consumer demand for more allergen information for foods that are not prepacked.

8. The Agency produced advice for caterers on food allergy that was published on the Agency website in May 2004. The Agency is now working with relevant stakeholders to produce best practice guidance on the provision of allergen information for foods that are non-prepacked. A public consultation on draft guidance was issued on 5 July and closed on 27 September 2006. The responses received will be assessed and the draft guidance amended as necessary. It is anticipated that the final guidance will be published in Autumn 2007.

Reference List [not printed]

5 October 2006

24 http://www.food.gov.uk/safereating/allergyintol/caterers
25 http://www.food.gov.uk/consultations/ukwideconsults/2006/allergeninfoconsult
Examination of Witnesses

Witnesses: Mrs Sue Hattersley, Head of Food Allergy Branch and Miss Gill Fine, Director of Consumer Choice and Dietary Health, Food Standards Agency; Ms Andrea Martinez-Inchausti, Assistant Director of Food Policy, British Retail Consortium; Dr Ian Leitch, Chartered Environmental Health Practitioner; and Mr Les Bailey, Food Policy Officer, Local Authorities Coordinators of Regulatory Services, examined.

Q381 Chairman: Good morning and thank you for coming. Can I welcome those of you who are giving evidence to us today and also members of the public who have come to listen in on this session. This is the sixth hearing of our inquiry into allergy. There is an information note of the declared interests of members of the Committee so we will not be repeating those today during our evidence session. I would like to ask those of you who are here to start off by giving us a short introduction with your name and where you are from. I also remind you that this session is being broadcast today, so it is being broadcast. Could I invite you to start, Mr Bailey.

Mr Bailey: I am Les Bailey from the Local Authorities Coordinators of Regulatory Services. We are the central local government body that acts to try to co-ordinate the activities of local authority environmental health and trading standards departments. I deal with food standards, food composition and food labelling issues, which includes allergens. My previous background is in trading standards.

Dr Leitch: I am Ian Leitch. I come from an environmental health background from Omagh District Council. I am presently project manager for a food allergy project to train environmental health officers in food allergen control. That is sponsored by Safefood which is the Ireland food safety body and by the EU through a programme called CAWT which stands for Co-operation and Working Together and it is for training in the border regions. I come from an environmental health background with a particular interest in allergen control.

Ms Martinez-Inchausti: My name is Andrea Martinez-Inchausti and I represent the retailers. I am here representing the British Retail Consortium which is the trade association that represents retailers to both governmental and non-governmental bodies. I work as the Assistant Director of Food Policy and I deal with the majority of the technical legislative issues. My background is veterinarian.

Miss Fine: My name is Gill Fine. I am Director of Consumer Choice and Dietary Health at the Food Standards Agency. The Agency was set up in 2000 to protect the health of the public in relation to food and drink and also to reflect their interests. I head up a group of three divisions, one of which covers food allergy as part of its remit. My background is as a nutritionist.

Mrs Hattersley: I am Sue Hattersley. I am also from the Food Standards Agency. I head up the Allergy and Intolerance Branch within the Agency so I have the overall responsibility for that area of work.

Q382 Chairman: Could I start off by asking you as a panel whether there is any evidence that there may be a link between changes in the modern diet and an increase in the incidence of asthma and allergy? Would you like to start, Mrs Hattersley?

Mrs Hattersley: There is evidence that the prevalence of different food allergies does vary in different countries, depending on dietary practices. We know that weaning practices have changed very significantly in the UK over the last 50 years. There is evidence that different weaning practices across different countries might lead to different incidence of food allergy. If you look for instance, at Jewish children in the UK, there is a very different incidence of peanut allergy in that group compared to Jewish children in Israel, where they use a peanut snack as a weaning food. There are very clear dietary differences in different countries. We also know that the introduction of new foods into the diet can lead to new allergies and we have done some research on kiwi which is an emerging allergen in the UK. We also know that cooking practices can change the allergenicity of certain foods. Roasted peanut, for example, is much more allergenic than raw peanut, but cooked egg is less allergenic than raw egg.

Ms Martinez-Inchausti: I would agree with what Sue has said. What has also triggered an increased amount of allergies has been the increase of awareness both by paediatricians or practitioners and consumers, and the development of methods to diagnose those allergies has also triggered an increase in the numbers.

Q383 Chairman: I wonder whether there is any evidence that sulphites and preservatives, possibly even including things like trans fats in pre-packaged foods affect allergy sufferers, and in which foods are they found?

Mrs Hattersley: We know that sulphites can trigger asthma attacks in people who already have asthma and that is why sulphites are included on the list of allergens that have to be declared in pre-packed foods. If sulphites are added to foods that now has to be labelled so that people can avoid those foods.

Q384 Chairman: Could foods be modified to remove such substances from them so that we would remove the substances potentially contributing to allergic disorders?
**Mrs Hattersley:** It is very difficult. There has been some work done to look to see whether they could remove some of the allergenic proteins from peanuts but we know that there is not just one protein in the peanut, there are perhaps half a dozen different allergenic proteins. If you try to breed a peanut that has less of one protein it may be producing more of the other proteins and very often in the nuts and seeds it is the storage proteins which are allergenic so there tends to be very high levels of those proteins in the foods.

**Q385 Lord Taverne:** What research is the FSA supporting to identify the characteristics of foods which can lead to the development of food allergy and intolerance?

**Mrs Hattersley:** We know that most food allergens are proteins so we have done some research to look at the characteristics of proteins that make them allergenic and there are certain characteristics which tend to be associated with allergenic proteins. They tend to be resistant to digestion; they tend to be present in very large amounts; they tend to have multiple binding sites for the IgE antibodies. Some non-allergic proteins also have very similar characteristics so we think there are other factors involved as well. Other molecules attaching to the protein affect the allergenicity as well, so it is still an area of on-going research.

**Q386 Lord Taverne:** I gather that some of your research has been into early life exposure and pregnancy exposure which suggests that low level environmental exposure to allergens can actually lead to sensitisation, rather than the opposite, as it were, of sensitisation at those very low levels.

**Mrs Hattersley:** There is certainly some evidence indicating that low level environmental exposure to some of the allergens, particularly peanut, may cause sensitisation, whereas if you have higher dose oral exposure then that may lead to tolerance. This is the evidence that we are getting from the study of Jewish children in Israel, where they use the peanut snack as a weaning food. It found that if you have a high level oral exposure that actually leads to the development of tolerance, whereas if you have just a very low level exposure—sometimes dermal exposure—that may be leading to sensitisation.

**Q387 Lord Taverne:** Dermal exposure to peanuts?

**Mrs Hattersley:** Yes. We know that peanut oil used to be used in creams for eczema. Also a lot of natural cosmetic and toiletry products have nut oils in them, so that may be another route of exposure. Also, if other people in the household are eating peanuts then there may be peanuts on people's hands and it is in the general environment so that may be leading to sensitisation at those very low levels.

**Q388 Lord Taverne:** What about the effect of latex-containing packaging? Is that possibly something which could trigger dermatitis or exacerbate it?

**Mrs Hattersley:** We know that there is an increase in latex allergy in healthcare workers, for example, who wear a lot of latex gloves. There is also work being done to look at latex allergy in food handlers because some food handlers wear gloves. The Agency has done some research to try to develop a methodology for looking at levels of latex in packaging materials, to see whether that transfers into the food. At the moment we are starting to develop that methodology and there is a further project underway at the moment trying to develop that further so that we have a reliable test to see how much latex might be getting into the food.

**Q389 Lord Taverne:** What is your method of dealing with proposals for research into allergy? Do you take unsolicited proposals or do you only support contract studies?

**Mrs Hattersley:** Normally we issue open calls for research proposals, the Agency will do that on a regular basis. Three or four times a year we will issue calls for proposals, which may include calls on food allergy. People submit their proposals and they are independently appraised before we contract any research. People can also come to us if they have particular research ideas. One of the examples was the work that we did on kiwi allergy. Somebody came to us asking whether they could do a pilot study to look at the characteristics of kiwi allergy and we funded that. Then we funded further study into it because it looked like there was an issue there. It can be via either route.

**Q390 Earl of Selborne:** Still on the subject of research funding for proposals, there must be a lot of international work in this field and I wonder whether the FSA is confident that it can keep in track with other relevant research in other countries, particularly for example with something like the kiwi fruit you have just referred to. Presumably one would go to South Africa or New Zealand or somewhere to look at some of the work on relevant populations.

**Mrs Hattersley:** In running our programme we have an independent adviser who is an expert in the allergy field so he helps us to keep up to date with the literature. We also scan the literature ourselves to see what work is being done elsewhere. As I said, when we call for proposals for new research we do have them independently appraised by external experts, so again it is bringing their expertise in to look at the work people propose to do so that we make sure we...
Q391 Viscount Simon: You mentioned IgE. In your submissions in the T07 research programme you put IgG. I wonder if you could explain the difference and why it is included in your research programme.

Mrs Hattersley: The IgE response is typical of the allergic reaction, in that you are producing those particular types of immunoglobulin proteins in response to the challenge with the allergen, but it is not just the specific IgE that is produced in response to, say, peanut or egg that seems to be relevant to the level of response seen in an individual. We think that IgG may help moderate that response but it remains unclear how, and certainly there are what are called T regulatory cells which are particular types of lymphocytes which also help moderate the immune response. It is a matter of looking at how that response is triggered and all the other factors that might moderate it. Both the IgG and the regulatory cells seem to be implicated in the development of tolerance and we are trying to do some research to see why it is that some people outgrow their allergies (egg and milk allergies are often outgrown by the time the child is five) and so if we can understand how that tolerance develops then we might be able to do something to moderate the types of reactions that happen.

Q392 Chairman: What is the research budget for food allergy research in the UK? Miss Fine: The research budget for the allergy work is around £1 million each year and that represents about five per cent of the Agency’s research budget. I should add, in response to the work on the international side, we are very keen that we get the best value for money from the research, so increasingly we are looking to see how we can work collaboratively with activities that are happening in Europe and internationally.

Q393 Viscount Simon: Is £1 million a year enough? Miss Fine: Research is quite a hungry beast and the Agency funds research across a wide range of food issues. We are very keen that we carry on with the research in this area. £1 million is a significant amount but whether it is ever enough I think is very hard to say.

Q394 Chairman: How does that compare to the US or European budgets, do you know? Mrs Hattersley: I am not sure about the budgets in the US but we are part of a very large EU framework programme which I think has about £12.5 million worth of research looking at the prevalence of food allergy and it is also looking at things like the food matrix and whether the type of food that the allergen is in makes a difference. They are also looking at quality of life issues. We are collaborating with them but by funding one particular arm of the study in the UK we have access to all that information so the collaborative research is a very good way of making our money go further.

Q395 Lord Colwyn: I am aware that the UK has been pressing for improved labelling of allergenic ingredients in food. How do current labelling regulations recognise allergens in foods? Who decides at what level an allergen must be listed? We have a list from the FSA here and I notice, for instance, that kiwi fruit is not even included.

Miss Fine: The current regulations require declaration of ingredients when they have been deliberately added and there is no threshold for that. If a manufacturer or retailer is using a food or ingredient that contains these allergens it must be declared on the label. The way in which that list is determined is that, because labelling is an EU competency, the European Commission asks the European Food Safety Authority for advice on which of the allergens are of public health concern across all Member States and that is where the initial list of 12 allergens came from. Subsequently there have been another two added in December last year. I think the key thing here is that it has helped to improve the clarity of the label for consumers so whereas before it would say “casein” in the ingredients it now says “casein from milk” so it helps the consumer understand more clearly where those particular allergens are coming from

Q396 Lord Colwyn: What are the other two that have been added?

Miss Fine: Molluscs and lupins have been added to the list. There will be a period of time before which the manufacturers and retailers have to declare it but they have now been added to the list.

Q397 Lord Colwyn: Obviously sensitivity levels for allergens vary amongst individuals. Would it be a good idea to define a level above which the packaging must list any particular allergen?

Mrs Hattersley: The legislation for the pre-packed food is that the allergen has to be labelled regardless of the level of addition, if it is deliberately added as an ingredient. The science at the moment is not yet able to let us set thresholds for the allergens in food. We have guidance on the advisory labelling to cover possible cross-contamination but at the moment we do not really have enough evidence to set even the clinical thresholds for the allergens (below which an individual would not react). As you say, individuals vary very considerably in their response, so it is how...
you would turn that information into a management level that the industry could use. We do not yet have
the scientific evidence to be able to do that but we are
actually working with this European consortium that
we mentioned earlier and are holding a conference
this summer to look at that whole question of how
you actually set the threshold levels for the food
because you have to work out the safety factors that
you need to include in those calculations to protect
the most sensitive individuals. Risk assessment in
that way is fairly well established for chemicals, for
toxicological evaluations, but no-one has yet tried to
apply that to allergens so this conference is going to
be pulling together experts from around the world so
there will be European and American experts there
to help us discuss how you actually do that risk
assessment. It is something that is in progress and we
know it is something that does need to be done.

Q398 Lord Colwyn: You refer to “we”; that means
the FSA does it?
Mrs Hattersley: Yes.26

Q399 Lord Colwyn: Who else is researching these
threshold levels?
Mrs Hattersley: Academics are doing research in that
area and certainly other government authorities are
doing work as well.

Q400 Lord Colwyn: You keep in touch with
other research facilities throughout Europe and
throughout the world.
Mrs Hattersley: Yes. We scan the literature and
through these international consortia we are in touch
with other people working in the area.

Q401 Lord Broers: Labelling at too low a level can
render the label relatively useless. This is the case with
sulphites in my experience. I declare an interest, being
allergic to sulphites. You find that in almost every
product it says there are sulphites there whereas it is
only above a given concentration that most people—
I think almost all people—are allergic to sulphites, so
by labelling everything as containing sulphites makes
the labelling virtually useless.
Mrs Hattersley: Sulphites actually are the only
allergen in the list that does have a threshold, so it is
when it is added above 10 parts per million that it has
to be labelled.

Q402 Lord Broers: So it is not labelled below that.
Mrs Hattersley: No. That is the one allergen in the list
that does have a threshold.
Ms Martinez-Inchausti: As Sue said, sulphites is the
only one for which a maximum level has been set
under the European legislation. It is very difficult to
set levels at the moment because of the lack of
information that we have. Attempts have started to
try to set up a level for gluten and there is an
international body called Codex Alimentarius which
has a draft proposal to set a level for gluten for over
20 ppm. There are associations which have been
using that level, for example Coeliac UK, to
determine whether something is gluten free or not.
However, if you were to apply the legislation
accurately any possible level of gluten present in food
should be labelled if the ingredient is deliberately
added. It is the only allergen on which they are
actually doing some work. With other allergens, for
example nuts, the sensitivity to that specific type of
allergen is so, so delicate and small that anybody
could trigger a reaction with a very minute amount
and it would be impossible to set a level.

Q403 Lord Colwyn: Does this extend beyond foods
to things like ointments and toothpaste and things
that are not necessarily always ingested but could be?
Mrs Hattersley: No, the legislation applies to food.
The EU have announced that they are reviewing food
labelling and there was a suggestion that they would
include non-food products in that but I am not sure
how widely that has been taken forward. It was in
their original proposal that they might look at some
other products.

Q404 Chairman: Going back to your comment
about trans dermal, were cosmetics included and all
of the so-called skincare products?
Mrs Hattersley: They are not part of the Food
Standards Agency’s remit. I think they come under
the Department of Trade and Industry. There are
controls on cosmetic and toiletry products.
Mr Bailey: There is an EC Cosmetics Products
Directive which is implemented in the UK through
UK legislation and that sets out general controls over
the safety of a whole range of cosmetic products
including their composition.

Q405 Baroness Perry of Southwark: You mentioned
the issue of cross-contamination and for defensive
reasons food manufacturers nowadays do tend to put
“may contain nuts” simply because there could be
some cross-contamination. It does make it very
limiting for people who have allergies if they see that
on a packet. Is there anything being done to minimise
this risk of cross-contamination, for example is there
any thought of bringing in legislation or regulation to

26 Guidance on Allergen Management and Consumer
Information (“May Contain” Labels)—We should also like to
clarify that “May Contain” was produced by the Food
Standards Agency, working in collaboration with stakeholders,
including the Food and Drink Federation and the British Retail
Consortium. We are grateful to them for producing the first
draft of the document, which was based on their own previous
guidance.
ensure that food manufacturers have separate production lines for things which contain nuts and things which do not.

Ms Martinez-Inchausti: First I would say that we firmly believe that the warning should be the last resort and that is the basis on which our members operate. We strongly believe that a warning should not be a substitute for controls or for good practice and we take the subject very seriously. We do not believe it is useful for the customer to have a “may contain” or equal warning splashed out on absolutely all the labels, so they would only use it when there really is a risk. The area of allergens is fairly new and I think we are all learning to see how it should be handled and controlled; we are all learning to understand allergens. Taking advice and gaining from the experience of some manufacturing and retail companies that are ahead of the game both the Food and Drink Federation and the British Retail Consortium decided to take the initiative to write some guidance to try to put on paper advice for other members of the industry on best practice to control the cross-contamination or the possible cross-contamination of allergens within industry. The most important part is to identify where cross-contamination occurs and once that is identified to set up control levels to try to minimise it. There are a lot of initiatives and a lot of actions which are taking place from training the staff, from labelling all of the ingredients as soon as they come into the factory, segregation of those ingredients, separating lines to changing the scheduling of production. One example could be in chocolate manufacturing. Chocolate manufacturers tend to produce both plain chocolate and milk chocolate. The way it has been produced up to now is that they would produce the milk chocolate, clean the line and then produce plain chocolate afterwards. Simply by changing the way in which the chocolate was produced by doing the plain chocolate first, cleaning it and doing milk chocolate afterwards has significantly reduced the risk of cross-contamination of milk on the plain chocolate. There are a lot of initiatives that are taking place and we are trying— together with the FSA who subsequently sponsored the guidance we wrote with the help of LACORS and the Anaphylaxis Campaign—to create awareness and help for the business gained from experience.

Q406 Baroness Perry of Southwark: I can see that you are doing a lot to offer guidance and so on, but do you think there is a case for providing incentives or even regulations which would minimise this kind of risk?

Ms Martinez-Inchausti: The labelling is certainly being reviewed in Brussels at the moment and in the last discussions that had with the Commission they believe that the scope of the labelling Directive should be extended to cover consumer information and within that scope the provisions on having to go through a risk assessment, having certain risk management controls in place and being able to identify whether a warning is necessary is one of the areas they are considering to be included in future legislation.
occur and be able to advise the business. Hopefully that will try to reduce down the number of examples where this defensive labelling is used.

**Dr Leitch:** If I can follow on from Les’s comment, the enforcement officers are visiting the businesses but this is a very complex area and it is very important that the enforcement officers receive detailed training so that they are giving the correct advice to the trade. That is my background at the minute, training. I feel that with the best will in the world unless you have the enforcement officers properly trained you can run into dangers of a false sense of security where you think the businesses are doing the right thing when they are not.

**Q408 Lord Taverne:** Coming back to defensive labels and the common label “may contain nuts”, is that necessary because of the ghastly consequences or is it not particularly helpful?

**Mrs Hattersley:** If there is a risk of cross-contamination, for instance in chocolate there could be a large piece of nut in a chocolate that is not supposed to contain nut and certainly that amount of nut would be enough to cause a very severe allergic reaction in some people. I think because at the moment there is not the scientific evidence to know what threshold level of the allergen is low enough that it is not going to trigger a reaction in people it is very difficult to make those labelling decisions. As I said, we have work in progress to try to help us set those levels so hopefully in a few years’ time we will be able to give indicative levels so that if, by analysis, they show that the risk of cross-contamination is down to a level below a certain management level then that labelling would not need to be added.

**Miss Fine:** If I could add one more thing, about confusing labelling. The Agency does investigate where there are instances of food being mislabelled and we would issue an alert notice if food was actually mislabelled, for example, if an ingredient was not properly declared or if there was confusion between the ingredients list and the allergy advice box, that food would need to be withdrawn. We do issue advice on that.

**Q409 Viscount Simon:** Mr Bailey, you used the word “regular”, how regular is regular?

**Mr Bailey:** All inspections are based on a risk assessment approach. There is a Food Standards Agency code of practice directed at enforcement authorities which contains a risk assessment scheme. Basically the more risk a business poses, the more frequently the business is inspected. Food producing factories producing a large number of individual items perhaps with a lot of allergenic ingredients would be visited perhaps once every six months or at least annually. A corner shop just selling pre-packed sweets would perhaps be inspected once every two or three years. It is all related to risk.

**Q410 Baroness Platt of Writtle:** The European Union is currently examining how to make food labelling clearer and more consistent. What involvement will the FSA have in the development of new European Union legislation and will the new regulations consider allergens?

**Miss Fine:** The EU is reviewing all food labelling. Over the years various pieces of legislation have grown up in a rather piecemeal fashion so this gives an opportunity to review all of that and to rationalise it into one piece of legislation. It also gives an opportunity to see what information is essential and must be provided for consumers and other groups, and what information could be provided elsewhere. The safety information, which would include allergy, is a key part of that. The Agency’s role is that we are the lead UK government department on food labelling so we will be taking forward the negotiations and as part of that process we will be consulting with a wide range of groups—consumers, industry and others—to look to see what actually should be on the label and how best it should be communicated, and also to ensure that the information which is then provided for consumers is clear and easy to understand. There is such a lot of information on the label at the moment and it can sometimes be difficult for consumers and others to pick out the information they need. It is a really good opportunity to take a clear look at what is actually needed.

**Q411 Baroness Platt of Writtle:** When will the new labelling come into force?

**Miss Fine:** At the moment the discussions are at a very early stage. We are expecting proposals later this year or the beginning of next year so there is still a lot of scope for having consultation and discussion as to what needs to go on the label. I cannot say exactly when we think it is going to happen, but we are very committed to make certain there is an improvement in the clarity and usefulness of the label.

**Q412 Lord Broers:** On a similar subject, the Food Standards Agency commissioned the 2005 report *Qualitative Research into the Information Needs of Teenagers with Food Allergy and Intolerance*. One of its recommendations for food labelling was “the introduction of a universal allergy warning symbol on the front of packs and a more consistent, clearer approach to the listing of risky ingredients on the back of packs”. What progress has been made towards implementing this recommendation?
Mrs Hattersley: We looked at teenagers and early twenties because we know that this is one of the groups that is at most risk of having allergic reactions to a food. What we were trying to do was find out how best we can communicate information to this age group so that they can manage their condition better. This research was conducted in 2005 and then the changes in the statutory legislation came in at the end of that year so there have been improvements on the information on the back of packs. As Gill mentioned previously the ingredients have to be declared with reference to the allergens that they come from, so that it has to say that casein is from milk. There is clearer information on the back of the pack. That legislation also removed a previous exemption in the labelling legislation which meant that if you had a compound ingredient added to a food previously you did not have to list all the ingredients within that compound ingredient if it made up less than 25 per cent of the whole food. An example would be the pepperami slices on top of a pizza. Previously you did not have to list what was in the pepperami—it just said “pepperami” in the ingredients list—whereas now you also have to list all the ingredients within the pepperami. That is clearer allergy information for those people who need to avoid certain foods. The recommendation on the symbols was one of the things that came out from talking to the teenagers. Superficially it looks like a very easy way of improving labelling but there are a lot of practical problems with symbols. Food manufacturing is very international so it would be a lot of practical problems with symbols. Food very easy way of improving labelling but there are a lot of superficial issues.

Mrs Hattersley: Yes.

Q414 Lord Broers: The report also suggested the development of an allergy chef card which could be prepared for young people with food allergies as a tool to aid communication with catering establishments when eating out. Has this idea been developed?

Mrs Hattersley: We have not taken that forward at the moment. What we have been doing is working with all the different stakeholders—the consumers and the caterers and catering suppliers—to try to produce guidance on the provision of allergen information for foods that are non-prepacked which are outside the current statutory legislation. At the moment we have a draft version of that guidance document which we have done a public consultation on and we are in the process of reviewing the responses to that. We anticipate publishing final guidance in the autumn, so that is trying to provide better guidance to the industry on how they provide the allergy information on the non-prepacked foods.

We will look as well at how we advise consumers so that they know what sort of questions to ask when they are eating out. Certainly we have provided leaflets for allergic consumers and for consumers with intolerances which includes a section on when they are eating out and what sort of things they can do (ring the restaurant beforehand, ask whether someone can supply food that is free from the particular food they are allergic to and how they can ask questions when they are actually in the restaurant). We are doing work to try to help consumers and educate consumers on how to manage their allergy when they are eating out.

Q415 Lord Broers: So these ideas are contained in the Food Standards Agency’s allergy action plan, are they?

Mrs Hattersley: Yes, there are a number of options we are looking at.

Q416 Chairman: Could I ask about a situation which I think is quite specific to coeliac disease in some ways, and that is to ask why some foods are labelled to say they have gluten or wheat when, according to the European Food Safety Authority, they do not? An example of that is glucose syrup.

Mrs Hattersley: When the legislation came into force it was realised fairly late in the negotiation process that there were certain very highly processed food ingredients that would no longer contain the allergenic proteins and so what the Commission did was ask the industry to submit dossiers on those very highly processed derived ingredients such as glucose syrup to justify them being exempted from the allergen labelling legislation. There is an EU
Directive which sets out a list of temporarily exempt derived ingredients so it includes the glucose syrups, it includes some of the fining agents (there can be isinglass or egg or milk proteins used to fine wines or beers) which are also temporarily exempt. That exemption finishes at the end of this year and industry is being asked to submit further information so that a final list of exemptions can be agreed. We certainly advise businesses that if they have one of the ingredients that is temporarily exempt that they do not label it because, as you say, that is confusing for the consumer and we do not want to over-label when there is not actually a risk.

Q417 Chairman: Am I right that chewing-gum is also exempt?
Mrs Hattersley: Chewing gum is regarded as food so if there are allergenic ingredients they would have to be listed.27

Q418 Lord Colwyn: Is there a third party that checks ingredients when it comes from the manufacturers? I think probably if I were a food manufacturer I might well put "may contain nuts" on it just to cover myself. Does anybody check the claimed allergens?
Dr Leitch: Normally when enforcement officers visit the premises, particularly the manufacturers, they will examine the labelling and they will ask the manufacturer how he verifies the labelling and normally that is done through either sampling and analysis or else checking the certificates provided by the original producer of the products.

Q419 Lord Colwyn: So that is a third party sampling.
Dr Leitch: Yes, that can be third party sampling. The environmental health departments and the trading standards departments have a role to play in that by testing to assess the truth of what has been said by the manufacturer. I think the enforcement side has a very big role there in not taking things on trust.

Q420 Earl of Selborne: Can I come back to the issues of catering establishments. Could I ask first of all about the instance of severe allergic reactions from eating out in catering establishments, is it getting better or worse?
Mrs Hattersley: I am not sure if it is getting better or worse. We know that this is the more risky situation rather than the pre-packed foods. As I said, we have been trying to produce guidance for the industry so that when someone asks them whether there is a particular allergen in a food they are able to give accurate information back to the consumer.

Q421 Earl of Selborne: If the FSA does not know whether this is a problem which is getting better or worse, do any other of our advisers here present know whether it is getting better or worse? Is there any monitoring?
Mrs Hattersley: The allergy clinics may record the examples where the allergic reactions happen so there may be some information coming from that side of things.

Q422 Earl of Selborne: You referred to the guidance which will be coming out hopefully in the summer which is guidance, as I understand, for the catering establishments; presumably there is also a role in the training programmes. People working in these establishments get qualifications from the environmental health officer courses and elsewhere. Is there sufficient training in the module for dealing with allergies and food intolerance?
Dr Leitch: I do not think that allergy has a very high profile in a lot of the training. I think it is mentioned in training documents as something that people in catering should be aware of but I do not think there is any great exploration of the detail. A lot of that is due to the fact that enforcement officers themselves are on a very steep learning curve.

Q423 Earl of Selborne: Would you feel that more needs to be done in training food operatives?
Dr Leitch: Yes. I think we should try to get it, particularly with the catering colleges where most of the food operatives originate. We need to make sure that it is on the training syllabus for them. I also think we need to make sure the enforcement officers are well trained so that we can get the cascade effect where the officers can pass the information on to the trade.

Mrs Hattersley: In terms of training for the caterers, the Agency did ensure that in the training for the hospitality sector through the National Occupational Standards there is an inclusion of food allergy in the food safety modules so that people who are being trained in the catering trade do have some awareness of allergy and the particular problems. Also the Agency produces guidance for the catering trade. In England it is called Safer Food, Better Business and there are comparable documents in Scotland and in Northern Ireland. There is an allergen safe method within that so that when they are thinking about cross-contamination for example of raw meat with
cooked meat they can also be thinking about cross-contamination of allergen containing foods and non-allergen containing foods.28

Q424 Chairman: I wonder if I could ask you, Dr Leitch, to be a bit more specific about how you feel that training could or should be improved. Are there some specific initiatives that you have in mind?

Dr Leitch: Can I just think about that for a while?

Q425 Chairman: While you do, I just wanted to ask whether there are any global initiatives over food labelling. We have spoken a bit about Europe, but we do have people travelling all round the world in every direction.

Mrs Hattersley: Codex Alimentarius which was mentioned previously does look at labelling and they are taking forward an initiative to produce a standard for gluten free foods. That work is on-going and there is a further meeting of that committee in October this year so we are hoping we will actually get an agreement on what gluten free should mean which will be helpful.

Q426 Chairman: Dr Leitch, have we given you enough time to think?

Dr Leitch: I would say that my perceptions are based on what I find as I talk to people in allergen control. I believe that the training needs to be more practically based. I think there is training, as Sue said, where documents are given to the businesses, the documents contain a section on allergen control—a short section—and every business should have that. However, in terms of looking at that from a practical view point I believe we need much more training from a workshop perspective so that people can explore the issues dealing with the allergens, where the allergens are found, what foods they may be hidden in. Issues like dealing with the customers as well. The biggest problem for someone with a food allergy is asking someone in the trade, “Is this food suitable for me?” Those issues need to be brought home in much more detail to the catering trade so that the catering trade do not give the wrong answer. One of the situations with the catering trade is that for generations they have been taught that the customer is always right and they try to be helpful and very often when they are trying to be helpful they are putting the customer in danger. That is one of the things that I think needs to be looked at in terms of training. I did some sampling work a couple of years ago in Northern Ireland to try to buy allergen free foods in takeaways because that is where most of the accidents occur. We got a 20 per cent failure rate amongst the foods and we were assured that those foods were suitable. We actually looked for a peanut-free chicken curry but we had a 20 per cent failure rate, yet everybody who sold that said that this is fine, it is suitable for the allergic consumer. They were not aware of cross-contamination issues and they did not know how the contaminates had got into the food. I think we need to focus much more on that detailed side of things with workshops where these issues can be explored rather than just straight information on paper. I can also go on to say that that is my feeling regarding the enforcement officers as well. It is all very well to have it on paper but whenever you are asked hard questions during an inspection you really do need to be much more familiar with the topic and you need to drill down into it in detail.

Q427 Chairman: Do I take that to read that you feel that the environmental health officers do not have an adequate understanding of food allergy and anaphylaxis?

Dr Leitch: I think that at the minute they have a superficial understanding, the sort of thing you would get from reading a leaflet. I think that they need a much more detailed understanding. I think we are going to cover that in the final question.

Q428 Chairman: Should we just go straight into that now?

Dr Leitch: Certainly, yes.

Q429 Chairman: Would you like to go straight into that question over the environmental officers per se?

Dr Leitch: I was involved in 2005 with the Food Standards Agency drawing up training materials for enforcement officers. I am now on secondment to Safefood and to the EU body CAWT to take that a stage further. We are involved in training workshops during the summer and we are bringing in the enforcement officers now. It is all environmental health officers because it is only environmental health officers who are involved in food control in Northern and Southern Ireland; the trading standards officers do not have any food involvement there and certainly we see the workshops as a very, very important tool that would bridge the gap between the book-based knowledge and the trade. I know in the UK that Sue and colleagues are running pilot training for environmental health officers which I think is very, very good. My only comment would be that that training should be rolled out across all environmental

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28 Enforcement Officer Training—in relation to training for enforcement officers, we described the training that the Agency is developing. However, you should also be aware that there are many commercial organisations currently providing training for Environmental Health Officers and Trading Standards Officers, including the Chartered Institute for Environmental Health (CIEH). The courses that they provide on food safety could be extended to include food allergy and intolerance and we are aware that there is a joint initiative between the Food Standards Agency Wales and CIEH Wales to raise awareness both of food allergy and intolerance issues with Welsh enforcement officers.
health departments as soon as possible and with trading standards colleagues as well because trading standards are very heavily involved in the food labelling aspects that we talked about earlier, making sure that the right labels are on the right products. I think that is very important as well.

Mr Bailey: The allergen training courses are being rolled out across the UK and they will be attended by environmental health officers and trading standards officers. The take-up from our officers has been very good.

Q430 Lord Colwyn: Most people who have an allergy problem carry an EpiPen or something like that. Do you think the time will come when catering establishments or restaurants, as part of their licence, might have to show that they have somebody on the staff who knows how to deal with allergies and they have to have an EpiPen? I have to say that it is only about a year ago since the EpiPens in this building were locked up at 5.30 and nobody could get hold of them.

Dr Leitch: I think it would be very useful in terms of their defence if anything went wrong because to show due diligence they need to show that they have assessed hazards and that they can control hazards. It is my belief that allergens are a hazard that you deal with in just the same way as any other hazard. As with food poisoning bacteria you should deal with the allergen hazard in just the same way. You need to consider the hazard and you need to put the controls into place. I would like to see a position where when environmental health officers are carrying out their inspections that allergens are assessed in the same way as any other hazard.

Mrs Hattersley: If I could just add about the training courses that we are running out, we are running 10 courses across different areas of England from January through to March. There will also be some courses in Scotland and in Northern Ireland. These courses are being held in different areas but there are people from a number of local authorities coming to each of these courses. When we advertised for these 10 we had at least 30 local authorities wanting to host these events so we will be rolling out more later on in the next financial year.

Miss Fine: Could I just add a point about the increased awareness that you were talking about, I think it is absolutely fundamental that there is much more awareness across all the different groups, not just the caterers but also the enforcers and consumers. One thing we have not touched on is the importance of working together to ensure that there is accurate information for consumers and to help people to be more aware of the issues (not just the individual but also their families and their carers, which is where there is also a concern). The Agency has been working with the British Dietetic Association to ensure that there is information on both food intolerance and food allergy to help people understand the nature of the condition but also how to take action to manage their condition and to avoid triggering a reaction. It is important that it is put into context, that people know where to go to get accurate help to manage their condition. I also want to add that in terms of information when foods are improperly labelled for whatever reason, Sue mentioned withdrawal notices. This information can go into food stores, and will probably be put into a press release, or information could be put into newspapers. We are very conscious that although this is very helpful it is perhaps not as immediate as it might need to be. We are therefore exploring other options and are about to introduce an SMS texting initiative. People can subscribe to this (those who do need to know when there is a problem with a label), and they can get immediate information about that. I think it is about raising awareness and providing practical help for individuals.

Q431 Lord Rea: In the training of environmental health officers do you feel that there are sufficient trainers of adequate calibre who have a detailed knowledge of allergies and problems associated with it to go round?

Dr Leitch: I do not think there are. I think it is a specialised area and it is important that you do not have people giving out the wrong information. That is certainly an area of concern.

Q432 Lord Rea: Where are they recruited from?

Who are we talking about when we talk about training people in allergy control?

Dr Leitch: I do some training. There are very few people who have completed any detailed training. There is a lady in the public gallery, Hazel, who has done an awful lot to raise allergy awareness and Hazel would be a trainer and I know Hazel has trained one other person. There are very few people with the detailed knowledge and training and that is perhaps another concern.

Mrs Hattersley: The Agency does provide its own training for environmental health officers and trading standards officers. This is the work that we are rolling out. That was the first step of what we are doing. What we want to do once we have those courses up and running is to then talk to the general training providers, including perhaps the undergraduate syllabuses for environmental health officers so that we can start to introduce allergy at a very early stage of training. That is certainly something we want to look at in the coming year.
Dr Leitch: I agree absolutely with that and I believe that that information will give training on a general level but it will be crowding into the syllabus with everything else that an undergraduate does. I believe there is certainly room for specialist training in that area.

Chairman: Do any of our other witnesses have anything else that you would like to inform us today in relation to questions? No. Then can I thank you very much for having come today, for your very clear answers which have informed the Committee. If there is anything else that you would like to give us information on, please feel free to write in after this session and it will be considered along with your oral evidence. You will be sent a copy of the transcript to correct for accuracy. Thank you.

Supplementary memorandum by the Food Standards Agency

The Food Standards Agency has had a commitment to address the needs of food allergic and food intolerant people and their families since it was established in 2000. This is reflected in the high level objective in our revised Strategic Plan for 2005–10, which will be published shortly: “To develop appropriate policies and standards to help ensure safety and choice for food allergic and food intolerant consumers”.

The Agency is meeting this commitment in three ways—by improving food labelling (both statutory and voluntary), by raising awareness of food allergy and intolerance with food businesses, enforcement bodies and consumers, and by commissioning research to develop the evidence base and improve knowledge and understanding of the mechanisms involved. The Agency has been instrumental in delivering a number of key improvements:

— The Agency negotiates on behalf of the UK on EU legislation and there has been a significant improvement in the statutory requirements regarding the declaration of allergenic food ingredients in pre-packed foods, leading to more accurate and informative labelling.

— The Agency is working with a European consortium which is investigating how best to determine management threshold levels for allergens in food products. This will provide a basis for helping the food industry manage allergens during food production, in particular their decisions on whether or not to use advisory labelling.

— The Agency works in partnership with food manufacturers, retailers, allergy and intolerance support organisations and enforcement bodies to produce best practice guidance on areas outside the scope of these statutory requirements. In July 2006 the Agency published best practice guidance on the management of allergen cross contamination and advisory labelling (such as “May Contain nuts”).

— The Agency is currently working with stakeholders to produce best practice guidance on the provision of allergen information for foods that are not pre-packed, such as foods sold in catering. Draft guidance was the subject of a public consultation last year and the final version will be published in 2007.

— In response to requests from enforcement officers, the Agency has recently developed a training course on allergen management to raise their awareness of allergy concerns and help them advise the businesses they visit.

— The Agency funds a significant research programme (around £1m per annum) to investigate possible causes of food allergy and the mechanisms involved in the development of either allergy or tolerance to food proteins. This programme has looked at the role of early life exposure to allergens during pregnancy and breastfeeding in the development of allergy or tolerance to food allergens. A key finding of the research is an improved understanding that early, low level environmental exposure to allergens (such as via dermal exposure if the food is eaten by other members of the household) may also be a route of sensitisation to food allergens. The Agency is currently considering further research proposals on the role of the weaning diet in the development of allergy or tolerance.

— The Agency provides a range of information for consumers via our website (www.eatwell.gov.uk) and through leaflets that we have developed in partnership with the British Dietetic Association, to help people successfully avoid the foods to which they react.
The Agency places a great emphasis on working partnerships with all stakeholders as this provides real benefits in raising awareness and improving understanding in this complex area. This has led to real improvements for allergic and intolerant consumers, while at the same time ensuring that any guidance produced is both practical and not unnecessarily burdensome for food businesses.

31 January 2007

**Further supplementary letter from the Food Standards Agency**

There are a few points I should like to clarify:

**Chewing Gum**

There are exemptions from most food labelling requirements for small packages and this exemption applies to chewing gum. However, if any of the specific allergenic ingredients are used in chewing gum these would have to be labelled. The current list of allergenic ingredients doesn’t include latex, so there is not requirement for this to be declared, although this list can be amended if an additional allergenic food of public health importance becomes apparent.

**Enforcement Officer Training**

In relation to training for enforcement officers, we described the training that the Agency is developing. However, you should also be aware that there are many commercial organisations currently providing training for Environmental Health Officers and Trading Standards Officers, including the Chartered Institute for Environmental Health (CIEH). The courses that they provide on food safety could be extended to include food allergy and intolerance and we are aware that there is a joint initiative between the Food Standards Agency Wales and CIEH Wales to raise awareness both of food allergy and intolerance issues with Welsh enforcement officers.

**Guidance on Allergen Management and Consumer Information (“May Contain” Labels)**

We should also alike to clarify that this guidance was produced by the Food Standards Agency, working in collaboration with stakeholders, including the Food and Drink Federation and the British Retail Consortium. We are grateful to them for producing the first draft of the document, which was based on their own previous guidance.

20 February 2007

**Memorandum by The Anaphylaxis Campaign**

**Introduction and Summary**

*The Anaphylaxis Campaign*

1. The Anaphylaxis Campaign is a national patient support organisation representing people who are at risk from severe allergic reactions including the most extreme form, anaphylaxis.

2. During anaphylaxis the whole body is affected. Symptoms include swelling in the throat and mouth, severe asthma, a dramatic fall in blood pressure and collapse and unconsciousness. Extreme cases can be fatal. Causes include foods (notably peanuts, tree nuts, milk, eggs, shellfish and fish); certain drugs; insect stings; and natural rubber (latex).

3. The Anaphylaxis Campaign is a registered charity (No 1085527) set up in 1994 to raise public awareness of severe allergic conditions, inform and educate those affected, and maintain dialogue with the Government, food industry and health professionals. Main sources of income are membership subscriptions and donations, fundraising by volunteers and corporate grants.
**Our submission**

4. Our submission will seek to demonstrate that allergic disease impacts severely on the quality of life of those affected and that currently the lack of NHS provision has a serious effect on those living with the condition both in terms of medical support and day-to-day living. Some of our evidence is supported by the evidence of research, and we also draw on 13 years’ experience of running a helpline, workshops, support groups and member anecdotes. We see much anxiety and serious impairment of quality of life.

5. Most of the facts, quotes and experiences highlighted in our submissions feature people whose allergy trigger is food. This is because the membership of the Anaphylaxis Campaign (7,904 people in October 2006) is made up primarily of people with food allergy problems. But we acknowledge that the other causes of anaphylaxis are also important, resulting in a significant impairment of quality of life.

6. Peanuts and tree nuts figure prominently in our evidence because allergies to these foods are the ones that most commonly cause fatal and life-threatening reactions. A recent study showed that the incidence of peanut allergy has tripled in the last decade and now affects one in 70 children across the UK.

**Allergy and intolerance: important differences**

7. The function of the immune system is to prevent harm to the body. It normally does this by fighting off invaders but in people who are prone to allergy, the immune system mistakenly registers harmless foods or substances as a threat. A person with an allergy produces allergic antibodies to a particular food or substance (known as an allergen). Contact with the allergen causes chemicals including histamine to be released from cells in the blood and tissues. These act on different parts of the body to cause symptoms such as swelling, skin rash, streaming eyes and nose, vomiting, breathing difficulties or asthma. For a few people, these symptoms may be extreme and affect the whole body (anaphylaxis).

8. Food intolerance is different. It is not triggered by the immune system, it cannot be diagnosed by standard allergy testing and must be treated different to allergy. Unfortunately many people who experience symptoms that seem to be connected to food—such as nausea, sickness, headaches, digestive difficulties or sluggishness—mistake this for allergy, when in fact it may be a form of intolerance. Furthermore, there are many people who believe themselves to be allergic or intolerant who in fact have some other underlying medical problem. All of these people—whether genuinely allergic, intolerant, or affected by some other disease—find it extremely difficult to access accurate information and obtain expert attention because of the lack of allergy services. This problem needs to be addressed urgently.

**Contents**

9. Because our work covers a variety of aspects of living with severe allergy, we have included evidence on:
   - Food labelling and eating out.
   - Allergy in schools.
   - Self-treatment of allergy and the dangers of alternative therapies.
   - Impact of allergy and quality of life.
   - Conclusion and future work.

**REFERENCES [not printed]**

**FOOD LABELLING AND EATING OUT**

**The nature of the problem**

1. This paper will demonstrate that people with severe food allergy face a genuine risk, not a hypothetical one, and that urgent steps need to be taken to address this. People seeking to avoid a particular food, or foods, encounter numerous barriers. Despite improvements provided by new European legislation, food labelling is frequently inconsistent and confusing. The explosion in “may contain” labelling—adopted by food companies to signal the small possibility of allergen traces—fuels this confusion.
2. Eating out poses an even higher risk because of the complexities of food production in catering establishments, lack of knowledge among catering staff, food enforcement officers and allergic consumers alike, and the fact that allergic consumers do not have the benefit of an ingredient list to guide them.

Defensive labelling

3. The Anaphylaxis Campaign has overwhelming evidence that allergic consumers have become increasingly angry and frustrated with restriction in their choice of foods, caused by the escalation in defensive labelling (eg “may contain nuts”). Food companies use this method of labelling to signify that a food product may have been subject to cross-contamination in the food production chain. This is not regulated by law, and there is little consistency across the industry in how warnings are presented on food packets. The confusion consumers face puts them at serious risk. Almost all of the young people attending Anaphylaxis Campaign educational workshops for allergic teenagers say that they disregard “may contain” warnings because they believe food companies are simply “covering their backs” and that the hazard is not genuine. This is dangerous behaviour. Allergen testing laboratories have demonstrated that allergen contamination is a real risk.

4. A “shopping survey” undertaken by the Anaphylaxis Campaign for the Food Standards Agency found that “may contain nuts” warnings appeared on a significant proportion of foods that do not have nuts as ingredients. They appeared on 69 per cent of cereals, 58 per cent of biscuits and 56 per cent of confectionery. The way these warnings were displayed meant that often shoppers could not find or read them easily. Warnings were found some distance from the ingredient list, in tiny, unreadable type, in coloured type on coloured paper and sometimes under a flap.

5. A membership survey undertaken by the Campaign drew many hostile comments, of which this one is typical: “I had always thought that food labelling was there to help and protect the consumer. But now I wonder if it really exists to protect the food industry.”

6. The Food Standards Agency has gone some way to address consumer concerns with its voluntary guidance produced in 2006. This is useful guidance and may help to bring about some consistency and better quality of “may contain” labelling.

7. However, it is insufficient on its own. Thanks to a grant from the Agency, the Anaphylaxis Campaign is developing the UK’s first certification programme to enable food companies to ensure optimum allergen control. This is currently the subject of a wide consultation exercise and the Anaphylaxis Campaign plans to launch the programme in 2007.

8. This certification programme invites the participation of the food industry on a voluntary basis. The question remains as to whether “may contain” labelling should be regulated by law. This requires much serious debate. Legislation takes many years to produce and action is needed now. Many food companies, particularly but not exclusively the larger ones, already follow good practice and we must wait to see whether the measures described here have any effect.

Allergy and catering establishments

9. The risks increase significantly when people eat out, largely because consumers do not have the benefit of comprehensive food labelling and must often rely on verbal assurances of catering staff. Every year, a minimum of six to seven deaths from food-induced anaphylaxis are reported. The true figure is almost certainly higher because of misdiagnosis or misreporting. Reports from the US and the UK confirm that the greatest risk for allergic consumers comes from complex foods prepared by restaurants and other catering establishments.

10. The following fatalities are just a small proportion taken from the Anaphylaxis Campaign’s register of allergy-related deaths.

11. Example one: A young Lancashire woman died after eating a curry that contained peanut. She had asked for a peanut-free meal. The environmental health officer investigating the case concluded that she died because of “a communication problem.”

12. Example two: A promising young athlete, who was allergic to nuts, died after eating a Coronation chicken sandwich which, unknown to him, contained nuts as an intended ingredient.

13. Example three: A Liverpool girl with a nut allergy collapsed and died during a formal dinner at university after she ate a dessert that, unknown to her, contained nuts as an intended ingredient.
14. Studies of allergy-related deaths have been undertaken thanks to an association between the Anaphylaxis Campaign and Dr Richard Pumphrey, of the North West Region Immunology Service. Our register of fatalities draws clear conclusions about the circumstances under which people with food allergies usually die. The intention is to learn lessons and save lives.

15. Three-quarters of the reported deaths occurred when food was bought in catering establishments, such as restaurants, hotels and takeaways.

16. In some cases where the victim had asked for a meal without nuts, the person serving (and in several cases even the caterer) had not been aware that the food contained nuts. In other cases, the request for nut-free food had either been misunderstood or forgotten.

17. Most cases involved the allergen being present as an intended ingredient, but unexpected or unrecognised by the food business, the consumer, or both.

18. In 22 cases out of 54 that were studied in some depth and published in the medical literature, the patient had never been prescribed emergency adrenaline. In some cases, adrenaline had been prescribed but was not being carried on the day of the fatal reaction. What was lacking here was patient education.

19. Despite a growing awareness of food allergy, deaths are still occurring. Important lessons are not being learned. The Anaphylaxis Campaign is aware of a much larger number of near-fatals reactions, where the victim was resuscitated thanks to prompt medical treatment. These cases do not make headlines. The Royal College of Physicians reported that hospital admissions due to anaphylaxis increased seven-fold in a decade.

20. In June 1999, before the Food Standards Agency was established, Mr Edward Davey, MP for Kingston and Surbiton, responded to the death of the young athlete Ross Baillie by telling the House of Commons: “When a fit, gifted athlete like him dies because of a few bites of a chicken sandwich, it is surely our duty to ask whether or not his death or deaths like it could have been avoided. We need to ask whether or not actions this house has the power to take could help prevent such tragedies in the future.”

21. In response, Food Safety Minister Mr Jeff Rooker said that one answer might be “an effective code of practice which will raise awareness, so that the industry takes responsibility.” He pledged to “take this issue forward” to see whether a code of practice would be “beneficial”.

22. The Food Standards Agency has recently made some progress towards addressing the needs of food-allergic consumers who wish to eat out. Draft guidance for the catering industry on management of allergens and communication of information is out for consultation. This is welcome, but it is voluntary guidance only and will only partially address the problem of allergy risks in catering situations.

23. We believe that the long-term solution to addressing the problem of food allergy in the catering sector lies in compulsory training programmes in allergy for food enforcement officers, particularly EHOs involved in the assessment of food safety management systems. They could then ensure better compliance and a more consistent approach to food allergen management by food businesses. In our view, this should be the Agency’s main objective.

24. Environmental health officers are the guardians of food safety in the UK. Officers are in regular contact with all catering establishments, seeking to ensure the safety of the food supplied. No other agency is involved in the regular assessment of food safety management systems. In many instances, particularly in the smaller businesses where self-regulation is not strong, the advice of the officer is taken as the law and work is carried out at their request so it is vitally important that these officers view allergen control as an integral part of the food safety inspection regime and that they ask the correct questions. Many officers may agree that allergen control is important but may not consider them during inspections.

25. A survey carried out among environmental health officers involved in food safety enforcement work in Northern Ireland in 2000 revealed that less than 20 per cent (6/37) of the officers considered serious food allergens (nuts/peanuts) when carrying out assessment of the premises’ food safety management system. Of the 31 who did not, 26 considered that they lacked knowledge and training in the subject of food allergen control. In 2002 another survey revealed that little had changed and 100 per cent (35/35) of the officers surveyed felt that they needed training in the area of food allergen control. Several officers expressed the view that training should integrate allergy into the HACCP food safety management system, perhaps because food safety management is the bedrock of the inspection process.

26. We conclude that training in food allergy must become a priority for local authority food enforcement officers. They must be given formal accredited allergen control training, and all guidance on food standards and safety/hygiene must reflect the need to consider allergens as part of the formal inspection process.
1. As stated in our introduction and summary, the incidence of peanut allergy has tripled in the last decade and now affects one in 70 children across the UK. It is estimated that 250,000 children are allergic to peanuts, tree nuts or both. Allergies to other foods (such as kiwi fruit) also appear to be on the increase.

2. Given this relatively high prevalence, it is probable that every school has at least one pupil who is severely food-allergic and it is unsurprising that there are often tensions in schools. Parents may make unrealistic demands (such as a total ban on the allergenic food), schools may be driven by fear to respond unhelpfully, and the result in all cases is that the child suffers. This is certainly the experience of the Anaphylaxis Campaign helpline staff.

3. The Anaphylaxis Campaign believes strongly that the risks faced by allergic schoolchildren can be managed and minimised. It is our experience that ignorance lies at the root of schools’ inability to cope. What they need is help, information, support and training.

4. A questionnaire study within the Severn NHS area of south west England found that schools are not sufficiently well-informed about management of acute allergic reactions. Forty-four per cent of the schools with an allergic pupil either did not have staff trained to administer medication or declined to respond to the questionnaire. Less than half of the schools with nut-allergic children said they gave information to all the teachers about this medical condition.

5. An audit of schools in the Nottingham area identified inconsistency in knowledge and awareness about treatment of allergic children. Gaps in training for both school nurses and school staff were identified, particularly for midday supervisors.

6. A study published in the British Medical Journal said that patients and GPs lack knowledge on when and how to use adrenaline auto-injectors. We conclude that if GPs lack knowledge, it should come as no surprise that there is ignorance in other sections of the medical community.

7. A questionnaire survey of 14 school nurses in the West Midlands, undertaken by the Anaphylaxis Campaign, showed that all the nurses surveyed would undertake training by the Campaign, if it was available, and 8/14 acknowledged that they required additional help and information (eg to ensure their knowledge is up to date). The West Midlands is an area where allergy awareness in schools is already relatively high, indicating that training is probably more urgent in other areas.

8. A 2006 study showed that most Scottish schools now have at least one child at risk of developing anaphylaxis within the school setting, and although most of these schools have trained staff with access to emergency medication and personalised care plans for these children, they continue to express concern about their ability to respond effectively in an emergency situation.

9. Some progress has been made. The Department for Education and Skills acknowledges that anaphylaxis presents a significant challenge for schools and produced a useful guidance document for schools. In 2004 the Anaphylaxis Campaign received grants from the Peanut Foundation and the American Peanut Council to set up a website specifically aimed at providing allergy-related information to schools. This website received 4,029 visits during the first month it was launched. The number of visits varies month by month between just under 2,000 to just over 4,000 and these levels are being maintained.

10. However, schools have needs that cannot be met by a website. School staff now have access to information but they also need active, personal instruction on how to recognise symptoms, how to treat them with injectable adrenaline and how to manage allergies on a day-to-day basis. In many schools, the key people who ensure that school staff are properly trained are the school nurses. They too need active, personal instruction. At present, the knowledge they possess varies in content and quality around the country. There is inconsistency and, in some cases, a dangerous ignorance of the facts.

11. The Anaphylaxis Campaign believes that the training of school nurses should fall under the Government’s remit, but in the absence of any Government training, the Campaign is now planning to set up a national training programme of its own. This was piloted in five areas of the UK in early 2006, and will be rolled out nationally in 2007–08.

12. The national roll-out depends on funding becoming available and therefore its success is by no means assured. Patient organisations like the Anaphylaxis Campaign live a precarious existence; vital educational and training programmes can only succeed with Government and/or corporate support.
13. Some corporate sponsors for this schools training programme have been identified, but others are urgently needed. Without high-quality training, of the kind that is proposed, children will continue to be at risk.

14. These risks may increase as a result of Government recommendations that form part of its “Transforming School Food” initiative. Whilst the Anaphylaxis Campaign supports the general principles of healthy diets for children, we are concerned with the Government’s comments that snacks sold in school vending machines and tuck shops may include nuts and seeds.

15. This recommendation raises the possibility that peanuts, tree nuts and seeds will become commonly eaten snacks in many schools. It raises the further possibility that allergic reactions will increase.

16. Primarily this is a cross-contamination issue. Proteins from nuts are notoriously difficult to clean and tend to become transferred easily from hands to surfaces such as tables, chairs and computer keyboards. There is a real risk that these allergenic proteins will be picked up on the hands of allergic children. “Casual contact” reactions caused by touch are rarely thought to be life-threatening, but they can lead to moderately severe symptoms requiring treatment—particularly if the child touches his or her mouth.

17. Evidence for this came in a paper published by a German medical team. They reported the case of a 32-year-old man with peanut allergy who suffered a serious allergic reaction during a card game. It transpired that his friends had been eating peanuts. Although they kept them well out of his way, peanut protein from their fingers found its way on to the playing cards. As the cards often stuck together, the player with the allergy licked his thumb to separate them. After one hour he felt swelling of lips and tongue as well as shortness of breath. He received emergency medical treatment.

18. The Anaphylaxis Campaign fears that if schools follow the Government recommendations in this respect, we will see an increase in allergic reactions in schools. At the very least, it will cause great anxiety for the families of allergic children, many of whom are unclear about the actual risks caused by “casual contact” with food allergens.

19. The Anaphylaxis Campaign has launched a series of monitoring exercises that will seek to find out whether the prevalence of nuts is actually increasing in schools and whether this is causing problems.

20. We feel the House of Lords Select Committee should be aware of this issue because it demonstrates that:
   — The Government’s “Transforming School Food” initiative appears to have taken little account of food allergies.
   — Research is needed to determine actual risk levels that people with food allergies face. There is still much debate about the degree of risk posed by “casual contact” but it causes extreme distress among the families affected.

REFERENCES [not printed]

Self-treatment of allergy and the dangers of alternative therapies

1. When avoidance fails, as it does for almost everyone with food allergy, the symptoms may be mild or they may be life-threatening. Mild symptoms are treated with oral antihistamines, obtained on prescription or over the counter. Serious symptoms constitute a medical emergency and require an immediate injection of adrenaline. Allergy doctors recommend that prescribed adrenaline treatment kits (EpiPen or Anapen) are available for those at risk.

2. Unfortunately there is a lack of consensus in the medical community over who should be prescribed adrenaline, how many treatment kits should be available, and at what stage of a reaction adrenaline should be administered.

3. Macdougall et al suggested that for children, the risk of a fatal reaction is exceedingly small and concluded that adrenaline injectors are over-prescribed.

4. Many other experts argue that carrying adrenaline saves lives. Hourihane argues that adrenaline provides an assurance to patients, parents and child carers alike that they are not powerless; they have a means to protect themselves.

5. This lack of consensus leaves general practitioners and others in primary care in a quandary: they seek guidance from experts but find the experts disagreeing among themselves.

6. The Drug and Therapeutics Bulletin provided sensible guidelines for those caring for severely allergic children but acknowledged there was a lack of reliable data on which to base decisions.
7. The Anaphylaxis Campaign advocates the setting up of national consensus guidelines for the management of severe allergy and the prescribing and administration of adrenaline.

8. This current lack of consensus guidelines leads to confusion among medical professionals and patients alike. At the root of the problem is the poor quality of Britain’s allergy services. Because reliable information from the NHS is so scarce, patients turn to other sources. Some of these are unreliable and inaccurate.

9. People may rely on information they see in the media, which is frequently misleading and sometimes dangerous. Such headlines as “60,000 kids at risk from peanuts” (Daily Mirror) are a serious overstatement in terms of the actual numbers of children whose lives are threatened. The internet may also be a tempting source of information but many websites provide information that is either inaccurate, confusing, out of date, unnecessarily alarming, written in terms lay people cannot understand, or promoting questionable allergy tests and treatments. There is also a temptation for patients to consult alternative practitioners, with the inevitable risk of misdiagnosis and inappropriate treatment.

10. A 2006 study found that a wide range of allergy tests are available from the internet, with about one-third being reputable tests but the rest of unproven value. The authors say that few websites offering these tests acknowledge the need for careful interpretation.

11. The Anaphylaxis Campaign helpline staff are aware that people with allergies will frequently seek and locate sources of help and information that may well be of dubious value. Often they have waited many months for an NHS referral and are desperate for answers. The types of testing considered include Vega, kinesiology, and hair and blood testing conducted by mail. Some of these testing methods are promoted in High Street health food shops. In addition, “cures” are offered by many practitioners including Chinese herbalists, oriental “massage” practitioners and others. Many of these methods have no proven value at this time.

12. During one Anaphylaxis Campaign support group in South London, a young woman with severe food allergy was advocating the use of “freedom technique”, a therapy whereby the patient, at the onset of a reaction, taps their index finger under the nose and above the top lip. She claimed this stopped an anaphylactic shock occurring and that she does it before taking adrenaline. The meeting was made up of (in our opinion) intelligent middle class women, most of whom were seeing a good allergy specialist in London, yet at least 50 per cent wanted more info and appeared to be considering this as a technique to try.

13. The situation we have described will continue. To summarise: There is a great need for an improvement in allergy services under the NHS; and there is a great need for national consensus guidelines for the management of severe allergy and the prescribing and administration of adrenaline.

REFERENCES [not printed]

IMPACT OF ALLERGY AND QUALITY OF LIFE

1. There is no cure for food allergy. People at risk must adopt avoidance as the first line of defence. They must commit themselves to learning management strategies, reading food labels scrupulously every time they shop and taking strict precautionary measures when eating out. Unfortunately these defensive measures frequently fail. Many of those affected describe food allergy as “a sword of Damocles” and perceive mealtimes to be akin to “playing Russian roulette”.

2. The risk they face is real, not theoretical. The following example is one of thousands reported to the Anaphylaxis Campaign during its 13-year history: A teenage boy ate two mouthfuls of apple pie bought in a supermarket. He suffered anaphylaxis requiring emergency medical treatment. The pie contained 0.006 per cent milk protein, quite legally undeclared (at that time).

3. Incidents like that are relatively common and lead to extreme anxiety and poor quality of life among the families affected. The Anaphylaxis Campaign helpline received 6,269 calls during 2005. Many of the callers showed themselves to be extremely fearful because of the unpredictable nature of severe allergy. Many of their fears are unfounded and result from common myths that give a disproportionate impression of risk (a process that is fuelled by media scaremongering). One of the common myths is that a severely allergic child is unlikely to reach adulthood.

4. The way to dispel those myths is better patient education and more research that clearly puts risks into perspective, as well as research that offers patients better treatments.
5. The anxiety linked with peanut allergy was quantified by a research study showing that children with the condition are more anxious than children with insulin-dependent diabetes mellitus. Children from both groups completed “quality of life” questionnaires and recorded with a camera how their condition affected their lives over a 24-hour period. The results were then analysed.

6. In comparing the two groups, the researchers found that children with peanut allergy were more afraid of potential hazards, more anxious about eating and felt more restricted regarding physical activities. The researchers believe this anxiety may stem from the feeling that they have little control over their lives. The team's report said this high state of anxiety among allergic children was unjustified and did not have to be permanent. With appropriate education about allergy management, children could be helped to develop self-confidence and a positive attitude.

7. In 2005 and early 2006 the Anaphylaxis Campaign undertook two surveys of its own members.

8. The first survey was conducted during November and December 2005. All 7,695 members were sent a letter asking them to write about their experiences of living with severe allergy. Of the 7,695 who were mailed, 1,021 replied—making a 13 per cent return. This is a very high return for public surveys.

9. One parent who responded told of a long wait to have her son properly diagnosed “When William had a severe reaction to peanuts we had to wait nine months before we could have him allergy tested.” Others were happy with the service but worried that the medical profession was over-stretched: “Staff fantastic, from GP to specialist, but definitely a feeling that they felt overwhelmed.”

10. A great many of those who responded said they were disillusioned by the NHS: “We have had to fight for medical assistance and still feel unsupported.” Some said they had been forced to go private: “The waiting time for a hospital appointment for testing was at least six months. We paid to go privately.” Many more were grateful that they managed to see a specialist but were concerned at the distance they had to travel to take up these appointments: “We recently went to our GP in Maidenhead who stated we would have to go to Southampton for any specialist treatment. This will be a round trip of 150 miles plus.”

11. One respondent recounted a dangerous piece of advice given by her GP after her son presented with allergic symptoms: “The GP said he had no training in allergies and a slow reintroduction of nut traces may be the way to go.” Another felt let down by the GP in the day-to-day management of allergy: “We have been offered very little help or information about his allergy from our GP or local hospital. We have gained nearly all our knowledge of his allergy from the Anaphylaxis Campaign.” Another parent said: “The GPs and nurses at our practice had no advice for us, other than do not give her peanuts.”

12. Experiences such as those quoted above are among the causes of extreme anxiety and poor quality of life experienced by people affected by anaphylaxis. Responding to our survey, one mother said her anxiety is so great she only manages it by having her grown up allergic son call her daily. Another spoke about her disabled son and stated “My son aged 10 has severe disabilities but the thing that most prevents us from leading an ordinary life is his severe nut allergy.”

13. A second, more formal survey took place in January 2006 to provide quantitative information. This time the membership was asked to complete an on-line questionnaire and this brought responses from a total of 1,117 members (patients or the carers of patients). This amounted to 14 per cent of the membership. The objective was to find out about the experiences of allergy services through the NHS as well as how living with allergy affects the quality of life.

14. Quality of life is a huge issue as our findings show. The people who responded have the benefit of the support and information of the Anaphylaxis Campaign, yet even they are profoundly affected.

15. Full results of both surveys are presented with the hard copies of this submission.

16. To summarise: The Anaphylaxis Campaign wishes to see: Better patient education for people at risk of severe allergies in order to improve their quality of life; more research that clearly puts risks into perspective; new and better forms of diagnosis and treatment.
Conclusions and Future Work

Government policies to date

1. We consider that the measures proposed in the Department of Health’s Review of Services for Allergy will fail to address a serious unmet need. It appears that the Department of Health has scant regard for the whole discipline of allergy as evidenced by the lack of any emphatic recommendations about the development of allergy services, despite all the evidence presented. We support the measures detailed in the Royal College of Physicians Report and believe that these are the answer to the significant problem of poor allergy services.

2. We call on the Department of Health to reconsider its recommendations in its recent review of allergy services in light of those made by the House of Commons Select Committee for Health in November 2004. They recommended 40 new specialist posts in the field of allergy which would greatly reduce the burden currently placed on the 27 whole time equivalent specialists and eight trainees who are working in the field at present. Once trained, these doctors will join the allergists currently at work in the NHS to become the core of a modern allergy service which can be available to patients across the whole country when they need it. Subsequently the more trained specialists there are the more trainees can be recruited, meaning a constant supply to replace those who leave the discipline for whatever reason.

3. On the other hand, the Food Standards Agency has made great progress towards addressing the needs of food-allergic consumers. We have worked with the Agency’s allergy branch since the Agency’s inception and are impressed with the strong grasp they have of the issues. Indeed, there have been many useful measures taken by the Agency, including guidance documents for caterers, food manufacturers, retailers and the allergic public, and the funding of individual projects undertaken by the Anaphylaxis Campaign. Furthermore, the Agency’s research programme is funding some vital work, and the Anaphylaxis Campaign hopes fervently that this funding will continue. Ultimately it is in research that the hopes of people with allergies lie. We outline in Point 7 below some the areas where, in our opinion, progress is needed.

4. Despite much progress, people are still dying of allergies. Further work in the catering sector—where most of the serious reactions occur—is vital. What is needed is a full national training programme for local authority enforcement officers. This is lacking at present.

5. On the subject of schools, we feel the House of Lords Select Committee should note that the Government’s “Transforming School Food” initiative appears to have taken little account of food allergies.

6. There is a great need for national consensus guidelines for the management of severe allergy and the prescribing and administration of adrenaline.

The need for future research

7. The Anaphylaxis Campaign would like to propose a number of areas for research. These have been compiled during discussions involving experienced staff members of the Anaphylaxis Campaign—“front line” people with regular direct contact with people with allergies.

   — “May contain” labelling: How often do reactions occur through people eating food labelled “may contain X”? What symptoms do they experience? What foods are they reacting to?

   — Food production: What are the threshold levels for individual food allergens (the amount of allergen below which a reaction will not occur)? What food production procedures and cleaning methods would be adequate to bring food to beneath this safety line?

   — Allergy care: Which patients should be prescribed adrenaline auto-injectors and which patients should be denied them? How many auto-injectors should be available to severely allergic patients at any one time?

   — Severity of reactions: Can it be determined which patients are at risk of life-threatening reactions and those that are likely to experience only mild ones? What percentage of people diagnosed with food allergy react to casual contact with an allergen (smell or touch)? What are the implications with regard to airline travel or being in another enclosed space such as a public house or club?

   — Psychological effects: Are allergic children as anxious about coping with allergy as their parents?
Development of allergy: Can sensitisation be prevented through pre-natal, weaning or early life interventions. How much does lifestyle increase the chance of becoming allergic? Why do people develop allergies later in life? Why does an apparently mild allergy become more serious during a person’s teens?

Emerging allergens: Can the risks posed by new allergens, such as lupin flour, be quantified so that appropriate advice may be given to those who may be at risk?

Conclusion
8. Even with a correct diagnosis, those living with severe allergy face a huge battle every day and their quality of life and that of their extended family is greatly affected. The shortage of information from the NHS, means that for many little is known about a potentially life threatening condition. The Anaphylaxis Campaign has 7,904 members who benefit from a newsletter three times a year and regular bulletins and updates but the estimated figure for those with allergy severe enough to require specialist care is up to three million. This means there is a huge shortfall of people who are not aware of all the facts and could be living without a suitable self-management plan. Quality of life is also compromised by the feeling of being out of control. The allergic population is reliant on the food industry to label correctly and the medical profession to diagnose and treat effectively. Both areas are flawed due to lack of services, education and knowledge.

9. We welcome the House of Lords Select Committee on Science and Technology’s investigation and are available to offer further information on request.

REFERENCES [not printed]

Supplementary memorandum by The Anaphylaxis Campaign

ADRENALINE AUTO-INJECTORS IN SCHOOLS

Background: Children with severe allergies face some risk when they leave the relatively safe environment of the home and face the unpredictable environment of school. Their parents suffer high anxiety levels. The Anaphylaxis Campaign believes the risks can be managed and minimised. What school nurses and staff need is information and training. Training should include instruction in the use of adrenaline auto-injectors. Unfortunately schools are hampered by a lack of national guidelines for the prescription and use of auto-injectors. There is no consensus about which children should be prescribed them or how many should be available to each child.

Evidence of need: During 2006, the Campaign helpline took 4,563 calls. School problems were among the common recurring themes. Knowledge about the use of auto-injectors among UK schools is patchy. In worst cases, schools and pre-schools have effectively excluded children who carry auto-injectors. There is published evidence to support the Campaign’s experience:

— A survey in the Severn NHS area found that 44 per cent of schools with an allergic pupil either did not have staff trained to administer medication or declined to respond to the survey. Less than half of the schools with nut-allergic children said they gave relevant information to all teachers.

— In the Hull and East Yorkshire area, 82 per cent of schools surveyed had no policy on allergic reactions, 55 per cent had no training to deal with reactions and 67 per cent wanted training.

— An audit of schools in Nottingham identified inconsistency in knowledge and awareness about treatment of allergies. Gaps in training for school nurses and school staff were identified.

— A survey by the Campaign of 14 school nurses in the West Midlands showed that all would welcome training by the Campaign. The West Midlands is an area where allergy awareness in schools is already high, indicating that training is probably more urgent in other areas.

Addressing the unmet need: The Campaign is meeting an unmet need by running a national training programme for school nurses. This has been successfully piloted in five areas of the UK. However, the national roll-out is subject to funding becoming available.

Generic auto-injectors in schools: We believe a solution to the lack of consistency in schools on the carrying of adrenaline auto-injectors could be to have generic auto-injectors available in schools where there are severely allergic children. Under this model, each child who had been prescribed adrenaline would have their own injector available. The generic injector, held by the school, would be available for any child who may need a
second dose. Subject to funding, a scheme along these lines will take place in Basingstoke from September 2007. The project has been devised with full input from the local allergy service, GPs, schools and school nurses.

Memorandum by Dr Richard Pumphrey

FATAL ANAPHYLAXIS (FATAL ACUTE ALLERGIC REACTIONS)

The UK fatal anaphylaxis register has attempted to record every fatal acute allergic reaction in the UK since 1992 and is the most accurate source available in the world for statistics on fatal anaphylaxis. From 1992–98, around half the UK fatalities were to medical interventions such as drugs used in anaesthesia or injections for special X-ray investigations. The remainder comprised fatal reactions to stings and to foods together with rare causes such as anaphylactic reactions to latex, hair dye, parasitic worms (hydatid cysts) and so on. Fatal anaphylaxis to food in the seven years 1999–2006 has followed a very similar pattern to the previous seven years: the data for stings and drugs is incomplete and further study is needed; from the data in the register so far it seems probable that the pattern will also be similar to the previous seven years.

A third of the population suffers from allergy but mostly their reactions are not dangerous. At least one person in a thousand has one or more serious reactions but fewer than one in a million will die from their allergy; of those who die, over half had no previous serious reaction, which makes it very hard to know who should take specific precautions, such as carrying an adrenaline pen for emergency self-treatment. Of the last 48 fatal reactions to foods, adrenaline pens had been provided to 19 (40 per cent) including 11/13 with previous severe reactions. Despite this, the rate of food allergy deaths is somewhat higher than it was in the previous seven years when fewer had pens. The reason the pens failed was in some cases obvious (pen time-expired, pen used too late in the reaction, pen not carried that day). Some of the pens may have failed because the patient was too fat for the pen to give the necessary intramuscular injection. Others used the pen correctly, were thin, had the correct dose and still died. One 16-year-old girl took the risk of eating a chocolate labelled “may contain nuts” because she had her pen with her. She used the pen immediately she saw nuts in the chocolate but nevertheless died from her reaction. Clearly pens cannot be relied upon to save someone with a food allergy reaction and patients must continue to take great care to avoid their trigger food even when they have a pen.

It seems that the mechanism by which anaphylactic reactions are fatal depends on the patient’s state of health. Those with asthma will usually die from an acute attack of asthma brought on by the allergic reaction; for such people, optimal daily control of their asthma will protect them from a fatal allergic reaction. Those with heart disease are more likely to die from shock; medical treatment for raised blood pressure makes allergic reactions more severe. Rarely, inflammation in other sites such as around the brain will be affected during an anaphylactic reaction, leading to different mechanisms of fatality. In some cases a very severe allergic reaction can kill an otherwise fit and healthy person by redistribution of the fluids in the body leading to shock; in such cases an upright posture may make an otherwise survivable reaction fatal.

These and other observations from the fatal anaphylaxis register have provided the evidence for logical treatment guidelines for anaphylaxis. The details of new cases on the register still provide new insights and it is essential this recording is continued in the future.

15 January 2007

Examination of Witnesses

Witnesses: Ms Mandy East, National Co-ordinator, Anaphylaxis Campaign; Professor Gideon Lack, Head of the Paediatric Allergy Service, King’s College London, Guy’s & St Thomas’ NHS Foundation Trust; Dr Richard Pumphrey, Consultant Immunologist, St Mary’s Hospital, Manchester; and Mrs Hazel Gowland, Allergy Action UK, examined.

Q433 Chairman: Can I welcome you all here today and thank you for coming. The individual members of the Committee will not be declaring their interests as we go round because that has all been noted in a separate document. I wonder if I could start off by asking you to introduce yourselves and then we will go into questions.

Mrs Gowland: I am Hazel Gowland. The reason why I am here primarily is because I have a severe, potentially life-threatening allergy to nuts and peanuts. I have a number of hats. You have called me today as Allergy Action. Allergy Action is basically me; I am self-employed. I have a sole trader business but I also work for the Anaphylaxis Campaign. As
Ian mentioned I am the person who has been delivering all this training. I have a number of roles to play. I give free information to anybody who is allergic who ever asks me for help. I have a formal role as the food adviser for the Anaphylaxis Campaign which is varied. It has involved liaising with Sue and the FSA team on all the policy documents and these pieces of guidance and so on. I also work with Dr Pumphrey on analysis of where people get caught out with allergic reactions so I have a research role from the practical, human point of view. I am delivering the training for the Food Standards Agency and for the project in Northern Ireland and across the border for the environmental health officers. Independently I also made a training DVD which I think I sent you. I do not know whether you have seen it, but it is an accessible training pack for caterers. I train caterers and other food handlers including schools, nurseries, childcare, chefs, etc. et cetera who call me on a commercial basis.

Q434 Chairman: Thank you, Dr Pumphrey?
Dr Pumphrey: I am Richard Pumphrey. I have many years’ experience in allergy clinics and in running a Health Service laboratory that undertakes allergy investigation of patients. My particular expertise here is that I have made a special study of everyone in the country who has died from an acute allergic reaction to food and that has produced a lot of new insights into what the problems are.

Professor Lack: I am Gideon Lack. I am a consultant in paediatric allergy. I work at King’s College London and St Thomas’ Hospital. I have been practising paediatric allergy for the past 15 years; my particular area of interest is systemic allergic disease or complex allergic disease in young children. I am mainly interested in the rise in food allergies and what may be the causes behind them and how to prevent them, particularly the relationship between early diet in the first year of life and subsequent development of allergies. My other particular area of interest is severe or difficult asthma in childhood and the role of allergies in contributing towards this.

Ms East: My name is Mandy East. I am the national co-ordinator for the Anaphylaxis Campaign which is a national support organisation for those living with the most severe of allergies that could lead to anaphylaxis. I also represent the Anaphylaxis Campaign to the National Allergy Strategy Group which is the coming together of many patient support groups and medical professionals set up to improve allergy services.

Q435 Chairman: Thank you. I think it would be helpful if I could ask you to start off by explaining to us the difference between food allergy, food intolerance and food anaphylaxis. Dr Pumphrey, would you like to start?

Dr Pumphrey: People can obviously react adversely to food in a number of different ways. At one end you have toxic reactions where nearly everybody would react to that food with an adverse response. Then there are different types of hypersensitivity reaction where most people can tolerate the food but for particular individuals that food will cause a problem. Those are now divided into those who have an allergic basis (that means anything that is immunological) and those which are due to other mechanisms. So you have non-allergic hypersensitivity or you have allergic hypersensitivity. Allergic hypersensitivity is now also divided into that which is IgE-mediated and that which is not (IgE is the allergic kind of antibodies that we can measure in a laboratory, which you get measured if you have an allergy test for example). Those are the principal different types of adverse response that you can have to a food.

Q436 Chairman: Could I just ask you, is so-called oral allergy syndrome a true allergy?

Dr Pumphrey: Yes. Oral allergy syndrome is generally caused by an IgE-mediated response. The allergic antibodies are key to the oral allergy syndrome. The reason it is only oral allergy is that the things you are allergic to in the food are very labile, they are destroyed by acid in the stomach and so the allergy does not spread beyond the mouth. It also needs to be something that is absorbed through the membranes in the mouth to cause a local response there.

Q437 Lord Taverne: Could you remind me about the non-IgE allergic response basis for that?

Dr Pumphrey: An allergic but non-IgE response typically would be something like gluten sensitivity where there is an immunological process underlying this in that you have IgA antibodies against one of the components of the food but also you have autoimmune response involvement as well and the lymphocytes are involved in the response, so you get a local destructive response in the lining of the gut, for example, as a result of eating food that contains gluten. That has an immunological basis to it but it is not IgE-mediated.

Professor Lack: Dr Pumphrey made some very important distinctions and in clinical practice we see these different sorts of reactions being manifested to the same foods. Part of the confusion can be in disentangling these diagnoses, sometimes they may even co-exist. To give an example, I may see a six-month old baby who comes in with eczema who has tasted milk formula for the first time. The face immediately swells up, there is vomiting, there are breathing difficulties; that is an immunological
reaction; therefore it is an allergic reaction. It is quick on-set; it is IgE mediated and you can test for this easily. In contrast a different child could come in at six months of age with severe eczema, diarrhoea, poor weight gain and has delayed on-set reaction to milk. Very often this child will have inflammation in the gut; there are T lymphocytes in the gut that are responsible for this. While this is also an immunological response to a food and therefore represents an allergic reaction, it is a delayed non-IgE mediated type of reaction. We are discovering a lot more about these delayed onset allergic diseases in children and in adults. The third type of clinical presentation to cow’s milk would be a child who has been drinking milk, who has had gastroenteritis, often due to a viral infection, and then the gut stops producing the enzyme lactase. This child has a metabolic deficiency—has a deficiency in the enzyme lactase—and therefore cannot break down lactose (which is the sugar present in milk) and consequently has diarrhoea and other symptoms. This is not immunologically-mediated, and therefore is not an allergic reaction. It is often short-lived, but in some people who are genetically pre-disposed it may continue into adulthood. The same child may manifest all three types of allergies to cow’s milk at different times in childhood.

Q438 Lord Colwyn: This is a question I should know the answer to, but when does a severe food allergy become anaphylaxis? I was under the impression that anaphylaxis was when respiration becomes impossible and the patient could die without medical intervention.

Professor Lack: The term anaphylaxis is used to a certain extent differently by different people and in some ways is viewed differently by our North American colleagues. Everyone is in agreement that a life-threatening food allergy represents anaphylaxis; so one that causes compromise of the respiratory system or compromise of the cardiovascular system (drop in blood pressure); is considered life threatening and therefore anaphylaxis. Some people also call a systemic allergic reaction—one which manifests all over the body or on different parts of the body—anaphylaxis. In children who have a food allergic reaction of the rapid on-set IgE type (the face swelling, for example), some 30 to 40 per cent of children at some point in their lives will have respiratory compromise as a result of these reactions and will need to seek medical assistance or need to use an asthma pump because of difficulty breathing.

Q439 Lord Rea: From what has just been said it is not surprising that the Institute of Food Research has said that estimates of the number of people suffering from food allergy are imprecise. Our attention was drawn to the BMJ article of 2 September where experts Professor Colver and Professor Hourihane give different estimates of the prevalence. How could studies be improved to more effectively monitor the prevalence of food allergy, intolerance and anaphylaxis?

Dr Pumphrey: The key problem here is the distribution of severity. You have a lot of people who have a very mild allergy and a few people who have very severe allergies. It is a continuous distribution so you have to make a choice as to where to put the cut-off point and a small change in your criteria could produce a 30-fold change in the numbers of people you are counting. I do not think that technically you are ever going to come up with an accurate, precise figure. You can say that three per cent of the population have food allergies providing you define what you mean by it. Or you could say that one per cent of the population have food anaphylaxis and you might get agreement with people. You can quite accurately say that only five to 15 people each year die from food allergies; you do have a cut-off there.

Q440 Chairman: Going back to the previous statement from Professor Lack, if someone has a mild, generalised reaction to food, is that anaphylaxis? If it is not, might that person go on to develop anaphylaxis on another occasion?

Dr Pumphrey: I can answer that from looking at the fatal reactions. Over half the people who die from a food allergy never had a severe reaction before. The only reaction they had before was a mild reaction so clearly people can go on from having a mild reaction to the next reaction being a fatal one.

Professor Lack: Just to add to that, there are certain risk factors for anaphylaxis. You can identify someone at high risk for anaphylaxis but you can never confidently say that someone is at low risk. I think that is an important distinction. I can see a child who presents with a mild egg allergy—this happens in clinic frequently—is given Piriton and told not to worry, the problem is going to go away. You do not see the child for a year and in the interim the child develops asthma and some of these children may develop difficult asthma particularly as egg allergy and food allergies put you at risk for other allergic diseases. Once the child has asthma, particularly if the asthma is poorly controlled and they encounter the food, then they have a much more severe reaction. So seeing a child early on or even an adult early on with mild symptoms does not reassure you, and does not give you or the patient the confidence that the reactions will be mild thereafter.

Mrs Gowland: Some of the work that I do for the Anaphylaxis Campaign involves making contact with families where somebody has died. Therefore I am able to work with Dr Pumphrey with the family’s
consent, and this involves two things which would otherwise be unavailable. I can find out what happened on the day in great detail with my own experience of having suffered allergic reactions and I can also find out a lot more about their background and the whole atopic history of the person on a very informal level (I am not medically qualified but I understand their life). Therefore I can listen to mothers of young adults—it is often a 20 year old person, maybe a 30 year old person—who say that the doctor said it was a mild nut allergy when they were two and they muddled along as I did through childhood, a bit wheezy at parties, a bit sick but never having fatal or potentially fatal symptoms until some other time of life. We seem to pick them up in adolescence and anecdotally that is the high-risk age for life generally. Lifestyle and life skills-wise you can understand why, say, first year students are particularly vulnerable. They are new adults, legally adult, away from home, choosing their own foods with new friends. Those are circumstantial issues apparently to do with allergy risk but too many of them have had minimal symptoms in early childhood. In a class of three-year-olds you would not be able to distinguish between two children with a nut allergy, which of those children might be the one that might die from it later.

Q441 Chairman: Dr Pumphrey, from your database what is the age distribution of the deaths?

Dr Pumphrey: It varies from one food to another curiously. Children dying from milk allergy the age range is from five months to about 16; for peanuts it is from 13 to 26; for tree nuts it is from 18 to 36 (with a few older people as well). Then you have fish, crustaceans and so on where we do not have large numbers to talk about a proper distribution; we cannot do statistics because there are so few cases.

Q442 Baroness Platt of Writtle: My question is to Hazel Gowland. Allergy Action offers advice and training on food allergen risk assessment and management. What type of businesses request material or training from you and how does your work feed into the work of the Anaphylaxis Campaign?

Mrs Gowland: When I joined the Anaphylaxis Campaign as a member I thought I would be a very ordinary member and there would be thousands of people like me. I quickly understood that there were a lot of people in my generation who, at the time, had young children and they were frightened for their allergic young children whereas I was an allergic adult who was confident—I was a school teacher at the time—and so going into a room full of people and telling them about life is where this work started, and giving them confidence as well. That has developed so that my work with the Anaphylaxis Campaign has led to talks, presentations and increasingly structured formats for different audiences. The key audiences now are various London boroughs who bring me in to train food handlers generally and nursery staff, people managing small children in particular, not just the people feeding them but the people looking after them day by day because obviously those little children, as Dr Lack has said, have a dynamic allergic status and require some supervision in their environment. Then there are the large, reputable catering organisations, the kind of companies that will have in-house catering—also banks, insurance companies, those sorts of people. I have worked for the John Lewis Partnership. Sometimes schools, sometimes regional branches of the professional bodies—the Trading Standards Institute, the Chartered Institute of Environmental Health—will call me to give a talk for them. Now this is increasingly structured because of the work that I am doing delivering these workshops. It started out as a half hour presentation on somebody else’s programme and we have now got a five-hour all-day package. I was doing one of these FSA workshops yesterday in Lincoln with 20 trading standards and environmental health officers, funded by the FSA, which has been one of the goals of the Anaphylaxis Campaign for a long time. When I started calling for that six years ago I did not realise it would be down to me to deliver it. I thought that something would happen, there would be a magic training fairy that would come and deliver this training, but it is me, so I am doing it. Those are my various ways of working.

Q443 Baroness Platt of Writtle: You cannot do all this on your own. You have talked about London boroughs, you have talked about schools, you have talked about businesses, but presumably there is a great need for people like you to be doing it on a wider scale.

Mrs Gowland: That is my aim. It is fantastic work, it is very rewarding and we can make changes; we can change the way people work.

Q444 Baroness Platt of Writtle: Do you have other people working for you in that field?

Mrs Gowland: The training yesterday was delivered by the first person I have trained to deliver a workshop. I go as an extra but it is a dovetailing process and gradually she is taking more of the script off me. Her background is that she was an environmental health officer so she has all the credentials of the local authority enforcement officer and she now works in the private sector so she is visiting and auditing every size and shape of business from huge factories down to little takeaways on a daily basis. I have had to teach her allergy and she has
taught me about her food safety world by return. I think if anybody could do cloning that would be useful.

Q445 Lord Taverne: There are two of you now but by the sound of it you need hundreds.

Mrs Gotteland: We do, yes. We do what we can. The Anaphylaxis Campaign has a special website which is called cateringforallergy.org which we wrote—I put a lot of content into it—which is another place where there is credible information. I will train anybody to deliver if they want to go and train. The NVQ question you asked earlier, it was 1995 when I went to the training bodies for the syllabus for the training of food handlers. I have been trying to get it on their radar but, as Dr Leitch suggested, getting new subjects on a fairly packed curriculum is not always easy. The other thing that was mentioned earlier which I will say is that on my Allergy Action website there are translations for people to go on holiday and they can help themselves. I have translations in certain languages—as many as I have been able to get—so people can talk to chefs when they go on holiday, they take a little card with them. There is a lot more work to be done.

Q446 Lord Colwyn: The Department for Education and Skills have a recommended list of healthy foods which of course includes nuts and seeds and no doubt kiwi fruit. Do you feel that children with food anaphylaxis or a tendency to that are sufficiently protected in their school?

Ms East: The Anaphylaxis Campaign have done a lot of work on this and we do not advocate nut bans in school; we have never been of the opinion that you should ban all nuts and all major allergens in schools. We believe more that management and for the child to learn to avoid is much better in equipping the child for later life. However, with the Department for Education and Skills suggesting that nuts and seeds are deliberately brought into schools we have had to take a stand. At present a vast majority of primary schools and certainly pre-schools do not have nuts in school deliberately and a lot of them actually ask parents not to send nut products and in some cases milk and egg products in with children’s snacks or packed lunches. With the primary schools this will probably be managed within schools because there is a great knowledge amongst head teachers that they need to be keeping their allergic children safe. However, our concerns are secondary schools where the children are much more independent, have control of their own money and a lot of these snack products will be provided through vending machines so there will not even be any human contact when people are buying the products. When you are looking particularly at nuts—peanuts and tree

nuts—you have to remember that the allergen is the protein within the nuts and it is extremely transferable so if somebody is eating nuts it will be passed to somebody else through hand contact, through hand to face contact and also through discarding of the wrappers. Obviously, as we were saying before, the thresholds of what people will react to are unknown but certainly a local reaction is extremely likely if someone were to touch you after they had been eating nuts. So although we are not saying that all these reactions could prove fatal, we are saying that it will directly affect the quality of life of the children attending the school. Anecdotally, since this has come out and it has been well known that this is going to happen, we have had very worried mothers and indeed worried young people speak to us to the point where a number of children are scared to go to school. Also this leads into the worry of possible bullying. This does happen, particularly in secondary schools, where if a child is different that difference will be picked up. Children have had nuts put into their blazer pockets and into their lunch boxes to try to contaminate their food. It is very much an issue that we are working on and we are trying to educate head teachers and teachers within the schools, but also educate the peers and the young people themselves. As we have already heard, from the ages of 11 or 12 upwards, up to when you would leave school and take on life independently, you are at an extremely vulnerable stage in your life. The answer to the question is that we are not particularly happy about it but we are working very carefully to make sure that if it happens it happens in the safest way possible.

Q447 Lord Colwyn: Can anything more be done to prevent this casual contact with these allergens? So far as I am aware, even handling a banister which has nuts on it from hands can trigger an anaphylactic shock? Or is that not right? Is that very rare?

Dr Pumphrey: We have looked at the source of allergen and severity of reaction, and in general, environmental contamination leads to a relatively mild to moderate reaction, not the most severe ones; it is very unusual to get such a severe reaction. Contamination can happen but nearly all the fatal reactions have happened from intentional ingredients.

Ms East: Can I just add to that that we do agree with what Dr Pumphrey has just said. We are of the opinion that the allergic population need to be more aware of the type of reactions they are having. However, for someone who is not medically trained and a young person who does not really know very much about their allergy it is still extremely scary to have a local reaction because they do not know and do not have the knowledge—because they are
not seeing allergy specialists to give them that knowledge—how that reaction will turn out. There is then a level of panic. That can lead to a different type of reaction like a panic attack or some type of worry because they do not know what is going to happen even though we know that medically it is very rare for you to have anaphylaxis through local contact.

Q448 Lord Colwyn: I am feeling rather humble in fact because my youngest daughter works for the advertising agency that does Mars and Snickers. I am just wondering whether the manufacturers of these sweets that contain nuts are doing enough to prevent the problem?

Mrs Gowland: You heard from Sue Hattersley from the Food Standards Agency this morning and if we are honest, in the UK these things are better dealt with than they are across the Channel and probably in America as well. The nature of the relationships between the consumers and the manufacturers and the retailers and those who influence controls and labelling is excellent; we really do have very close relationships. There are some insurmountable problems. One of them is that you do not wash in a chocolate factory because water in a chocolate factory adds a microbiological risk so if you want to clean a chocolate line what you do is just push more fat down the line and it is supposed to pick up the contaminants or whatever along the way, or you push chocolate through the line. Anecdotally I have had a life threatening episode when I was at a high risk age from a chocolate that was not meant to contain nut but had picked up some contamination probably because of rework. That is another thing that happens in factories, you recycle something that was not used and you put it back in. You can take the chocolate off the wonky ones and put it back in the system and make new chocolates. There are some things which are very difficult to manage. There are some companies that have gone to great lengths and even made it their main purpose to exclude particular allergens from their production, but there are some very practical issues and if you think that the aim of a manufacturer is to make things as cheap and simple as possible, which essentially means having the most flexibility between what you run down a line and keeping the line going night and day so that you can get the best use out of your resources, whereas the optimum for the allergic consumer is to have separation, segregation, protection, limits (ie changes of uniform, controls of air, lots of extra hand washing and so on). You can see that there is a crunch there and it is always going to be a compromise.

Q449 Viscount Simon: In oral evidence the Department for Education and Skills said that “all school nurses are trained nurses and many are qualified children’s nurses, and this means that they will all have had some training and experience in the management of anaphylaxis”. How does the Anaphylaxis Campaign respond to this assurance?

Ms East: Obviously the statement is not untrue, however a lot of school nurses had their nurse training many years ago—some up to 30 years ago—and a lot of them do not have the training in anaphylaxis that is needed today. A lot has changed in the management of anaphylaxis and the treatment of allergies in general, certainly over the last 30 years. Even more recently the way that the adrenaline auto-injector is given has changed and a lot of nurses will not be aware of that change because once they have had their training in order to qualify them there is no obligation for them to be retrained or have any refresher. Obviously we agree that school nurses are trained nurses, however a lot of research is being done into schools and the school system and whether the nurses and medical professionals in charge are able to cope. In the Select Committee for Health report in 2004 a survey conducted in the Hull and Yorkshire area of the country showed that 200 schools were surveyed and 82 per cent of those schools had no policy for dealing with allergy and anaphylaxis yet they had children within the schools who were actually living with those conditions, and they were schools with school nurses in so those school nurses were not confident enough to give the adrenaline auto-injector if needed or manage local reactions. The Anaphylaxis Campaign are now in the second stage of a UK-wide project in order to train school nurses and the background for doing that showed that there was a definite, genuine need to get school nurses trained to a level where they can actually administer medication as needed or just manage the reactions in children. To date 99 nurses have been trained and of those trained 21 told us that they had never had any form of training for allergy management. About 40 per cent of those they were schools with school nurses in so those school nurses were not confident enough to give the adrenaline auto-injector if needed or manage local reactions. The Anaphylaxis Campaign are now in the second stage of a UK-wide project in order to train school nurses and the background for doing that showed that there was a definite, genuine need to get school nurses trained to a level where they can actually administer medication as needed or just manage the reactions in children. To date 99 nurses have been trained and of those trained 21 told us that they had never had any form of training for allergy management. About 40 per cent of those

Q450 Lord Taverne: Could you give us some assessment of what you think of the treatment within the National Health Service of patients with food allergy and anaphylaxis and the quality of the advice they are given about managing their condition?

Dr Pumphrey: That is a difficult question. It is difficult because I think the standard of care differs across the country. There are different areas and different practices. Partly it is due to different opinions about what the correct management is. One could take a simple example, adrenaline pens. There is a range of opinion across the country as to who it is appropriate
to give an adrenaline pen to. In some areas they will be given to anyone with mild allergy. If you are managing someone with asthma and peanut allergy they will automatically be given an adrenaline pen. In other areas there is a great resistance to this because it is thought that the evidence of these pens being helpful is not that clear. There are some people for whom adrenaline pens are less likely to be effective, for example people who are overweight may not get benefit from them. There are a lot of ifs and buts. I think the quality of care across the country is patchy.

**Professor Lack:** I would have to agree that the quality is patchy but overall if you look at numbers of specialists in the country in adult allergy and paediatric allergy, we are not only the poor man of Europe but to a certain extent the poor man of the world because we do not have specialists and if you do not have specialists it means you do not have people in secondary care or in primary care who know much about allergies. There is a general lack of knowledge about allergies right across the board. Sweden has 96 paediatric allergists paid for by the health care system; the UK has a handful, most of whom are on academic funding. The numbers reflect similar under-staffing in adult allergy. I am sure you have heard evidence on the prevalence of allergic disease and it is no remarkable coincidence that the waiting lists for allergy clinics have sky rocketed and are very difficult to control, particularly within primary care so many people will present to primary care in the expectation that they must have some specialist care. There is not a specialist referral I think that that kind of system is not acceptable.

**Ms East:** Can I just add as well that from a patient point of view the problem is not just there are not enough specialists, there is a lack of knowledge in primary care so many people will present to primary care with allergic disease and quite often that allergic disease should be managed within primary care, there is no need for a specialist appointment. However, there is a fear with the parents or the allergic person that they must have some specialist care. There is not the specialist to refer to, the GP does not know how to manage it and so they are often referred to the wrong specialist. So somebody who presents with eczema might be referred to a dermatologist but they do not actually get to the root of the problem. There is not the holistic approach to allergy. The people we hear of are coming to us for advice because they are not getting it from the National Health Service.

**Q451 Lord Taverne:** In this depressing picture are there any particular areas which are even worse than others? The treatment of immunotherapy, diagnosis? Is there any special weakness that one should be aware of?

**Mrs Gowland:** The most frustrating thing is that allergy is cheap. I live with allergy; I am not using adrenaline injector pens because I am very good at avoidance. If a person is more sure of what they are allergic to and how they can avoid it, then their life will improve. It is a whole life thing. If they are in a woolly haze and hanging on a waiting list or desperately trying to pay for some alternative allergy option for diagnosis, then they will be in a muddle.

**The Earl of Selborne:** I would have to agree that the quality is patchy but overall if you look at numbers of specialists in the country in adult allergy and paediatric allergy, we are not only the poor man of Europe but to a certain extent the poor man of the world because we do not have specialists and if you do not have specialists it means you do not have people in secondary care or in primary care who know much about allergies. There is a general lack of knowledge about allergies right across the board. Sweden has 96 paediatric allergists paid for by the health care system; the UK has a handful, most of whom are on academic funding. The numbers reflect similar under-staffing in adult allergy. I am sure you have heard evidence on the prevalence of allergic disease and it is no remarkable coincidence that the waiting lists for allergy clinics have sky rocketed and are very difficult to control, particularly within Government waiting-list targets at the moment. The patients who manage to come to our clinic do so via a very convoluted process. They often come after years of having allergic disease without proper treatment. We see on a daily basis children coming into our clinic who have asthma, bad eczema, hay fever, multiple food allergies. Their asthma is not properly controlled; they have not been diagnosed properly; they have not been told specifically what foods to avoid; they keep having reactions and this is not acceptable.

**Dr Pumphrey:** The great difficulty about being a general practitioner is that you are just that and you have to be able to cope with everything that comes to you. Over the last few years we have had great use of specialist nurses in the hospital practice and we were looking at the possibility of having specialist nurses who would go and help the general practitioners with their allergy patients. From the point of view of screening out those who can be dealt with at a local level and those who do actually need specialist referral I think that that kind of system could be an economical way of approaching it.

**Q452 Earl of Selborne:** Is there a risk that genetically modified food may introduce new allergies?
**Professor Lack:** I do not believe the risk of genetically modified foods introducing new allergens is any greater than the risk of introducing novel foods, naturally produced foods. There is always a risk when you introduce a new food into a society or into a culture that allergies to that food will develop. That has been the case with the sesame seed and kiwi for example. We did not eat kiwi fruit 50 years ago and we did not have kiwi allergy in this country. Intrinsically there is no increased risk by the process of genetic modification of producing more allergenic type foods.

**Q453 Earl of Selborne:** Conversely is there any possibility of reducing allergens by use of GM food?

**Professor Lack:** No, you should not increase the risk of producing allergens by GM foods. In theory a mistake could occur where an allergen in an existing food—a protein in an existing food—that causes allergies is transferred into another food but that will not happen because we know what these allergens are. Whenever a gene is transferred identification of that gene is made. If it is a known allergen it does not take place.

**Q454 Lord Taverne:** Is there any prospect in the foreseeable future that work done, for example by Buchanan and his colleagues in the United States, could produce some sort of elimination of the allergenic properties of certain kinds of food?

**Professor Lack:** One of the problems is that most foods that cause allergies, it is multiple proteins within the food. If you are going to genetically modify each protein you will end up with an essentially different plant and that plant will lose its properties that give it its taste and appearance that make it a favourite food. However, what I would say is that genetic modification at the level of individual proteins in a food may give rise to a plant that is not particularly tasty but to a product that can be used for medicinal purposes to try to switch off allergies because that product becomes tolerated in the allergic patient. It could be given in an injectable form or in an oral form or together with some other medication to try to desensitise the patient in a safe way. There are a few groups working on that principle, the idea of making a hypoallergenic peanut or some other food that you could then treat the patient with to desensitise them.

**Q455 Chairman:** How is drug allergy distinguished from other forms of adverse reactions to medicines? Is there adequate data on the prevalence of drug allergy in the UK and who records it? How are patients with drug allergy managed in the NHS and are there adequate facilities for diagnosing and managing drug allergies?

**Dr Pumphrey:** That is a very long and difficult question. I attended a three-day conference in Liverpool on that topic which barely scratched the surface. The long and short of it is that there are many different types of allergic process and drugs can trigger any of them. Some of them are IgE-mediated like the ones we have been talking about, some of them are IgG-mediated, some of them are cellular mechanisms and some of them work through even more convoluted processes. We are very bad at recognising which drug is causing which and something as simple as penicillin will cause many different types of allergic response. Some of them are dangerous, some of them are not and it is very difficult to predict with any individual patient who has had, for example, a rash from penicillin, whether their next dose will be tolerated without any problems or will cause a major reaction. It is a difficult area and in the Health Service we have very few clinics that can cope with this and also there is a range of opinion within the clinics about how useful the tests are that we use to investigate these allergies.

**Q456 Chairman:** Is it being done better in other parts of the world?

**Dr Pumphrey:** I do not think it can be done much better, but I am sure the French would say that they do it better because they have far more clinics and they have more people interested in the subject and are prepared to look into patients very readily.

**Professor Lack:** I agree that the mechanisms are complex; a lot more work needs to be done on that. One of the problems is that the perception of drug allergy, particularly penicillin allergy, is much higher than the reality. One of the jobs of the allergist is to undiagnose drug allergies and in childhood up to 10 per cent of children—or the families of these children—may think they have a particular drug allergy to a common antibiotic which means they never get that antibiotic and it makes clinical practice very difficult. The tests are not perfect but a good clinic should be able to sort out which child has allergies and which does not and tell them which antibiotics are safe. We do need more specialist clinics.

**Chairman:** In the light of your experience, Dr Pumphrey, I wonder if you might like to write in after this session a short piece perhaps summarising what you learned in three days at Liverpool and also from your own personal life’s work experience because I think it will be very valuable to us and we have not been able to do justice to that in this session. May I thank you all for coming and for having informed our deliberations.
At the meeting on 31 January, Baroness Finlay of Llandaff asked me to prepare a brief written statement about the investigation and treatment of drug allergy.

Almost every drug has caused adverse effects in a proportion of those being treated. The range of these effects is wide and the underlying mechanisms varied and often poorly understood. When the drug reaction is due to hypersensitivity, this may be non-allergic or allergic, and if allergic, may be IgE-mediated or non-IgE-mediated.

**IgE-mediated Drug Allergy**

This type of reaction characteristically causes rapid development of symptoms after exposure to the drug, commonly including rashes or swellings but in more severe cases involving shock or difficulty breathing. Tests for this type of allergy are based on the binding of the drug to IgE in a specimen of the patient’s serum, or by challenge with a small quantity of the drug by skin prick test. More reliable but potentially dangerous is a drug challenge (drug provocation) test, when the patient is given a dose of the suspected drug under conditions where it is hoped the adverse effect will be limited and the patient can be rescued from any reaction that occurs.

The most severe form of IgE-mediated allergy is termed anaphylaxis. In the UK around 10 deaths are attributed to drug anaphylaxis each year.

**Non-IgE-mediated Drug Allergy**

Many different processes are lumped together under this heading, previously grouped as type II, type III and type IV hypersensitivity. Some can be tested in the laboratory, some by skin tests, some by microscopic examination of biopsies. Some mechanisms thought to occur in humans by extrapolation from the results of animal experimentation cannot yet be routinely investigated in the clinic or laboratory.

The most severe forms of non-IgE-mediated drug allergy include a group of related conditions known as Stevens Johnson Syndrome and Toxic Epidermal Necrolysis. A few patients die from these conditions each year.

The least severe reactions include drug rashes: these are very common and mostly cause problems because they are thought to signify the potential for a more serious reaction if the patient is given that drug again, leading to future treatment with more expensive and sometimes less effective or less safe alternative drugs. Unfortunately we do not have reliable tests that will allow us to assess the risk of a recurrence of the reaction, though in most cases it is probably rather low.

**Non-allergic Drug Hypersensitivity**

Many different processes fall into this category. For example, angiotensin converting enzyme (ACE) inhibitors are widely used for treatment of blood pressure. These are good effective drugs but cause side effects in a small subset of those taking them, for example swellings that may be fatal if they occur in the throat and block the airway. The mechanism for this is known in considerable detail and there is potential for simple tests to predict who might be affected—however, in practice the drug is given to anyone who might benefit and those who react are then changed to an alternative treatment; this approach results in one or two deaths each year. Many other examples could be given, often dependent on single gene differences affecting the metabolism of the drug or the structure of receptors that can bind to it.

**Treating Drug Allergy**

Although much is understood of the principles of different drug reactions, it is usually difficult in any individual case to be sure that which mechanism is truly the cause of the reaction. The usual management is to avoid the suspected drugs in future and use alternatives that are thought to pose less of a risk. Often one has to balance the risk of avoiding the suspect drug against the risk of using it despite the suspicions that it may have caused a reaction.

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29 IgE is the abbreviation for immunoglobulin E, the class of antibodies involved in triggering immediate-type allergic responses.
A particular set of problems is caused by reactions during anaesthesia. Most of the fatal drug reactions are of this type and have been thought to be due to muscle relaxants, opiates or antibiotics. One difficulty is due to modern anaesthetic techniques where multiple drugs are given in quick succession at induction of anaesthesia; this can make it difficult to identify which drug was to blame. Further research is needed to improve the sensitivity and specificity of the tests used to investigate such reactions.

SPECIALIST CLINICS FOR DRUG REACTIONS

This brief synopsis should make clear the difficulties faced by those who have reacted to a drug. They are unlikely to get ideal advice from any but the best informed of specialist clinics. I recently undertook a survey of the majority of UK clinics offering this type of testing. The variety of approaches and heterogeneity of findings suggests the need for further research into the most effective approaches and guidance for such clinics to raise the standard of all to that of the best.
WEDNESDAY 7 FEBRUARY 2007

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Memorandum by the Chartered Institute of Environmental Health (CIEH)

The CIEH[^30] is a professional and educational awarding body with some 10,500 members working both in the public and private sector, many of whom are at the forefront of tackling poor health and housing conditions.

According to a recent report[^31] from the Department of Communities and Local Government (DCLG) there are 3.2 million vulnerable households living in the private sector in 2005 of which 1.1 million live in non decent homes.[^32] The existing Government target will still leave over 800,000 vulnerable households in non decent homes in the private sector by 2020. In contrast the target is for all social housing to be made decent by 2010. Recent research carried out on a Sheffield Decent Homes health impact assessment, “Decent Homes: Better Health”,[^33] has produced evidence that demonstrates the health benefits of making homes drier and warmer. A conclusion made from this is that children will be the main beneficiaries with a reduction of the likely incidences of Asthma.

Since April 2006, the HHSRS provides a tool for local authorities to deal with conditions that include respiratory and allergic attacks. The system has used available evidence to support the approach of hazard assessment and, in this instance, it is particularly relevant for the hazards of excess cold, damp and mould and domestic hygiene, pests and refuse. Local authorities have enforcement powers to improve conditions in the private sector but whilst they use those powers when and where necessary in the private rented sector they are reluctant, for obvious reasons, to use them on owner-occupiers. Enforcement action alone cannot be expected to improve poor housing conditions and more incentive is required to encourage all home owners to repair and maintain their homes, particularly owner-occupiers. The Home Information Pack, being introduced by DCLG, provides an opportunity to improve matters but the inclusion of a house condition report is voluntary so there is still insufficient emphasis on the condition of homes compared with their value.

The CIEH has formed a Commission on Housing Renewal and Public Health[^34]. The Commission’s interim report has found that the rate of replacement of very poorest areas of housing has fallen to very low levels. It is inevitable that in these poorest areas of housing there is an increased risk of exposure to allergic conditions yet the assessment of these areas lacks any specific reference to health. The Commission recommends, amongst other things, that the DCLG guidance on Neighbourhood Renewal Assessment[^35] is revised to include a health impact assessment of the different options for action.

Internationally, particularly in Europe, a great deal of work has been done on air quality and its harmful effects. In particular, the World Health Organisation (WHO) Europe has developed a number of projects in the last few years. One such project has been to develop indoor air quality guidelines. Another is the children’s environment and health action plan for Europe (CEHAPE) which has produced a table of child specific actions for member states including indoor and outdoor exposure to allergens. They also have been developing environmental health information systems (ENHIS) which includes information on the health impacts of poor indoor air quality and suggestions for policies in relation to this.

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[^30]: Fuller information on CIEH can be found on the website http://cieh.org/
[^32]: Decent home: is one that meets the following four criteria:
(a) It meets the current statutory minimum standard for housing (fitness standard for the reporting period of this survey)[h].
(b) It is in a reasonable state of repair (related to the age and condition of a range of building components including walls, roofs, windows, doors, chimneys, electrics and heating systems).
(c) It has reasonably modern facilities and services (related to the age, size and layout/location of the kitchen, bathroom and WC and any common areas for blocks of flats, and to noise insulation).
(d) It provides a reasonable degree of thermal comfort (related to insulation and heating efficiency).
[^h]: From April 2006 the fitness standard was replaced by the Housing Health and Safety Rating System (HHSRS).] The detailed definition for each of these criteria is included in A Decent Home: Definition and guidance for implementation, Communities and Local Government, June 2006.
[^33]: Decent Homes: Better Health, Sheffield Hallam University, July 2006.
[^34]: Fuller information on CIEH can be found on the website http://cieh.org/library/Knowledge/Housing/HOUSINGpercent20COMMISSION.pdf
In America, a study\(^{36}\) has confirmed that the presence of rat and mouse allergens in the home as being associated with asthma attacks. This is also a concern bearing in mind the reported increase in the rodent population in the UK in recent years. A similar study\(^{37}\) has demonstrated the potential harmful effects associated with cockroach allergens.

**Examination of Witnesses**

Witnesses: **Mr John Bryson**, Chair, Commission on Housing Renewal and Public Health, Chartered Institute of Environmental Health, **Professor Adnan Custovic**, Professor of Allergy, University of Manchester, **Dr Paul Harrison**, Director, Institute for Environment and Health, Cranfield University and **Mr Grant Ager**, Director, Fairfield Housing Cooperative, examined.

**Q457 Chairman:** Good morning and thank you for coming. The session is being web cast. I am Lady Finlay and I chair this Select Committee inquiry. There is a paper declaring the interests of the members of the Committee so we will not be reiterating those as we go round today. I would like to start by inviting you to introduce yourselves and then we will start asking questions. Would you like to start, Mr Bryson?

**Mr Bryson:** Good morning. My name is John Bryson and I am here representing the Chartered Institute of Environmental Health. I am the Chairman of their Policy Development Board and recently chaired a commission on housing renewal.

**Dr Harrison:** Good morning. I am Paul Harrison, Director of the Institute of Environment and Health at Cranfield University. I am a toxicologist interested in the interactions between environmental factors and human health.

**Mr Ager:** Good morning. I am Grant Ager, Director of Fairfield Housing Cooperative in Perth who commissioned one of the first allergy homes in the UK.

**Professor Custovic:** Good morning, I am Professor Adnan Custovic. I am Professor of Allergy at the University of Manchester.

**Q458 Chairman:** I would like to start by asking all of you how allergic diseases such as hayfever, perennial allergic rhinitis, allergic asthma and atopic eczema impact on the quality of life of sufferers.

**Professor Custovic:** Obviously talking about life threatening diseases like anaphylaxis is quite easy but what I would like to emphasise is the enormous impact that a disease as simple as hayfever—allergic rhinitis—can have on quality of life of sufferers. Let us not forget that this is a disease that affects almost a quarter of our children and young adults. A lot of people in primary care in particular would say that it is just a little bit of sneezing and runny nose. I put to you that it is much more than a bit of sneezing and runny nose. Some fabulous recent evidence from the UK suggests that children with hayfever are twice as likely to drop grades in their GCSEs as compared to children without hayfever. If, on top of that, they take sedating antihistamines for the treatment of the disease this risk goes up three fold, so you may be two to three fold more likely to drop a grade between the mock exams in December to the real exams in June when the hayfever season kicks in. That is much, much more than a simple case of sneezing and a runny nose. Clearly not only can it affect the way you feel, but it can affect the long term prospects in life of quite a substantial proportion of our children. Let us not forget that all the major exams take place exactly during the time of the year when pollen levels are highest. This is not a disease to sneeze at.

**Q459 Chairman:** Can I ask if our other witnesses want to add anything to that?

**Dr Harrison:** I would just add that it can be debilitating in the sense that a child with asthma or allergic rhinitis is likely to opt out of sporting activities so not only might it affect their learning abilities but also their well-being in the sense of being fit.

**Q460 Lord May of Oxford:** We have heard that the hygiene hypothesis suggests that better living standards these days and increased hygiene is the cause of the rise of allergenic disease. I wondered if you could tell us a bit more about the extent to which this idea is borne out by evidence and understanding and is not just correlation without causation.

**Professor Custovic:** Hygiene hypothesis within the context of allergic disease was proposed in 1989. It is a hypothesis so I think that says it all. It is still a hypothesis so I think that says it all. It is still a working hypothesis. It is in a great umbrella under which we are looking to understand the cause for the incredible increase in allergic diseases that we have witnessed over the last 30 to 40 years. Let us not forget the increase has been three to four fold thus allergy epidemics are environmental. Hygiene hypothesis is one of the working hypotheses,


probably the most likely one. Hygiene hypothesis originates from epidemiological data but there is also quite solid basic immunology data that would support that at least part of the hygiene hypothesis—this concept that the increase in allergy is partly due to us becoming cleaner—may well be correct. Let us not forget that it is still a working hypothesis and not a fact.

Q461 Lord Taverne: What I find difficult about that hypothesis is that the instance of allergies generally is much higher in the United Kingdom and we are not notably more hygienic than countries in continental Europe which have a much lower rate. I can see the stories that are told about the apparent correlation between the two but does the continental experience really cast considerable doubt on that hypothesis?

Professor Custovic: Let us not forget that we are talking about the differences in the prevalence of allergic disease in the developed world. We are talking about shades of grey; we are talking about a difference between 23 and 27 per cent. Real differences lie between countries that are currently on-going transition; real differences you can see in areas of the world like Africa, and Africa give you a great example of the potential role of hygiene. For example, numerous studies have demonstrated unequivocally that the prevalence of allergic diseases is markedly higher amongst affluent populations which have adopted westernised lifestyle compared to populations living in the same areas but not adopting westernised lifestyle. That is where you see the differences of two to three fold rather than percentage differences. Without any doubt there is not a single thing that would explain the overall incredible increase in the prevalence of allergies. We are looking at different facets, at different parts of a puzzle that we are trying to put together and hygiene may well be one of them.

Q462 Lord May of Oxford: What, if any, are the other competing hypotheses?

Professor Custovic: I think we are all fairly certain about the fact that the increase in the prevalence of allergic diseases is environmental which raises the really beautiful question as to what is environment. I personally subscribe to Einstein’s definition of environment which is that environment is everything that is not me. Within this very broad description of environment you have hygiene or, broadly speaking, exposure to microbes but also another very important aspect, diet. Diet has changed tremendously. There is indoor environment and I am sure that some of my colleagues are going to talk about indoor environment much more. There are changes in the pattern of exercise that kids have undergone. There are quite a number of aspects of modern life so we should not be saying that the increase in the prevalence is due to a single factor; almost certainly not.

Q463 Lord May of Oxford: I did ask because what many of the subsequent questions are going to do is explore the fact that we do, as you have just said, tend to lead more sedentary lives in houses that are by and large less draughty and we spend less time outdoors.

Professor Custovic: Absolutely.

Dr Harrison: I would like to say that there is evidence that supports the hygiene hypothesis but not every study confirms it, so it clearly has some kind of role in the etiology. But if you think about what it means, it is suggesting that excessive hygiene—that is the prevention of early life exposure to allergens/antigens—could have negative consequences because the body is not able to build up its natural resources to combat later exposure. That might be true for some substances in the environment but it might not be true for others. In other words, early life exposure to some antigens could be a good thing; early life exposure to some others could have a negative consequence later on. There are very many confounders, as with many scientific studies, which make it very difficult to quantify any one factor.

Q464 Lord May of Oxford: Do you think enough is being spent in basic research to try to answer this question and essentially on the basic interplay between the semantic construction of the immune system in the first few years of life and the environment in which it is being constructed, which is not really a mainstream fashionable thing as I understand it in the molecular biological kinds of studies of the immune system?

Dr Harrison: I am not an immunologist but maybe my colleagues can comment.

Professor Custovic: The answer in terms of investment is that clearly not enough money has been spent. We are suffering from the fact that we are not in one of these big identified programmes like cardiovascular disease or diabetes. If you look at the proportion of the population that is suffering from allergic diseases and respiratory diseases and the proportion of funding that goes towards allergic diseases and respiratory diseases you will see an incredible discrepancy.

Q465 Baroness Perry of Southwark: I wondered if any of the studies or research there has been an investigation to look at the total overload of the change in the environment. It is not only the things you referred to earlier but different materials—we wear man-made fibres; we have man-made fibres in
Mr Bryson: Could I just to add to that on the housing conditions, clearly one of the factors in this is the way that older housing has been improved. In older housing quite often what you find is that there is a presence of warmth and dampness. The features we majored on where trying to control the environment within the houses to keep the heat and moisture at a level where dust mites would not want to try to do that. I think it is better to be very focussed on the activities that are undertaken and the efforts that are made to reduce levels and to reduce exposure. There are certain housing features which predispose a house to have high house dust mite levels and those, as I said, are extended periods of warmth and dampness.

Mr Ager: As Paul mentioned, you cannot completely get rid of dust mite and I do not think that was our intention; it would be impossible to create a sanitised environment where there would be no dust mites present. The features we majored on where trying to control the environment within the houses to keep the heat and moisture at a level where dust mites would not produce as much. That was done mainly by looking various strategies, mainly ventilation for

Q468 Lord Taverne: What success is there to point to in attempts to eliminate house dust mites in either secondary or primary prevention of asthma, rhinitis or eczema?

Dr Harrison: I would say that there has been a lot of debate about this as to what practically you can do to help alleviate symptoms in people that might be suffering from reactions to house dust mite. It is very difficult to totally eradicate house dust mites from a home, but what they enjoy is warmth and moisture. They like living in certain places and some of those places are very important for personal exposure. For example, they like living in pillows and mattresses so there are very practical things that can be done to reduce exposure by eliminating or at least removing either the source or exposure to the source of allergens in those materials where close contact occurs; but it is probably not very productive or cost effective to believe that you can totally remove house dust mites from a whole house, or even that you would want to try to do that. I think it is better to be very focussed on the activities that are undertaken and the efforts that are made to reduce levels and to reduce exposure. There are certain housing features which predispose a house to have high house dust mite levels and those, as I said, are extended periods of warmth and dampness.

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cleaning the air in the house, creating, if you like, a sponge effect wall which took water out. In older housing it is easier to describe. Damp would sit on walls or windows and water is taken away which reduces the environment so that the dust mites cannot breed. It certainly worked and it is becoming more and more common in housing where breathing walls, as they are called, are used.

Q470 **Lord Taverne:** Is there any conflict between the low energy approach and the elimination of dust mites in the sense that you need more ventilation?

**Mr Ager:** I think the building sector has become very focussed on energy and creating airtight boxes that are easy to heat and reduce energy costs but the other cost has been indoor air quality which is not focussed on as much. We have become obsessed with as cheap heat as possible and creating, if you like, vacuums where people spend 90 per cent of their lives and the air quality in the modern homes is not high.

Q471 **Chairman:** What is the evidence for the specific link between house dust mite and eczema?

**Professor Custovic:** Probably the best house dust mite allergen avoidance trial comes from eczema rather than from asthma carried out by Peter Friedman in Liverpool about a decade ago, probably one of the very, very few clear, simple mite allergen avoidance studies showing unequivocal beneficial effect. I really would like to draw a parallel here between what we are talking about—asthma, allergic rhinitis or eczema in a community—with occupational allergic disease. Occupational allergic disease gives us a beautiful example as to what actually may be going on, an individual getting into a situation of a novel exposure (be it in a laboratory with rats or whichever) developing sensitisation and then soon after symptoms of allergic disease. The treatment of choice is removal of that individual from the exposure situation. Providing we remove the patient quickly, providing the diagnosis is established early in the natural history of the disease, we have a potential for cure. If the patient is left in this occupational environment exposed to sensitising allergens for a long period of time, even complete cessation of exposure will not result in the improvement of the disease because the disease becomes a self-perpetuating process. This really teaches us several very important lessons. If we are going to try to address the disease by environmental control then we have to develop methods to reduce exposure very, very substantially. We can send patients to Switzerland and they improve but we need to do something about creating that sort of environment in our homes. That is one challenge. The other challenge is identifying patients who may benefit early enough in the natural history of the disease because a lot of studies are confounded by the simple fact that we have drawn patients who have had the disease for 20 or 30 years. They could have started with allergy but by the end of this long process the allergy is not the only—and certainly not the main—reason for the perpetuation of the disease. The message is, identify individuals early and reduce exposure substantially if there is going to be a benefit.

Q472 **Lord Colwyn:** Moving on to other allergens, we are aware that there is a wide range of fungal and bacterial species which can be isolated from indoor air. Is there evidence that specific moulds, fungi and bacteria can trigger sensitivity and allergic diseases such as asthma, rhinitis or eczema?

**Dr Harrison:** There is a difference between biological allergic responses and responses that individuals can show which do not have, at least at the present time, biological explanations—these are the sensitivities or intolerances that individuals specifically show. To answer your question, the evidence that I reviewed—a few years ago now, admittedly—showed very clearly that children in damp and mouldy homes have self-reported symptoms of respiratory disease. When measurement is made of specific mould species it is not possible to relate any one particular mould, for example, or certainly bacteria, to the outcome. That is because it is, in any case, a mixed exposure that people are having. Moulds and bacteria consist not only of the antigenic properties but also they might produce toxic metabolites and components of their cell walls can induce a response. There is a kind of mixed medium, if you like, of potential insults to an individual’s health. Apart from possibly Alternaria species, where there have been studies that show a specific risk factor from exposure to those moulds, generally speaking the evidence shows the connection between damp and mould generally rather than with specific species.

Q473 **Chairman:** Am I correct that Alternaria is associated with asthma but not rhinitis?

**Dr Harrison:** I do not know that.

**Professor Custovic:** That is correct, moreover it is associated with very severe asthma and with asthma deaths. In the UK what we have is a fairly clear association between sensitisation to moulds and asthma severity. Sensitisation to moulds is overwhelmingly present amongst individuals with very severe asthma.

Q474 **Lord Colwyn:** I gather that penicillin is often found in this air; might that be associated with penicillin sensitive reactions? How do you relate the exposure to small amounts against something like peanut allergy where we are beginning to find out that exposure to small amounts of peanut might
Mr Ager: They are not prohibitive in cost. A heat exchanger would be about £350; installation is slightly more.

Mr Bryson: Could I just add that the types of householders that environmental health practitioners meet very often have no money at all. If you try to explain to them that trying to control condensation, dampness and mould is partly within their own hands, that is a very difficult concept to put across them. What they want to find is a simple cause for it. It is not about the way they use the heating and ventilation. As was mentioned, the educational side of it is a very big thing, to try to educate people on this. For a lot of the people who suffer those conditions, the prospects of even spending £300 would be impossible; we are talking about people at the very bottom of the housing market.

Q477 Chairman: Can I go back for a moment to mould exposure because we live in a climate with high environmental humidity, but as far as I understand it some of these studies have been done in parts of the US where the atmosphere is very dry. I wonder if there are problems transposing across and also, if you are looking at mould exposure, whether detection of IgG and possibly IgE would give you an idea of exposure to different moulds.

Professor Custovic: You are asking all the right questions and we do not have answers to most of them. Certainly the work on alternaria has been done predominately in Tucson because it is big, it is seasonal, et cetera, beautifully reproduced by Jon Ayres in Birmingham. Asthma is in part due to exposure to pollen, in part due to exposure to fungal particles. There is very little doubt about the fact that potentially fungal exposure may be important, but until we can assess not only the biological effect of exposure but also measure exposure it will be very, very difficult to make a dose response curve trying to estimate the effect of exposure on any of the outcomes. Let us not forget that it may as well be pretty non-specific; they may act as adjuvants, they may act as irritants; we simply do not know. What we do know is that in all the epidemiology the association between them and mouldy houses is much more than the association between dust mite and asthma. The fact of mouldy homes overwhelms the effect of dust mites alone. The strongest evidence of that probably comes from Holland and I would put to you that their climate is pretty close to ours and that is where the real strong body of evidence comes from.

Q478 Viscount Simon: What impact do pollutants, such as airborne particles, carbon monoxide, formaldehyde, pesticides and cleaning agents have on allergic diseases?
Dr Harrison: I alluded before to the fact that exposure to substances in the home can exacerbate the responses to allergen exposures. I mentioned formaldehyde because it is a well known respiratory irritant and sensitizer in its own right. I think people tend to be worried, for example, about low levels of pesticides but they do not seem to be so concerned about the liberal use of bleach and ammonia. A personal thought that I have is that individuals who are exposing themselves to levels of ammonia and bleach, for example, that could actually irritate the respiratory system, could well be making themselves more susceptible to allergic insults. I think there is a role for chemicals in that sense and a role possibly in the sense that some might be responsible for so-called multiple chemical sensitivity or idiopathic chemical sensitivity. In terms of biological allergenicity it is really those irritant substances that are going to be most important.

Professor Custovic: I think the evidence is pretty unequivocal that if you are asthmatic or if you are a patient with established allergic disease exposure to a high level of indoor air pollution may make your disease worse. Whether it will cause it per se is much more speculative. The evidence up until now is probably again. There is also quite an interesting body of evidence mounting on the real problem of course is the multitude of exposures, to try to answer these very important questions. The real problem of course is the multitude of exposures, very few of them being independent of each other and trying to tease out what exactly is the role of one as opposed to another is sometimes not easy. Dr Harrison: The question of research into consumer products has been left behind a little bit. There have been scares recently about the use of air fresheners and children's health in the home and causing migraines in mothers. It is rather speculative work; it is a rather Cinderella subject and requires a little bit more focus.

Q479 Viscount Simon: Are you aware of any research being done into the effects of chemicals in, let us say, woodworm and dry rot treatments, fly papers (the things that hang up), plug in air fresheners and fabric conditioners? If research is taking place, do you know who it is being done by? Dr Harrison: The question of research into consumer products has been left behind a little bit. There have been scares recently about the use of air fresheners and children's health in the home and causing migraines in mothers. It is rather speculative work; it is a rather Cinderella subject and requires a little bit more focus.

Q480 Chairman: What about the Bristol study where they are monitoring children long term? Professor Custovic: The Bristol study is one of a whole range of prospective birth cohort studies. We are extremely fortuitous in the UK to have probably the best prospective birth cohort studies which are currently, for the first time, all acting together as a consortium trying to understand these very important questions. Five major British birth cohort studies—Bristol, Manchester, Aberdeen, Kent and Isle of Wight—have agree to work together in order to try to answer these very important questions. The real problem of course is the multitude of exposures, very few of them being independent of each other and trying to tease out what exactly is the role of one as opposed to another is sometimes not easy. It is very much like a diet: is it vitamin C or is it eating an apple that is good remains quite interesting as a concept.

Q481 Baroness Platt of Writtle: Do current building regulations adequately take into account the needs of allergy sufferers in the home? Mr Ager: No, there is no policy that I am aware of in building regulations on the use of formaldehyde or chemicals used in insulation or gas cookers and there is no regulation which covers air quality within the home. Arguably you could include air quality within that but it is not in there at the moment, it is more for physical disability.

Mr Bryson: The building regulations are a minimum building standard so they are the basic minimum. There are two things about that really, one is that they only apply to new dwellings or conversions; they do not extend to existing buildings so they cannot be applied to those as well. Bearing in mind the length of time that houses currently standing will have to
remain occupied, the recurrent rate of replacement is about a thousand years.

Q482 Baroness Platt of Writtle: Are there any ways in which you think these regulations could be improved to control exposure to allergens and other pollutants more stringently? Of course you have just mentioned older houses, particularly in that context. Dr Harrison: It is very difficult through building regulations alone and ventilation requirements alone to make a big impact because of the vast proportion of existing housing that cannot be easily remedied. I know there is a lot of science that goes into the establishment of the ventilation requirements and I would not criticise that. I just think there is a limit to what can be achieved through the building regulations.

Mr Ager: In Norway there is an allergy specification included within building regulations and standards but again that applies to new build and not what is there at the moment.

Dr Harrison: I think there is an option for looking at labelling and emission standards for building products and materials so that materials used in homes are not high emitters of potentially polluting substances like formaldehyde. There are standards in existence but I think more could be done to encourage the use of cleaner materials in that sense and lower emitting substances and lower emitting appliances used in the home.

Mr Ager: We would support that but it is actually quite hard to source materials in the building centre at the moment to meet needs. For fourteen units we could not source the materials so the supply is not there at the moment. It can be there but it is very expensive.

Q483 Baroness Perry of Southwark: Returning to the issue of existing housing stock, there is now a requirement when you are selling your house to have a survey done yourself and passed on and I know there has been some discussion that that might include, for example, tests for energy efficiency for your house so that the person purchasing it is warned they are buying a house which is not very energy efficient. Would you see a case in the future for including the allergy count of your house? Apparently houses on average change hands every seven years so you soon begin to tackle the existing housing stock.

Mr Ager: Personally I am not sure of the value in that because unfortunately it does not drive people when they are buying a property. Energy efficiency will but unless you have someone within your family who has an allergy or asthma I do not think it is a selling point.

Q484 Baroness Perry of Southwark: Forty per cent of the population does suffer from some kind of allergy and that is a lot of purchasers who do care about it.

Mr Ager: That is true but there is this sort of dichotomy in the realms of affordable housing and I am not sure of the value personally.

Mr Bryson: I think the introduction of the house condition report in the home information pack is voluntary at the moment and there seems to be some question as to whether it will be made compulsory. I think that is unfortunate personally. Averages, as ever, do not tell the true story; there are a lot of people who live in the same dwelling for many, many years so a house condition report would be of limited value to them. On the sale of houses, of course, people are more interested in the value and the cost than they are the condition.

Q485 Baroness Perry of Southwark: Is there also a tension between the building itself and the contents which the people bring with them? From what you were saying most of the house dust mites would be residing in the furnishings rather than in the building so they would bring their own house dust mites with them in their beds and pillows.

Mr Ager: Arguably that is true. As I said before, you can have the cleanest house and controlled environment but when you walk in you pollute it immediately. If you bring in furniture you pollute it immediately. That reinforces what I was saying earlier.

Dr Harrison: The behaviour of the occupants has a large impact on the conditions inside a house.

Q486 Earl of Selborne: Is there a role for the Government to issue guidelines to the public on either how to reduce the risk of developing allergic diseases or minimising their aggravation by substances in the home or changes in lifestyle? Would it be feasible for the Government to offer such advice?

Dr Harrison: I think so. I once worked in what was then the Department of the Environment in the indoor air quality branch and I actually addressed the question of setting guidelines. That was some 13 years ago I think and last year or the year before the Committee on the Medical Effects of Air Pollutants did produce a document which is called Guidelines for Indoor Air Quality (or something to that effect). It deals with a number of chemical or gaseous pollutants in the home and it suggests guideline values which line up very much with the WHO standards. It also suggests behaviours that would help improve indoor air quality. Unfortunately that document has not been very widely circulated and accessed. It remains on the DH web site but I do not think enough people have seen it and I think it is a
Mr John Bryson, Professor Adnan Custovic, Dr Paul Harrison and
Mr Grant Ager

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good starting point to Lord Selborne’s question about really giving good guidance to individuals about what they can practically do to improve their own situation.

Q487 Earl of Selborne: Dr Harrison and I have both at one time sat on the Chemical Stakeholder Forum which was to try to identify chemicals in general use or in the environment which might be toxic or bio-cumulative or persistent in one form or another. One of the issues which is mentioned in the Fairfield study is that the resin which is most benign for sticking lino down was available in Holland but not in this country. Is there not an issue here that we are not making available some of these benign materials for some reason?

Mr Ager: I do not think the market is fully developed for them yet. In the UK there is not a market for them. The Fairfield project is now four years old; there has not been a project to replicate it repeated in the UK to my knowledge. Certainly some of the factors that were put within the project have been used but there is not a huge market for them. There is no incentive for private developers. They will produce energy efficient housing but there is no incentive for them to enhance air quality. The materials are not there at the moment. Perhaps the Government has a role in looking at that.

Q488 Earl of Selborne: This seems to be a market failure. If this would be even a modest help should we not try to encourage the building industry and do-it-yourself stockists to take it more seriously.

Mr Ager: Possibly, yes.

Dr Harrison: There has been an advance in the production of low VOC emitting paints and companies like B&Q created a symbol which they put on their products to encourage the use of low VOC emitting products and I think more can be done in that way. The use of symbols and labels as well as possibly other regulations to encourage the manufacture and use of low emitting products may be of use.

Professor Custovic: That is very, very similar to the way the food labelling is going towards identifying what may be the healthy option; I stress what may be the healthy option. We pretty much know what good indoor air quality is without going into details.

Q489 Baroness Perry of Southwark: When we talk about affordable low allergy housing, what exactly are we describing? Can you give us some of the features that would be found and what special adaptations such houses would have?

Mr Ager: A dwelling that was designed avoiding where possible known pollutants or irritants to allergies at that present time and obviously focussing on air quality. There were four relatively simple features in the house which you do not really see. The most crucial thing was moisture management creating an environment that dust mites could not breed in by use of various ventilation strategies, your normal trickle strategies and fans, mechanical heat recovery methods and we also did five with the breathing wall method and the breathing ceiling to create an environment where dust mites find it difficult to breed. We completely avoided gas heating and gas cooking (so no naked flame or appliance within the home). There were two reasons for that, electricity being more sustainable and the fact of the evidence of naked flames, central heating and gas cookers do have an impact on allergy sufferers. We worked to non-toxic specifications where possible and we tried to look at taking out formaldehyde, toxic materials and preservatives where possible. We avoided Upvc windows and went for wooden windows because they do not have as much chemical content in them. More importantly, within the buildings themselves, we sourced linoleum floor covering for tenants who wanted that and we spent a great deal of time with the people going into the houses as an education as to how to use the house properly. In terms of features, to walk in you would not think there were any different features from a normal home but they are there.

Q490 Baroness Perry of Southwark: Was it expensive to produce that?

Mr Ager: Arguably at the time it was but the cost today probably not. When you do a pilot the building industry is slightly nervous of what you are trying to do but the more you do it the easier it becomes. I do not think it was hugely expensive to do that.

Q491 Baroness Perry of Southwark: Are there several projects of this kind or is it fairly rare still?

Mr Ager: We were the first in the UK; I believe there is one other one in London but I am not sure where. We have not tried to replicate a new build of what was done there completely. We have used the mechanical ventilation strategies and again the paints. Going back to refurbishment of existing property, we have refurbished a small number of flats taking into account the principles we used, using a non-toxic specification.

Q492 Lord Rea: What is the evidence that living in a low allergy house has an effect on either the allergic sensitisation or aggravation of existing allergies?

Mr Ager: The research was, like a lot of things, inconclusive. It showed that the quality of the air within the home was increased quite substantially between the three different types. It was something like five to six per cent better in the houses with the
ventilation strategies rather than the conventional house type. We did have the feel good factor with people within those houses; certainly people with asthma felt better and their reliance on inhalers and other medication decreased. However, I do not think the sample was big enough to give a conclusive answer. There was a slight improvement but you would need to do it over a much larger scale to look at it properly.

Q493 Lord Rea: The change is sufficient to warrant at least the builders and the occupants thinking that it was worthwhile.

Mr Ager: Yes, definitely. Going back to what one of my colleagues said about the age of people and allergies, the people in here generally are older and the disease is well developed and, as I said, they showed significant improvement because of the air quality within the home.

Dr Harrison: I would say that this is a very good idea but it should not be seen as a panacea. I do not think it should be expected, almost miraculously, by living in a house like this that all your problems will disappear. It is certainly the case with allergic sensitisation that very often people who do not get allergic to house dust mite will get allergic to something else, if they are susceptible to that. I think in terms of well-being it is a very good idea to have these houses built with low emitting substances, certainly good ventilation, heat recovery et cetera, but all the studies that have been done that I know about have struggled to show a statistical improvement over a prolonged period of time and where, in the extreme case in Scandinavia, homes have been built with no man-made materials at all in the hope that people who suffer from chemical sensitivity will have a better life, this has often failed because wood emits turpines and other volatile materials which are similar to the chemicals that are present in man-made substances. Just because something is natural does not mean it is not potentially toxic. We have to be careful in making assumptions about the benefit of such housing, although it is clearly not a bad thing.

Q494 Lord Rea: From the comments you have just given I can probably guess what your answer will be to my next question which is whether you think that low allergy specification should be incorporated into the design of all new housing and, to add to that, major refurbishment of older property requiring planning permission.

Mr Ager: I do agree with Paul that it is not the magic answer but certain factors should be considered. The mechanical heat ventilation recovery systems are an excellent way forward. However, there is the big question, how do you track back and tackle existing housing stock and existing problems that are already there? Again, arguably, most people within social housing just want to be able to heat their home efficiently without anything else on top of that, so there is a big challenge there to be tackled as well.

Dr Harrison: Yes, I would agree. I think that heating and ventilation is important. Also I think to not use substances which emit formaldehyde would be a good idea and to educate people in the way to manage their home so it does not build up high levels of house dust mites and mould would be a good thing.

Professor Custovic: We have to stress that probably the emphasis on the term low allergen housing is wrong because what we are talking about is healthy indoor environment. Pretty much like healthy eating options you have healthy indoor environment. I think that by and large allergens are probably the least important part of the overall concept of healthy indoor environment.

Q495 Lord Rea: What needs to be done to the current building regulations to ensure that houses that are built in the future conform to these specifications?

Dr Harrison: There are ideas put forward by the Building Research Establishment (BRE) about healthy housing schemes. I do not know the details of those but I would suggest they were well thought out and worthy of consideration as to optimal design for new houses. Whether some or all of that should or could be built in with the building regulations I do not know.

Mr Ager: Certainly air quality management could be built in but, as John said, building regulations are very basic at the moment and that is quite an advanced step forward.

Mr Bryson: The building regulations react to development in construction in actual fact rather than lead the way.

Q496 Lord Colwyn: You have ruled out the use of gas. Assuming you agree it is not a brilliant idea to live underneath power cables, can you say whether you believe that modern electronics—heaters, TVs, microwaves, computer screens—have any effect on the immune system and then possibly the introduction of allergic disease? Do we still hear about sick building syndrome? Is there such a thing as that?

Professor Custovic: Oh yes.

Dr Harrison: Certainly there is. Although nobody can say what causes it there have been various ideas. There was an interesting study done on microwaves which nobody could quite understand. It might not have been to do with the microwave but to do with the diet that the people were eating, using the
microwave to cook their food. Again it is very difficult to tease out causative factors.

Professor Custovic: I will step away from what I believe (because I kind of struggle with the concept of belief being part of an inquiry into what the evidence is); I do not think there is any evidence for the time being.

Q497 Chairman: Mr Bryson, you very helpfully gave us some additional information which we have tabled today for the Committee and in it you point out that the Chartered Institute of Environmental Health has formed a commission on housing renewal and public health and that the commission recommends that the guidance on neighbourhood renewal assessment is revised to include a health impact assessment on the different options for action. I wondered how you envisaged this actually happening.

Mr Bryson: What the commission found was that a lot of the emphasis in actual fact was partly on housing condition but predominantly it was about economic factors and social factors and in their submissions to the commission hardly any of them was a health assessment part of it. There was no particular assessment of that. The final report has not been produced but in the interim report the recommendation is that that could be part. There is what is described as a Neighbourhood Renewal Assessment Manual which is provided by the Department of Communities. It would not be difficult to introduce a health impact assessment into that. In our submission to the sub-committee, I think we also point to the work that has been done on Sheffield Homes to show the beneficial effects that can be produced by linking housing and health. At the moment our view is that there is an inadequate link between the two.

Q498 Chairman: Given that we understand that the development of allergic diseases is determined by the interaction of genetic and environmental factors, I wondered what each of you feel is the main future thrust for research into environmental factors associated with allergic disease and where the research energy should go.

Professor Custovic: I firmly believe that the day and age of simple public health advice where something is good for everybody is over. We are different individuals. What is very good for me may not necessarily work for you or may indeed really be bad for somebody else. We need to move away from the concept of one size fits all and that is in terms of intervention, in terms of drugs, to very targeted interventions aiming to make a difference in susceptible individuals. In order to develop that we have to ultimately understand how environmental factors interact with genetic predisposition in giving us the disease. The real tricky concept of all of that is that in the long term it may well be that in order to prevent allergy we will have to remove house dust mites or to add house dust mites or to remove microbes or to add a little bit of microbes. Each intervention is going to be specific for specific individuals at risk. I think that is the way to go. The way is to go in a much cleverer, holistic medicine way. We will appreciate and understand the individual susceptibilities of our patients and not look at them as mean patients derived from clinical studies.

Q499 Chairman: From the non-clinicians’ viewpoint?

Dr Harrison: I think that unfortunately interventions which seemed a very good idea at the time sometimes just do not work and then people rub their chins and wonder what went wrong. It is because we do not understand everything that is happening in the cause-effect chain. To answer your question, it seems to me that there are interesting impacts of exposure at different stages in life and it would be very useful to understand a bit better the important windows of exposure through one’s lifespan which are important for different aspects of the environment we are exposed to. That I think would be a good focus for research.

Mr Bryson: Obviously I am not qualified on the medical side. All I would say is that while any further research is taking place what is important from our point of view is that indoor air quality is improved and housing conditions are improved because quite clearly it is not improving people’s health living in damp conditions and conditions where allergens can thrive.

Mr Ager: I would not disagree with that. As a total non-clinician, I think we can get carried away with some of these allergy projects. It does add value but I think what is important is to research how we can improve existing homes to improve air quality. The knowledge is there for new build homes but it is looking back which is the predominant stock in this country, and how people modernise and improve. I think research should be focussed there.

Q500 Chairman: Earlier on, Mr Bryson, you spoke about the group of the population who are living in poor socio-economic conditions and the difficulty of educating them to adjust their lifestyle. I wonder if you have any more comments to add to that.

Mr Bryson: I think one of your colleagues mentioned about possible incentives to do that. Unfortunately we live in a world where often people need some sort of incentive and unless it is possible to explain to them the direct health benefits, some other incentive may be required to try to put the message across. I would never suggest it is easy, but at the moment I am
not sure there is enough effort being put into that to try to make sure that people can help themselves to a certain extent.

**Q501 Chairman:** If we look at the concepts of genetic and environmental interactions and research do you think eventually we will see a turnaround or even prevention of allergic diseases?

**Professor Custovic:** My aim as a physician is to make physicians obsolete; that is what we are there for. Then my career would be fulfilled. Yes, we will get there but if we stop allergies today there will still be a lot of patients for the next 30 to 40 years and the real tragedy of today is this little rule of numbers: we have a conservative estimate of 15 million patients; we have an optimistic estimate of 24.9 allergists in the country. That is a real, real scandal and tragedy of our situation. Our patients need to live three thousand years in order to be able to see allergists. If there is something we could do now, we could make a big difference in a very short period of time. Do I believe we will prevent allergies? I most sincerely hope so because that is what we have devoted our careers to do. It will come too late for the 15 million people who have the disease now and what are we going to do about that now?

**Mr Bryson:** Could I partly echo what Professor Custovic has just said? It does not go down very well with colleagues when you say that ultimately you want to reduce the number of them that are required, but that is also part of our philosophy: prevention is far better than cure and some of the work that we want to try to do is to prevent those situations rather than constantly be on the curative side.

**Chairman:** Can I thank you all very much indeed for having come today to give evidence to us. You will be sent a transcript in draft form for you to correct if necessary and if there is other information you think the Committee may find helpful after today then please do send it in and we can circulate it to the Committee as part of your evidence from today. Thank you very much indeed.
1. SUMMARY

1.1 Homeopathy is a safe, effectual and cost-effective form of medicine for the treatment of a range of allergic responses, increasingly being sought particularly by parents with young children. Indeed, for many parents facing the prospect of steroidal treatments, homeopathy is the treatment of choice. Yet, despite the growing demand for homeopathic treatment, access remains extremely limited for families and individuals who cannot pay and do not have access to private medical insurance.

1.2 The Society of Homeopaths would particularly encourage the Government to introduce measures to make homeopathy more available to patients suffering from allergies, on the NHS. In particular, the Society calls on the Government to send a stronger signal to primary care organisations that homeopathy has an excellent evidence-base in this area and to give them permission to refer patients to registered homeopaths (RSHom) for treatment.

2. THE SOCIETY OF HOMEOPATHS

2.1 The Society of Homeopaths is the largest and most representative body for professional homeopaths in the UK. We have 1,500 members on our Register, most of whom have completed recognised courses and have undergone at least one year’s supervised clinical practice and a six-month CPD-based registration process. Our Registered Members are subject to a rigorous Code of Ethics and are insured to £3 million professional indemnity.

The Society’s development as a professional organisation was commended by the House of Lords Select Committee’s report on Complementary and Alternative Medicine in 2000, which states, “under The Society of Homeopaths, the non-medical homeopaths have organised themselves well and their professional organisation should mean the transition to statutory regulation does not present too great an upheaval.”

2.2 Our Registered Members increasingly engage with health professionals such as doctors and nurses in providing complementary care for allergy sufferers. Where homeopathy is provided on the NHS (Wiltshire, Yorkshire, Nottingham and London) patient opinion surveys consistently reveal high satisfaction with the service.

DEFINING THE PROBLEM

3. The homeopathic approach to allergies

3.1 The homeopathic approach to the treatment of allergy entails a full assessment of the patient and takes into account hereditary features (chronic allergic patients tend to have a family history), allergic “triggers” and factors affecting their symptoms. Treatment aims to boost the immune system, reduce toxicity within the body, and provide symptom management of acute flare-ups. Homeopathic medicines are taken internally as pills or liquids for short periods; some homeopathic preparations are also applied topically (eg Calendula cream for eczema). Dietary and/or lifestyle advice may be given.

3.2 Homeopaths believe the incidence of allergy and allergic diseases is rising owing to a lower immune function in more individuals. This is probably brought about by a variety of factors that could be considered “triggers”: toxins in the environment; diets poor in unrefined foodstuffs and rich in additives; and possibly the over-vaccination of very young children before inherent immunity has developed.
4. Treatment and management with homeopathy

4.1 Homeopathy is a safe, gentle yet highly effective system of medicine, frequently used to treat allergies. Owing to the high dilutions used, homeopathy is safe to use in small children and in acute situations (attacks), unlike some conventional medicines which may cause unacceptable side-effects or an unacceptable risk to long-term health.

4.2 Evidence has shown that homeopathy can be a useful intervention in the treatment of acute and chronic allergies:

— eczema;
— asthma;
— allergic perennial rhinitis; and
— hayfever.

4.3 Parents of small children are increasingly choosing homeopathy owing to their concerns about the suppressive treatments generally prescribed for eczema and asthma, often involving repeated use of steroidal preparations and antibiotics to combat complications of the disorder.

4.4 In addition to being a safe, effective, and cheap method of treatment, homeopathy helps patients and their carers to feel more involved in their progress to health. Patients are equally able to manage their allergies with homeopathy.

4.5 Whilst there has been some good research undertaken into the treatment of allergies with homeopathy, but The Society of Homeopaths would urge the Government to consider more research in this area a priority. We believe there would be a high degree of compliance for such research from health professionals in the field.

4.6 Whilst we would encourage more research into the efficacy of homeopathy, particularly for allergies, it is imperative that such research is designed with the principles of homeopathy in mind. Often research into our modality to date has relied on inappropriately designed trials. Real-life clinical trials and in-practice pilots offer suitable models to explore the role of homeopathy within an integrated healthcare system.

Government-funded research carried out by Dr Weatherly-Jones RSHom (University of Sheffield) to develop relevant research models for homeopathic treatment is important in helping to inform the design of future trials.

Patient and Consumer Issues

5. Choice in Healthcare

5.1 In the NHS Plan the Government set out a new vision for the National Health Service—a health service designed around the patient. With 25 per cent of the population registering their interest in seeing complementary therapies on the NHS, the provision of homeopathic treatment in the area of allergies, will go some way to meeting patient choice.

5.2 It is estimated that 470,700 adults use homeopathy annually, spending over £30 million per year. This growing market for homeopathy is being recognised by the private sector. Private Medical Insurance companies, for example, increasingly allow referrals and self-referral to Registered Members of the Society of Homeopaths. Royal Sun Alliance, The Hospital Saturday Association, Health Shield, Healthsure, Anglia Healthcare and Civil Service and Employees Health Insurance schemes, all cover such referrals.

5.3 As the former Secretary of State for Health acknowledged in his speech to the Social Market Foundation in April 2003, patient choice has historically been the preserve of the wealthy. As Alan Milburn stated, “For too long choice in health care has only ever been available those with the means to pay for it. Those with more money have been able to exercise more choice. That is the real two-tier health care in our country.” This is true not only of conventional medicine, where patients are able to jump queues to access faster treatment, but also in complementary medicine, which remains to a large extent the reserve of those able to pay for it. Currently the vast majority of patients who want to use homeopathy to manage their allergies have to pay privately for treatment. A private course of treatment costs anything between £100 and £300.
6. **Barriers to Choice of Homeopathic Treatment**

6.1 In December 2001 the Secretary of State for Health announced that complementary therapies that can demonstrate proof of effectiveness will be made available on the NHS. Yet, in our members’ experience, patients are still finding it difficult to access homeopathy on the NHS. PCTs in particular are still not referring patients to registered homeopaths even where evidence exists. The Society believes that there remain some significant barriers that prevent referrals to homeopathy.

6.2 “Permission”: The reluctance of GPs in particular to refer patients to a registered homeopath does not appear to be a consequence of personal beliefs in the effectiveness or not of the treatment. Rather, our members have found that the key issues are simply that they do not have a history of doing so and are not being encouraged to by the PCTs. Despite the announcement by the Secretary of State that complementary medicine should be available to those who want it, many GPs appear to be under the impression that their own PCT would not allow it.

6.3 The Society is therefore calling on the Government to send a stronger signal to primary care providers that referring patients to registered homeopaths is “permitted” within the NHS.

6.4 **Understanding of homeopathy amongst NHS practitioners:** If patients are to exercise their choice, they need to be made fully aware of all of the options available to them. Yet, too few doctors, nurses and midwives themselves are familiar with how complementary medicines can benefit allergic patients. The House of Lords Select Committee, in its report on Complementary and Alternative Medicine, expressed concern about this lack of awareness, stating: “We were concerned to hear that, unlike the medical schools, there seems to be little or no evidence of a trend within nursing schools to ensure that student nurses come into contact with the main issues connected to the practice of CAM therapies. This is despite the fact that nurses are probably the most likely of all conventional health practitioners to use CAM techniques in their day-to-day practice”.

6.5 **Financial Resources:** In our members’ experience, NHS managers sometimes claim that they simply do not have the resources to fund complementary medicines as well as conventional. However, research undertaken in a number of pilot projects indicates that referring patients to registered homeopaths can help to alleviate the burdens on GPs, including the financial pressures. Case studies produced as part of a study in Bradford-on-Avon, for example, show that the cost differences between treating a patient with conventional medicine and homeopathic therapies can be significant for a GPs’ practice.

6.6 In order to assess the cost implications of giving patients access to complementary medicine in more detail, the Society calls on the Government to fund a number of pilot projects across the country, incorporating general medical practices, as well as NHS allergy clinics.

6.7 **Regulation:** A further reason given by NHS managers refusing to refer patients to complementary medicine therapists is that they believe that the quality control and regulation of the sector is insufficient. The Society of Homeopaths is working hard to raise the standards of professionalism in homeopathy and the complementary medicine sector. The Society is a key player in the Council of Organisations Registering Homeopaths (CORH), working to establish a single register for the profession. This will enable all patients who require homeopathic treatment, as well as GPs and midwives who refer their patients to a Registered homeopath, to be sure of the professional standards, competency and accountability of the homeopaths they employ. We believe that it is essential that the new single register sets the highest possible standards for professional homeopaths and we will be supporting the most rigorous options for the development of this register.

**References** [not printed]

**Letter from Professor Chris Corrigan, Professor of Asthma, Allergy & Respiratory Science and Consultant Physician, Guys Hospital**

I am pleased to submit written evidence for this Committee in my capacity as Consultant Allergist and Researcher at Guy’s Hospital, London, which is one of the biggest NHS centres for treatment of allergic disease in the UK, as Educational Supervisor to two allergy SpR trainees, as Secretary of the Joint Committee on Higher Medical Training Specialist Advisory Committee on Allergy and as counsel member of the British Society for Allergy and Clinical Immunology, the professional body for clinical and non-clinical doctors and allied health and other scientific professionals working in the field of allergy.
ALLERGY: EVIDENCE

21 February 2007

DEFINING THE PROBLEM

Allergic diseases represent a particular class of immunological “hypersensitivity” reactions (“hypersensitivity” reactions are immunological responses produced in certain persons which, instead of being advantageous to the person, such as in fighting off infections, are actually harmful by causing tissue damage, disruption of vital organ function and even death). Allergic hypersensitivity reactions occur because certain individuals have a propensity to produce an allergic antibody called IgE, which recognises external foreign proteins which find their way to the mucosal surfaces of the skin, airways or bowels of predisposed patients. The particular proteins which set off these responses are collectively called “allergens”. It is not known why some individuals make IgE antibodies to allergens whereas others do not, even though everyone is exposed to a broadly similar range of allergens by breathing them in or swallowing them. Once the allergic IgE antibodies are formed, they coat the surfaces of special inflammatory cells in the tissues or circulating in the blood called mast cells and basophils respectively. Further exposure to allergen then causes these cells to degranulate or burst, releasing a number of toxic inflammatory substances including histamine, leukotrienes and prostaglandins. Allergic reactions are characterised by their immediacy: that is, exposure to allergen causes mast cells and basophils to release their toxic inflammatory substances within seconds of exposure. This is why allergic reactions belong to the class of hypersensitivity reactions called “immediate hypersensitivity”. Histamine, prostaglandins and leukotrienes induce generalised effects on the body, particularly lowering of the blood pressure which can lead to fainting, collapse and cardiac arrest, constriction of the bronchi or breathing tubes, causing shortness of breath and wheeze which may be particularly severe in asthmatics, and the swelling of the tissues, which may cause a rash on the skin but also swelling of critical organs such as the larynx which may block the airway and is another potential cause of death in severe allergic reactions.

As allergists we recognise quite clearly which diseases are caused by, or made worse by allergic “hypersensitivity” reactions. These include asthma, allergic rhinitis (including hay fever), eczema, anaphylactic reactions to bee and wasp stings, reactions to latex proteins and some, but not all reactions to foodstuffs and drugs. In contrast the general public and many medical and allied health professionals, because they have had little training in allergy, tend to classify a much wider range of reactions to external agents as “allergic” inappropriately. This is typified by the situation with food allergy and intolerance. Food allergic reactions are immediate, reproducible and evolve with a very typical pattern in allergic individuals. It is possible to tell whether or not patients have true food allergy with a brief history and relevant simple tests. On the other hand, many patients (and often their doctors) attribute a range of non-specific symptoms to foods which occur much later after they have been eaten and very widely in their clinical manifestations. There is little or no evidence that such late reactions are caused by reactions to foods, and the term “allergy” is in this case not appropriate. If late reactions to foods do occur (and there is no definite evidence that they do except in rare patients with very well defined inborn areas of metabolism which cause biochemical abnormalities after eating certain foods, and with the exception of coeliac disease, a rare non-allergic hypersensitivity reaction to gluten found in various grains), their mechanisms are uncharacterised and consequently there are no suitable diagnostic tests.

Allergic disease is characterised by the so-called “allergic march” in which infants predisposed to allergy typically developed severe eczema soon after birth. This is followed by manifestations of food allergies, typically to cow’s milk, egg, grains, nuts and fish which develop about the time these foods are introduced into the infant’s diet, and later allergic rhinitis and asthma. In such patients, allergic reactions to foods and airborne allergens such as pollens and animal danders can be demonstrated by simple tests such as skin prick tests. One of the major mysteries in allergy, however, is the fact that many of these diseases tend to remit clinically as the child gets older, yet this is not usually accompanied by produced production of allergic IgE antibodies. Having an allergic reaction is not, therefore, simply a question of whether or not the body makes IgE antibodies. Clearly, there are whole layers of understanding to be uncovered about what governs the presence and severity of clinical allergic reactions in patients and how this varies with time. It seems very likely that environmental factors, as well as possible genetic predisposition of certain individuals govern these processes, but little or nothing is known about their nature.

Although there is unequivocal evidence that the prevalence of allergic diseases is rising with epidemic proportions, it is also very clear that the burden of disease is grossly underestimated for all types of allergy. There are several factors operating here. First, because allergy has only recently existed as a separate medical speciality in the UK, specific allergy training never has been, and still is not included in undergraduate and postgraduate medical training curricula, much of it goes unnoticed. For example, many patients with chronic allergic rhinitis are characterised as having a “permanent bad cold” and suffer needlessly for years on end when they could be helped by appropriate allergy diagnosis, identification of causal allergens, appropriate allergen avoidance advice and ancillary medical treatment. Many cases of acute “asthma” presenting to casualty
departments are in fact acute anaphylactic reactions (a severe, generalised allergic reaction which may be fatal) caused by oedema of the larynx referred to above, and not asthma at all. Even experienced accident and emergency and general internal medical consultants have had little training in the recognition and subsequent management of allergic diseases. Food allergy reactions in infants often go unnoticed, since the symptoms of anaphylaxis are less dramatic (but still potentially lethal) in infants as compared with adults. Yet food allergy can cause untold suffering in children, with exacerbation of coexisting eczema, asthma and rhinitis. A further gap in recognising the burden of disease is that, because there is not NHS infrastructure for the management of allergic problems, many patients elect to treat themselves, often very unsatisfactorily, and never present to a medical practitioner. In many areas of the UK, there exist no allergy specialists to see these patients even if they do decide to seek help. A clear solution to all of these problems is to establish a network for allergy treatment across the UK, a course of action which was recommended recently by the House of Commons Health Committee but sadly ignored by the Department of Health.

The socio-economic impact of allergic disease is tremendous and largely unrecognised. Untreated allergic rhinitis, for example, is in the top five causes of lack of sleep in the general population. It is also in the top five causes of loss of time from paid employment. Asthma rates slightly higher in the league table of causes of loss of days at work or school, with enormous socio-economic implications. For example, over 12.7 million working days are lost to asthma each year. Asthma costs the NHS an average of £889 million annually. One child in every year of every school in the UK now has peanut allergy, and in some children this is potentially fatal. Away from impressive statistics, bad hay fever in the summer ruins the social lives, morale and examination performance of millions of young adults every summer.

**Treatment and Management**

Until recently no known treatment was proven to alter the natural history of allergic disease. There are recent exciting suggestions that certain forms of immunotherapy, particularly with modified allergens, may do so. While pharmacological and non-pharmacological therapies (not least sensible and authoritative allergen avoidance advice) have had a major impact on the burden of allergic symptoms, the key to cracking allergy is prevention.

At present the level of research aimed at understanding the natural history of allergy, the role and scope of primary prevention and altering the natural history of the disease for the better is grossly inadequate. We have been lucky enough to set up, in collaboration with King’s and Imperial Colleges, Asthma UK (the country’s leading asthma charity) and the Medical Research Council the first MRC Centre for allergic mechanisms of asthma. Apart from this, allergy research is performed in isolated centres of excellence by a small handful of interested individuals. The lack of an organised and structured NHS allergy service has greatly hampered this process, resulting in few young doctor trainees who are interested in doing it, and lack of nationwide access to patients to participate in research projects.

The most promising areas of research into preventing or treating allergy at present might be summarised as follows:

1. **Strategies for prevention:** attention to maternal and foetal nutrition, and other early interventions, such as allergen vaccination, which may alter the evolution of allergic disease.
2. **Measuring and assessing life-time allergen load and exposure.**
3. **Drug allergy:** organised clinical and epidemiological research, with assessment of outcomes of management by allergists.
4. **Further development of allergen immunotherapy** (the practise of exposing allergic individuals to progressively large quantities of the allergen at a distinct mucosal surface, such as by injection or under the tongue) is of proven therapeutic benefit. For example, patients with anaphylactic reactions caused by allergy to bee or wasp stings can now be cured of this problem with immunotherapy. With hayfever, immunotherapy can vastly reduce symptoms and transforms sufferers’ lives. There is also evidence that immunotherapy reduces the need for conventional medical therapy in asthma. Most interesting of all, however is the evidence that early immunotherapy may reduce the incidence of new allergic sensitisations and the emergence of clinical allergic disease in infants and children. Advances in the formulation and practice of immunotherapy are being made all the time. For example, sublingual immunotherapy for grass pollen allergy has recently become available in the UK. New modifications to allergens to increase their ability to turn off the allergic immunological hypersensitivity response, through better understanding of the immune system and how responses to allergens are regulated, are emerging all the time. There is abundant scope for a nationwide
initiative to investigate the efficacy and long-term effects of these interventions. This is likely to save the health service millions of pounds in the medium to long term, not to mention the socio-economic impact of reduced loss of time at work and school.

(5) Investigation of what factors determine an individual’s susceptibility to allergic disease. As mentioned above, this is not simply a question of whether or not they make allergic IgE antibodies to a particular allergen. Virtually nothing is known about this field, yet it promises such scope for understanding the role of heritable and environmental factors in turning clinical allergic reactions on and off.

(6) The impact of early intervention in food allergy, in terms of manipulation of maternal diet and the introduction of possible ancillary substances which will head off the development of an allergic response. Despite increasing interest in the role of a foetal and maternal environment in governing the evolution of allergic disease in susceptible patients, few concrete recommendations have so far been possible, and this reflects lack of appropriate and directed research.

**GOVERNMENT POLICIES**

To my knowledge, apart from the publication of pollen counts which are generally measured by private organisations, no government policy has directly addressed the epidemic of allergic disease or produced sufficient public information to aid sufferers with self treatment or by providing the impetus to seek specialist allergist advice. Housing policy and regulations pay little or no attention to allergy, even though the environment likely plays a major role in the epidemic rise in allergic disease. Factors such as nitrogen dioxide emissions from gas burners, the emission of volatile organic compounds from mass produced furniture and the growth of moulds and other allergens in damp or ill ventilated homes may all play a very important role in the epidemic of allergy. Simple design of homes to minimise the accumulation of allergens such as dust mites, or more research into effective means of ventilation and control of humidity might revolutionise suffering from allergic disease. Food policy and labelling regulations have gone some way to help food allergy sufferers, but on the other hand, largely to protect themselves from legislation, many companies have overstated the likelihood of their products containing particular allergens (a typical example is the label that a food “may contain nuts”). Such practices are not helpful to the sufferer who may die from anaphylaxis from accidental nut exposure, and the situation may require expert dietetic input which is really only available at dedicated allergy centres.

**PATIENT AND CONSUMER ISSUES**

Even notwithstanding the impact of allergies on the quality of life of sufferers and their families, the figures, only a few of which I have quoted above, really speak for themselves. It is absolutely inconceivable to allergists how these issues are ignored when allergic disease is one of the leading causes of morbidity, suffering, NHS expenditure and socio-economic loss in the UK. It is widely perceived that this outrageous anomaly arises simply because allergic diseases are not political “hot potatoes” like cancer and heart disease. Certainly, government spending, health priorities and public education are certainly not the slightest bit attuned to the prevalence and impact of allergic disease.

Finally, may I say a final word about “over the counter” allergy tests. Many so called “allergy” tests performed, for example, in health food stores or alternative medicine emporia are of no diagnostic value whatsoever. Furthermore, they are misleading in the sense that the patients are often given a completely erroneous and ad hoc list of foods or other substances they should apparently avoid, which not only does not treat the allergic disease but also leads to inappropriate dietary restriction, sometimes to the point of starvation, particularly in children with anxious parents. Even “over the counter” tests of accredited diagnostic worth, such as RAST (a blood test for allergic IgE antibodies), are effectively useless unless interpreted in the light of the patient’s history, which can only be done by an experienced allergist. It is a constant source of dismay to allergists that practitioners offering so called “allergy tests” of no diagnostic value are allowed to set up shop and dupe the public in such an outrageous manner, seemingly with no legislative control at all. The fact that these services are used so widely is on the other hand no doubt a reflection of the desperation of allergy sufferers in obtaining access to any form of help at all.

In conclusion, allergy could effectively be managed in the long term if the Department of Health was to allocate adequate resources and “kick start” the service across the country. This would lead not only to a structured system of management of patients with allergic diseases across the UK, but would also form an invaluable platform for research.
At present, after rising from the ashes about six years ago, the speciality of allergy is once again struggling at the brink of death in the UK. Despite recognition of the speciality and a clear, full and exciting training programme, there are currently just eight young trainees in allergy across the entire UK. They are increasingly disillusioned about their future careers and see no growth of specialist centres where they can practise their art. The situation is something of a vicious circle since there are correspondingly few centres at which allergists can be fully trained. A career in allergy is exciting and offers a real opportunity significantly to improve the lives of a vast range of people, young and old. It is imperative that the Department of Health facilitates a career pathway for these young people by undertaking the clear recommendations of The Royal College of Physicians and of the House of Commons Select Committee. I therefore implore the honourable members of the Committee to consider this dilemma gravely and beg them to take the appropriate action.

6 October 2006

Examination of Witnesses

Witnesses: PROFESSOR JONATHAN BROSTOFF, Professor Emeritus of Allergy and Environmental Health, King’s College London, MS KATE CHATFIELD, Research Ethics Committee, Society of Homeopaths, PROFESSOR CHRIS CORRIGAN, Professor of Asthma, Allergy and Respiratory Science, School of Medicine, King’s College London, and PROFESSOR EDZARD ERNST, Director, Complementary Medicine, Peninsula Medical School, Exeter, examined.

Q502 Chairman: Can I start by thanking you very much for coming today to give evidence to our Committee? I am Lady Finlay. I chair this select committee of science and technology sub-committee inquiring into allergy. Can I also welcome those who have come to listen in to the session, who are seated in the public gallery? There was an information note produced and that has the declaration of interests of all members of the Committee so we will not be restating those as we go through with our questions. We have a lot of questions and I would therefore ask you if you could please be precise and concise with your answers to enable other people to make a comment and to make sure that we get through the questions. Can I ask each of you to introduce yourselves?

Professor Ernst: My name is Professor Ernst. I am professor of complementary medicine at the Peninsula Medical School Universities of Exeter and Plymouth.

Professor Corrigan: I am Professor Chris Corrigan, a professor of asthma, allergy and respiratory science at King’s College, London School of Medicine, Guy’s and St Thomas’s Hospitals.

Ms Chatfield: I am Kate Chatfield. I am here to represent the Society of Homeopaths and I am a senior lecturer in homeopathy at the University of Central Lancashire.

Professor Brostoff: I am Jonathan Brostoff, professor of allergy and environmental health at King’s College, London.

Q503 Chairman: Ms Chatfield, could I just clarify your professional background? Is that in nursing?

Ms Chatfield: No. I am trained as a homeopath.

Q504 Chairman: Specifically?

Ms Chatfield: Yes.

Q505 Chairman: I wonder if I can start by asking all of you which techniques allied to complementary and alternative medicine are currently used in the UK for the diagnosis and the treatment of allergic diseases?

Professor Ernst: It is a difficult question because we are dealing with a flavour of the month type of therapy and they come and go quite frequently. A little while ago, we tried to assess this systematically by looking at seven leading lay books in complementary medicine and for allergies we found 57 different treatment modalities. It is big.

Q506 Chairman: Would you be able to provide us with a list of those after the session?

Professor Ernst: Not offhand but if you give me a little time, yes.

Professor Corrigan: The four commonest ones used for the treatment of asthma and allergy are acupuncture, herbalism or phytotherapy, homeopathy and various physical techniques, spinal manipulation and the like. Some of these techniques claim to diagnose as well as treat allergy. For example, homeopaths and herbalists diagnose. Others take the diagnosis as read and work from there. There are lots of tests available on the Internet, by post and in shops that are claimed to diagnose allergy including leukocytotoxic testing, electrodermal testing or Vega testing, kinesiology, pulse testing and various other miscellaneous ones including iridology.

Ms Chatfield: In homeopathy we have a very different definition of diagnosis. It is not diagnosing a specific allergy according to a specific allergen. A homeopathic diagnosis for us literally means finding
the right remedy for the person, so it is not a conventional diagnosis in that sense.

Professor Brostoff: Some of the so-called scientific tests for diagnosing allergy and in particular food allergy that are marketed have dubious clinical validity, even when put to double blind studies. That is one aspect, even if the techniques used in the laboratory are robust but the interpretation, I am afraid, is fallacious. In terms of the allergy patients that I see, many have used herbal treatments and I think we did the first double blind placebo controlled trial of Chinese herbs in eczema in the early nineties which showed it to be remarkably successful, but we were careful to exclude toxic elements in the herbs. As the Chinese have been doing it for about 1,500 years, I think we might have a lot to learn from them!

Q507 Chairman: That is an example as to my second question which is whether there are certain types of complementary medicine that are more suited to particular allergic diseases than others. You have cited one, Professor Brostoff. I wonder if others would like to comment?

Professor Corrigan: There is a vast body of literature that suggests that there is no net clinical benefit from many of these procedures, including acupuncture, homeopathy and various physical techniques. Some physical techniques have been shown to improve the quality of life for some patients—for example, asthmatics—probably by teaching them how to breathe properly but there is no evidence that they improve the disease. With herbalism you have to be careful. We must not forget that many of the drugs we use today have been derived from plants. It is likely that there are still a few more to be discovered. The problem with herbalism as it is applied currently is that the preparations are not standardised. The active ingredients are not known. The prescription of these substances is rather ad hoc and, because the whole process is unregulated, there is the problem of poisoning. There are well documented cases of toxins such as organophosphorous pesticides in herbal remedies and other toxic agents. Whilst there is scope for looking at allergy treatments derived from plants, this research should be organised more systematically and the active ingredients should be isolated and their properties characterised. With the one exception of herbalism, I do not believe there is any good evidence that any other form of alternative medicine produces a tangible benefit in asthma. There are many studies and summaries of studies to back this statement up.

Ms Chatfield: In homeopathy, as far as I am aware, we do not have any significant evidence from randomised controlled trials for the treatment of asthma but we do for allergic rhinitis and hay fever and a lot of clinical of evidence suggests that homeopathy could be of great benefit in eczema, particularly with the kinds of patients that we get. We have a very high percentage of children coming with eczema and related allergies.38

Professor Ernst: There are virtually dozens of complementary therapies that have been submitted to clinical trials. We have summarised them in a book which I have here and which I am happy to donate to the Committee. This material is systematically and transparently summarised. I agree with my colleague. For no treatment modality is there good evidence that it is clinically effective in asthma, atopic eczema or hayfever. These are the three conditions that we have included in our systematic review.

Q508 Chairman: I just wonder whether you might be able to comment on the term “holistic allergy therapy”. Professor Corrigan. I also wondered what you feel the evidence is for the role of physiotherapy in breathing techniques in patients with asthma.

Ms Chatfield: I have no idea what holistic allergy therapy is. I have never heard of it.

Professor Corrigan: There are various breathing techniques which can strengthen the respiratory muscles and these are of proven benefit in some patients with asthma and indeed chronic obstructive airways disease. Anxiety plays a natural role in many of the symptoms of asthma and teaching patients to calm and control breathing, techniques allied to physiotherapy, have been shown to improve asthmatics’ quality of life, presumably because they help them to calm down and breathe more naturally. There is no evidence these techniques improve the severity or the natural history of the disease.

Professor Brostoff: Because allergy services in the UK are minimal for the number of people who complain of allergy, patients will be forced to go and see people who might use Vega machines or apply kinesiology. Anecdotally, many of these patients improve. Whether that is placebo or due specifically to the technique, or it is a subgroup of patients who respond, it would take very little to produce a clinical study of sufficient power to show that the Vega or applied kinesiology in controlled conditions was effective, either globally in groups of patients or in a subgroup. I think it is very sad that effort is not put into this but it is quite understandable. Private practitioners are not going to pay for clinical studies.

38 Out of a total of 11 randomised controlled trials investigating the efficacy of homeopathy in the treatment of seasonal allergic rhinitis, eight demonstrate a significant positive effect. Results of a six-year study at Bristol Homeopathic Hospital, published 2005, show that over 70 per cent of patients with chronic diseases reported positive health changes after homeopathic treatment. The most marked improvements were seen in children. 89 per cent of under 16 year olds with asthma reported improvement and 75 per cent felt “better” or “much better”, as did 68 per cent of eczema patients under 16.
Q509 Lord Colwyn: May we assume that none of you has a problem with the efficacy of the placebo effect?
Professor Brostoff: I wish I could treat every patient with the placebo effect. It would be much less contentious and have far fewer side effects.
Professor Ernst: I have absolutely no problem with placebo effects. In fact, as a clinician, I used to try to maximise them but I would like to point out that you do not need a placebo in order to generate a placebo effect.

Q510 Lord Taverne: Professor Ernst said that his clinical testing of alternative remedies and treatments did not show any effect. Could he comment on what Professor Brostoff has said about the use of Chinese herbs?
Professor Ernst: This is very complex because Chinese herbs are a whole world in themselves. There are very few people who understand them and I am probably not one of them. They are usually given as individualised treatments so if you all have asthma and I am a Chinese herbalist I would take your pulse, look at your tongue and your constitution and so forth and give you all different herbal mixtures, often containing a dozen or more herbal ingredients and plants. The potential for interaction, for instance, is huge there. This approach has not been submitted to a clinical test. It can be tested, this individualised approach, but it has not been. What my colleague spoke of was a standardised formula of certain herbs targeted for eczema in this case and there were indeed some positive results. Later on there were some negatives as well with that particular formula. That is a different way of dealing with herbalism. There is the standardised herbalism where you buy a pill in Boots, or whatever, and there is the individualised herbalism. The individualised herbalism is the one that has been practised in this country by all herbalists and it has not been submitted to clinical tests in relation to allergy. For some other conditions it has and the results have been negative. 
Professor Corrigan: There are herbs that have been shown to be efficacious in isolated studies because they contain known, active, pharmacological medicines. For example, butterbur is a herb which impairs the immune system and may treat asthma very much along the same lines as conventional steroids. Coleus is another herb which contains forskolin which is a bronchodilator. There are many drugs in some herbs which may be effective but what I deplore is the ad hoc use of these unpurified medicines which may not be safe in an unsystematised and untried fashion.

Q511 Lord Rea: Could we go back to Vega testing and kinesiology which have been mentioned briefly? Could you remind the Committee exactly what these techniques consist of and how are they used to diagnose allergic disease?
Professor Corrigan: A Vega test or an electrodermal test is based on a couple of wires being connected to a small galvanometer or battery which generates a small voltage. The machines look very impressive. They have lots of knobs, switches and dials. They impress the customers. There are various variations but the basic technique is that the subject holds one wire in one hand; the other wire is placed in various areas of the skin or other parts of the body which are deemed to be of diagnostic importance. Sometimes there is a plate in the circuit containing a vial of allergen which looks very impressive to the customer. The only galvanometer readings that are generated by this process are caused by flow of electrical current across the skin and depend on how sweaty the patient is or where exactly you put the electrodes. From these measurements, typically a list of substances is produced and given to the subject and they are told that they are allergic to these substances. These lists are entirely ad hoc and random. There is no evidence that this technique can diagnose allergy. Applied kinesiology is the science where practitioners claim to be able to diagnose allergy from the tension in the muscles of the outstretched arm. They will ask a patient to outstretch an arm and apparently, with years of training and experience, when the patient holds a vial typically of allergen in the other hand they can detect changes in the weakness of the muscle of the opposite arm and thereby diagnose whether or not the patient is or is not allergic to the vial of allergen that is being held in the opposite hand. This can be practised with surrogates. In other words, if you have an uncooperative child, the kinesiologist can hold the adult’s hand and hold the adult’s hand again when they are holding the child’s hand. Again, they claim to be able to diagnose what that child is allergic to. This is all completely bizarre and, I am afraid, utter nonsense. There is no scientific evidence or mechanistic base to suggest that these tests could be remotely effective.

Q512 Lord Rea: Is the diagnostic part of these techniques the same as treatment—as the therapeutic effect—or once the diagnosis has been made is a different treatment applied?
Professor Corrigan: These diagnostic tests do not necessarily proceed to treatment. Often, the patient is just presented with a list of substances to which they are putatively allergic and then they are just allowed to walk away with it. They are not the basis for specific therapeutic regimens.
Ms Chatfield: They are then told to avoid those substances.
Professor Corrigan: Yes, typically they are and typically they do to their detriment.

Q513 Lord Broers: Presumably this leads to a positive placebo effect anyway, does it? The very fact that people have been treated with an elaborate machine must—
Professor Corrigan: Of course. It is the fact that they have been treated with an elaborate machine and that they have often paid a large sum to do so which gives them the firm impression that the diagnosis must be right, which is appalling.

Q514 Lord Rea: Have we any evidence at all about the efficacy of these techniques and could you give us an idea about how much a typical treatment would cost?
Professor Ernst: Both these techniques have been submitted to proper scientific tests. Some of these tests have been of high methodological quality. When they have, they have resulted in negative findings. In other words, there is no validity to either of these two tests. I cannot comment on the costs. I believe it is around £50 per go.

Q515 Lord Rea: Would it be possible to suggest that the efficacy is related to the skills and experience of the practitioner rather than the complicated techniques and equipment that they use?
Professor Ernst: In these tests, obviously the practitioners were experienced and, yes, there was no reproducibility, specificity et cetera, which you require from a diagnostic test to be valuable.
Professor Corrigan: It is difficult to define what an experienced practitioner is in these cases. One can define an experienced practitioner of physiotherapy because there is a set training course but, with these procedures, there is no standard training manual written down. There are sets of instructions with the individual kits but it is difficult to know how somebody does become professional in these techniques.

Q516 Lord Rea: I was thinking, rather than skill or training, of the personality of the practitioner.
Professor Corrigan: I suspect that has a very great deal to do with it, yes, somebody who looks knowledgeable, authoritative and presents you with a piece of paper in a solemn tone which you take as gospel.

Q517 Lord Taverne: My question is really addressed to Ms Chatfield. What is the difference between homeopathy and isopathy and how do these therapies, do you argue, compare with more conventional treatments in efficacy and cost?
Ms Chatfield: As Professor Ernst was pointing out, with herbal practitioners there are different ways of applying and prescribing herbal medicines, but it is the same with homeopathy. A homeopathic prescription is based on the symptom picture that the patient presents with. The remedy is prescribed according to the symptoms that the patient presents with. With isopathy, the remedy is not individualised according to the symptoms but according to the specific or primary allergen that has been identified. For example, in the case of a birch allergy, it would be betula that was used as the remedy to treat that if it was an isopathic prescription. The remedies would still be highly diluted as they are with homeopathic remedies. That is the difference between isopathy and homeopathy. Generally speaking, I think homeopaths would consider homeopathy more effective than isopathy but I do not think we have any evidence to show that.

Q518 Lord Taverne: I was asking about the comparison with conventional treatment.
Ms Chatfield: If you look at the outcome studies we have, obviously they do not involve the placebo question but we have various high levels of improvement in large scale outcome studies all over the world with this kind of treatment. In terms of cost effectiveness, we do not have enough information on that either. What I would specifically like to see would be research trials which compare the conventional treatment directly with homeopathic treatment in terms of efficacy and cost.

Q519 Lord Taverne: In a recent debate in the House of Lords, the president of the Royal Society said that if medicines can really work even if only a single molecule is left this would entail some fundamentally new scientific principle with amazingly broad ramifications and fundamental implications for experiment over the whole of science. Could you explain how the mechanism is supposed to work that achieves these astonishing results?
Ms Chatfield: I think you know very well that I will not be able to because we have not discovered that yet. I am of the opinion—and I think a lot of homeopaths are who were initially sceptical when they came in and, for a number of reasons, are convinced by the evidence—that science is not a static thing. It changes all the time and just because we do not have an explanation currently we do have a lot of people proposing different theories about how it may work. Just because we cannot explain it now does not mean it does not work. Yes, it will mean that science is revolutionised and I do not see that as a bad thing.
Professor Ernst: There is a fundamental difference in saying we have not discovered the mechanism yet. 50 years ago, we did not know exactly how Aspirin worked but we always knew that there would be a mechanism there because it is pharmacology. With homeopathy, this is fundamentally different. Science tells us that there is no mechanism by which it can work and that is an important difference. If we find the mechanism then we have to rewrite our textbooks of physics, pharmacology and chemistry.

Professor Brostoff: I do not think there is a problem with rewriting any textbook if new facts arise. The critical data is: has homeopathy in a sense been shown in model systems in the laboratory. The answer is very likely to be yes, both in the haematological system recently and also a long series of experiments in Paris. I know there was controversy over those. The fact that the clinical trials in the homeopathic hospital in Scotland, David O’Reilley’s studies, in three separate studies showed that these were statistically significant in terms of active versus placebo suggests that whatever the mechanism is it does bear thinking about.

Q520 Lord Taverne: A Lancet paper recently compared 110 homeopathy trials with 110 conventional medicine trials and found there was no evidence whatsoever that homeopathy performed better than placebos.

Ms Chatfield: The conclusions the authors came to were based on eight trials of homeopathy, not 110. What they did was single out what they called the high quality homeopathy trials and narrowed them down to eight trials of homeopathy, none of which were reflective of homeopathy as it practised in the real world. These trials involved a combination of isopathy, and therapeutic prescribing, not individualised homeopathy. It was unbelievable that they could draw that conclusion from eight trials that homeopathies would not even consider homeopathy.

Professor Ernst: Unbelievable or not, the importance of this Lancet paper that you quote lies not in that it may be the only paper questioning the efficacy of homeopathy. There are to my knowledge well over a dozen such systematic reviews published in the peer reviewed literature which all show the same thing, so the importance lies in yet another confirmation of something that has been shown a dozen times before.

Professor Brostoff: The fact that there may be a meta analysis showing that many trials are negative does not negate, for example, three positive trials that David O’Reilley did in the hospital in Glasgow. The fact that you have lots of negatives does not deny a positive.

Q521 Lord Colwyn: I am sure the panel would agree that, despite the criticism, there is no doubt that these techniques—we can go back to kinesiology and Vega testing and also homeopathy—have successes. I have referred patients to a kinesiologist for 30 years and I do not think he has ever got one wrong.

Professor Corrigan: I am afraid that is the sort of anecdotal report we have to be very careful of. Such observations mean nothing outside a properly controlled trial. Anybody can convince themselves they have benefited, particularly the person who recommended them, but I am afraid that does not constitute scientific evidence.

Q522 Lord Colwyn: It constitutes a grateful patient usually.

Professor Corrigan: We are all in the business of making patients happy. If that is all we are doing, maybe there is room for that but if we are talking about real science that is a different matter.

Q523 Lord Broers: Professor Corrigan, would you agree that homeopathy at least does not suffer from the dangers of herbalism in that if there are toxins they are diluted beyond action?

Professor Corrigan: Yes, absolutely. It is hard to see how they would be toxic but I do not agree that they are necessarily harmless because they may delay accurate, valid and pressing diagnosis.

Q524 Baroness Platt of Writtle: There is some concern that seeking help from complementary medical practitioners may delay the diagnosis of allergic diseases by more evidence based therapies or even lead to misdiagnosis, which could have potentially fatal consequences. How would you respond to this suggestion?

In the same paper the authors established that a far higher percentage of homeopathy trials (21 per cent), than conventional drug trials (8 per cent), were of highest quality. This does beg the question as to how we are ever able to trust the conclusions of conventional drug trials.

40 It is misleading of Professor Ernst to quote results from systematic reviews of homeopathy as if they are all negative. In actual fact most systematic reviews and meta-analyses are positive, and this includes comprehensive reviews and those focused on specific conditions including influenza, arthritis and allergic rhinitis.
Ms Chatfield: In homeopathy we do not pretend to diagnose in the way that conventional medicos do. Most of the patients that come to see us have already tried everything else. Then they try homeopathy. It is a last resort kind of treatment for most people. We also have a strict code of ethics and practice which our practitioners are bound by and within our code of ethics and practice practitioners are told that they should always point out to their patients the necessity to visit a GP. We have never had a complaint of that nature in the 29 years of the Society of Homeopaths being in existence.

Professor Brostoff: The fact that allergy is taught at a remarkably low level in medical school, the fact that there are probably under five trainees in allergy for the whole of the United Kingdom and the fact that several allergy clinics have now been shut means that patients are not getting a fair crack of the whip in standard allergy clinics. To take the questioners point, I have seen patients who have been to two or three allergy clinics where a very important and significant medical condition has been missed, potentially fatal in one case, but the boot is sometimes on the other foot. If we train enough allergists of a high quality, I do not think this question would be worth considering, but sadly we do not.

Q525 Baroness Perry of Southwark: My question is about the standard of proof that the Medicines and Healthcare Products Regulatory Agency uses. As you will all well know, it registered its first herbal medicine last November and, as I understand it, a herbal medicine gets onto the register only if its maker can prove that the substance has been used in traditional medicine for many years. They do not have to prove that it is efficacious. Do you think this is an appropriate standard of proof or should complementary medicines have to prove their efficacy to the same extent as more conventional medicines?

Professor Corrigan: I am afraid this is appalling nonsense. We have been campaigning as allergists to get allergen immunotherapy licensed by the MHRA for years. This is a very scientifically validated treatment which is of great benefit to thousands of sufferers with hay fever and still the MHRA turned us down because some patients have reactions to the injections. It is very frustrating that they then condone the use of these untried, uncharacterised and untested concoctions on the basis of no evidence at all. It is completely impossible to understand and very frustrating for the practise of proper, scientifically conducted allergy.

Ms Chatfield: Of course, I do not think it should be taken in isolation as a form of evidence but it is still a kind of evidence. I think the Chinese would be horrified by what you have just said, that because their medicine has not been scientifically proven it should not be used.

Professor Ernst: I agree with Professor Corrigan. It is a nonsense and it is very regrettable because it sets a double standard for the first time in medicine regulation and, for me as a researcher, it is particularly detrimental because it just puts any impetus to do any further efficacy research down to the level of zero. We are freezing our knowledge of potentially beneficial herbal treatments if we do not ask for proof of efficacy.

Q526 Baroness Platt of Writtle: Professor Ernst, you did say earlier that private practitioners clearly are not concerned with funding research into the efficacy of what they do, but is there a need for real research into efficacy and are there any charities or other bodies that are funding research of this kind?

Professor Ernst: Research funding is the most difficult thing in my life to obtain. It is nearly impossible and it has become even more impossible over the last few years because regulation of clinical trials is now such that it is very expensive, mostly geared up to large pharmaceutical trials, and to conduct a trial of homeopathy or herbal medicine under these circumstances would be very difficult indeed. Public funds are by and large not available. The science select committee seven years ago recommended large funds to be made available. That has not happened. Industry funds are non-existent so we are reliant on charitable funds which are very scarce indeed.

Q527 Lord Colwyn: It has been about 10 years since I visited you in Exeter. What is your level of research staff at the moment? Do you have a number of DHS fellowships and PhDs there?

Professor Ernst: We have about 10 research staff in Exeter which makes us by far the largest unit of that nature in Great Britain. We have no government funding at all. We did not get any despite various attempts. Basically, we live on charitable funds, the most important of which is the Laing Foundation.

Q528 Chairman: How many prospective comparative studies do you have under way at the moment?

Professor Ernst: Zero. It is not out of ambition; that is my expertise and I cannot fund them any more so we have shifted our emphasis towards meta analysis of clinical trials, not because we particularly think they are important. We think they are important but

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41 Although it is not in the form of randomised trials, surely well-documented use in real life cases over hundreds of years holds some value.
clinical trials would be more important. It is simply by default.

Q529 **Chairman:** I wonder if you could explain to us the difference between immunotherapy and enzyme potentiated desensitisation and any dangers of adverse reactions with either?

**Professor Brostoff:** Classic immunotherapy as practised in the NHS and in the UK is incremental immunotherapy. That is, for the most part, it starts at a low dose and builds up. It is allergen specific based on skin testing and serology. Many studies are done on that. We did the first study of sublingual immunotherapy which is a little more comfortable for the patient and that has now been accepted by the European Academy of Allergy as a validated treatment for inhalant allergy—that is, hay fever and sometimes asthma. There are other variations on this form of immunotherapy using titrated doses. EPD is enzyme potentiated desensitisation which contains enzymes and a low level of allergen. This has been used for almost 40 years. It has had one study published in the *BMJ* on hay fever which showed no difference between active and placebo. I understand there were significant problems with that study. Anecdotally, the side effects are minimal and anecdotally many patients respond well to it.

**Professor Corrigan:** I am afraid I cannot answer in a professional sense but you only have to walk down the high street to see that there is a great deal of deregulation still in existence. So far as I am aware, any practitioner can put up a brass plate and sell herbal medicines. Is that not the case? Certainly you can walk into any high street shop and have a Vega test. I do not see any regulation at all as it safeguards consumer issues and so forth but, if you are regulating in my view nonsense and that will result in nonsense.

**Ms Chatfield:** I would like to reiterate what Professor Ernst has said. My understanding is that they are well on the way to regulation. They are in the last stages.

Q530 **Lord Haskel:** If we could move on to the provision of complementary and alternative medicines, some seven years ago this Committee produced a report and one of the proposals was that they should introduce statutory regulation for practitioners of herbal medicine and acupuncture. The government decided to act on this in 2005. What progress has been made towards implementing these proposals?

**Professor Corrigan:** I am a little bit concerned that you have only have to walk down the high street to see that there is a great deal of deregulation still in existence. So far as I am aware, any practitioner can put up a brass plate and sell herbal medicines. Is that not the case? Certainly you can walk into any high street shop and have a Vega test. I do not see any regulation at all as it safeguards consumer issues and so forth but, if you are regulating in my view nonsense and that will result in nonsense.

**Professor Ernst:** We have recently published a little piece of research where we have shown that chiropractors, after having been regulated in the United Kingdom, have totally fallen asleep as to research. That proves the point that I have tried to make previously, that regulation is seen as a substitute for evidence. Once we are regulated, we do not need to show the world any more that what we are doing is any good. That seems to be happening on a major scale and therefore I am happy for regulation as it safeguards consumer issues and so forth but, if it is used as a substitute for efficacy or safety research it worries me.

**Professor Corrigan:** Regulation does not mean the treatment is effective. At best, it may protect some patients from being poisoned and it may protect some patients from charlatans. Once you do license them, they are under less obligation to show that what they do is of any benefit, which is counterproductive.

**Lord Haskel:** Is there any useful guidance for the general public?
**Professor Corrigan:** Not that I know of.

**Ms Chatfield:** It is not something I have seen, that there is a decreased interest in research. That has not been my observation at all. The decrease in research is due to the drying up of any funding. That is the primary factor that affects the level of research. Certainly within the professions there is still the drive to carry out the kind of research that improves practice. It is not just about proving efficacy but trialling different techniques.

**Q533 Lord Taverne:** On the question of guidance, I know that opinion on the panel will be divided but would it not be useful guidance to issue a health warning when so many people do resort to alternative therapies?

**Professor Brostoff:** It might be interesting to issue a health warning about going into hospitals these days. If you take malpractice, if you take 10 per cent of hospital admissions being due to drug reactions plus MRSA, plus clostridium difficile, that would be more appropriate at the moment and it is also a much larger problem.

**Professor Ernst:** From my perspective, guidance against complementary, alternative therapies is nonsensical. Guidance against unproven or disproven treatments, yes. Many treatments in complementary medicine are unproven or disproven, but not all. Some have very good evidence, not in the area of allergy, I am afraid. In these cases, guidance should favour the usage of these treatments. It is not about a label, complementary versus mainstream; it is about proof of efficacy and safety.

**Q534 Viscount Simon:** It seems that allergy sufferers feel as if they are driven to try complementary medicines and therapies because the conventional treatments do not appear to be there. Is this right?

**Professor Ernst:** I think all the evidence points to the fact that it is used in addition, as a complement to, rather than because it is not there and therefore we have to use the other type of medicine. The reasons why people seek it out are obviously complex. A level of understanding, empathy and even time which medicine at present does not afford within the NHS is, in my view, a very strong motivator for patients to turn towards complementary practitioners.

**Professor Brostoff:** There is a frustration with the availability in the allergy field and the provision in the National Health Service is so limited. My particular interest is food intolerance. If patients do go to conventional allergy clinics, the conventionally trained allergist is often not very interested or involved in food intolerance. For brittle asthma, for example, John Ayres’s study in Birmingham was of 60 patients put on an extremely rigid diet. He found that in about a third of the patients their asthma improved very significantly when specific foods were eliminated, and of note these are patients where skin tests and blood tests are negative, so it is a completely different mechanism. I of course would put in a plea for more interest in food intolerance.

**Professor Corrigan:** I agree with Professor Ernst. A lot of patients use complementary medicine more as an adjunct to existing therapy than anything else. A lot of it is peer pressure, pressure from the media: I have tried this and it has worked for me for 10 years. It is a very important factor in people seeking help. One will seek help from anywhere if one is desperate enough. I think we can all understand that sort of sentiment. That has played a role but largely I think it is also peer pressure and modern society that force people to look at these medicines.

**Ms Chatfield:** What you call “peer pressure” I would call word of mouth and stories of successful treatment. Certainly that is where most of our patients have come from when we have looked at the motivation for coming. They have heard stories from other people who have been successfully treated. That is why they come. I cannot call that peer pressure. When we are looking at particularly children with allergies, their parents most often bring them because they do not want to use conventional treatment or, if they have used conventional treatment, they are worried about the side effects and the long term usage of that. That is one of the main motivators for parents who bring their children.

**Q535 Viscount Simon:** Would I be right in thinking that if more allergy specialists were around the place the demand for alternative medicines might reduce?

**Professor Corrigan:** In my view, dramatically, yes.

**Q536 Viscount Simon:** Professor Brostoff, is there a role for complementary and alternative medicine in severe brittle asthma?

**Professor Brostoff:** What I am interested in, which is food intolerance and aspects of nutrition, I would not call complementary medicine. I would call it mainstream medicine and my brittle asthmatics all go on diets. If I get one in three better, I think that is an enormous yield. Keeping somebody out of hospital six times a year, to me, is not a little matter.

**Q537 Earl of Selborne:** There are currently five NHS homeopathic hospitals which offer homeopathic and other complementary treatments such as
acupuncture. Should we have more on the National Health Service and should the range of treatments alongside conventional treatments be extended to such therapies as Vega testing and kinesiology on the National Health Service?

Ms Chatfield: I do not really want to comment on Vega testing and kinesiology. I think that is a separate issue but certainly with homeopathic hospitals we would welcome far more provision of homeopathy on the NHS because at the moment there is very little provision available and it remains the preserve of the people who can afford to pay for it in most instances. We would welcome any opportunity to increase provision.

Professor Corrigan: I think it is sad that we consider such an option when the conventional and professional allergy services that are available on the NHS currently are so few and so limited. It is possibly a question of priorities, but that should be regarded as a secondary issue. We are all in the business of making people feel better. If people do feel better, even if there is no tangible benefit, one might argue that that might be a suitable alternative to spending more than two minutes with your GP discussing your problems, or even your priest or your mentor. I could not condone expansion of homeopathic hospitals or any other alternative therapy to the detriment of setting up a well accessible, conventional allergy service within the NHS.

Q538 Lord Broers: I have a simple, technical question about homeopathy and drugs. Is it possible to distinguish between homeopathic drugs after they have been diluted? Is there any means of distinguishing one from the other?

Ms Chatfield: Only by the label.

Q539 Lord Taverne: The question was about possibly expanding and financing more hospitals. Do you think, as an alternative to this that, given the shortage of funds in the health service, the present expenditure on these five homeopathic hospitals is justified or can be justified? Ms Chatfield obviously would say it is justified.

Ms Chatfield: Of course it is justified. I think you will find when you look at the cost effectiveness of homeopathy and what the provision costs, it is a very small proportion of the NHS budget. When you look at putting money into that kind of provision, you will ultimately save money in other areas.

Professor Ernst: I cannot think of a logical justification for treatments which are disproven or unproven. In as much as these hospitals use proven treatments, they are justified. In as much as they do not, they are not justified.

Professor Corrigan: I would agree with that and if we are talking about cost effectiveness do not forget that it costs the NHS £100 million a year to treat asthma and allergy, not to mention the socio and economic losses from loss of time at work or school and poor performance in exams. The cost effectiveness of an effective allergy service in this country would be overwhelmingly positive.

Professor Brostoff: If you take general surgery or most surgical operations, probably 90 per cent have not been put to a true double blind clinical study and we are using empirical methods which sometimes work better than others. If homeopathy is satisfactory to the patient and adds something to their quality of life and keeps them away from the NHS, I would support it fully.

Q540 Viscount Simon: I would like to go back, if I may, to what Professor Corrigan was describing, the equipment for Vega testing. If someone went along and was Vega tested and the result was X, would the result be the same X if they went along to someone else half an hour later?

Professor Corrigan: No. There have been well designed studies around this issue. This is one of the few useless tests that has been conclusively proven useless by very well performed trials in which various practitioners were asked to analyse the same patients and came up with answers which differed no more from random. I think one can safely say that no is the answer.

Q541 Chairman: I wonder if I could ask you all a question in relation to research and research evidence that we have heard often is not there and whether the outcome measures that are being used to assess these different modalities have possibly been the wrong outcome measures? How much have quality of life assessments been incorporated and how have the domains in those quality of life assessments been evolved and validated?

Professor Ernst: This is a question about any patient centred outcome measure. In the past, medicine has been accused of measuring what is measurable rather than what is relevant. That has dramatically changed. We have, if anything, too many quality of life measurements rather than too few these days. Any good trial these days must include a measure of quality of life both in mainstream and in complementary medicine. In complementary medicine, it has largely been adopted so I do not know of any reasonably good trial that totally neglects the patient’s view in that sense.

Ms Chatfield: I would agree with that in the main. Things have improved a great deal recently in respect of how people are looking at the various outcome measures and how we can improve them and make
them more suitable to the testing of the outcome that we want to measure, of course. With the kind of holistic treatment that we are measuring in homeopathy, we still do not have an outcome measure that successfully can measure the effect on every level. By their very nature, randomised control trials are trying to measure very specifically. Homeopathy is going to affect the whole person. It is very difficult to measure an outcome for a whole person.

Q542 Chairman: I wonder if any of the work that was done in the cancer field such as in Sequoia, which is a very personalised quality of life measure, has been used in assessing any of these?

Ms Chatfield: It would be if we had the money to carry out the trials. We would be looking at all of those things.

Professor Corrigan: There are well designed quality of life measures for asthma and rhinitis which are used in conventional, clinical trials but sadly not in trials of homeopathy, for example.

Ms Chatfield: They are.

Professor Corrigan: I have just picked one at random from this year’s homeopathy where this doctor has treated 147 asthmatics and claimed that all but two of them got better, based on his personal observation and no objective measurements whatsoever.

Ms Chatfield: That is one paper. I would disagree there.42

Q543 Chairman: One of my questions relates to the overall usage and if you have any figures on how many patients are using complementary and alternative medicine, amongst the population with the different allergies. We know in the cancer field about 50 per cent of patients who are undergoing conventional cancer treatments are also using some form of complementary or alternative medicine. Indeed some, such as reflexology and aromatherapy, are provided within the NHS setting. I wonder if you have any comments on that in relation to patients with asthma?

Professor Corrigan: Yes I do. Interestingly, there is a recent paper by Slader and colleagues, three Australian physicians, who address this very question: Complementary and alternative medicine in asthma: who is using what? They estimate that 59 per cent of adolescents and children are using complementary alternative medicines and somewhat fewer adults, but less than 10 per cent of them make it known to their general practitioners without general or specific questioning. So probably thousands of people in the UK with asthma are using them.

Professor Ernst: According to our own publication which we conducted with the National Asthma Campaign in this country, and which dates back now about seven years, it is around a third of British patients who use complementary therapies. I would not want anybody however to over-estimate these surveys because they are fraught with lots of difficulties. For instance, depending on how you define any of these umbrella terms like “complementary medicine” you can generate any prevalence figure. If I remind you that drinking tea is a herbal remedy, strictly speaking, then all of us use complementary medicines.

Chairman: On that note, could I thank you for coming. If there is additional information that you would like to submit to us as a Committee, I would invite you to do so following this session and it will be considered as part of the evidence that you have given today. I would be grateful, Professor Corrigan, if we could have a copy of the paper that you referred to in the last couple of minutes. Thank you very much.

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42 Generally today researchers in any form of complementary medicine have to strive harder to ensure validity and reliability of their methods than their counterparts in conventional medical research. It is more difficult for them to get research ethical approval, to get funding and to get published. Extreme bias can mean that their work is scrutinised to a high level. Even the authors of the Lancet meta-analysis that was so damning of homeopathy concluded that the homeopathy trials were of better quality than the comparison trials of conventional medicine. The mode of action of homeopathic remedies in the body is not yet fully understood but there is growing evidence from bioassays that ultra-high dilutions have an effect on living cells.

Supplementary memorandum by The Society of Homeopaths

The Society of Homeopaths is the largest organisation regulating professional homeopaths in the UK, with over 1,300 Registered Members (RSHom).

Homeopathy is a well-established Group 1 complementary and alternative medicine with a unique approach to illness. In common with other holistic therapies, homeopathic prescriptions are normally specific to the individual rather than the disease.

The evidence for homeopathy in the treatment of allergies is extensive, from randomised controlled trials, large outcome studies and NHS practice-based services.
DIAGNOSIS

Homeopaths take a full case history and detailed symptom picture in order to find the remedy or remedies that most closely match the patient. They therefore “diagnose” an illness according to the homeopathic model.

Patients increasingly choose homeopathic treatment for a range of mainly chronic conditions, including allergy, often because conventional medicines have not helped them. Homeopaths regularly treat people of all ages and many parents choose to consult homeopaths about their child’s allergies after consideration of possible side-effects of conventional treatment.

COST-BENEFIT

The Smallwood Report acknowledged that homeopathic treatments offer potential for substantial cost savings, particularly in drugs bills for primary care as well as fewer adverse effects than conventional medicines plus a reduced need for follow-up appointments.

GPs are able to refer NHS patients to registered homeopaths and most private health insurance companies and cash-plans consider homeopathic treatment a good investment. Consultation fees range between £30 and £100 and an episode of care may cost the NHS around £250 per patient.

The Society of Homeopaths would welcome a full clinical assessment of the cost effectiveness of CAM by NICE as well as an overall increase in research funding.

INTEGRATION

Homeopathy has long been available on the NHS through five NHS homeopathic hospitals. Registered Members of The Society of Homeopaths (RSHom) are largely engaged in private practice. 13 Society members offer their services to SureStart (family medicine) and other members run well-integrated services within the NHS in Nottingham, London and Wiltshire. The Smallwood Report concluded that homeopathy could be relatively easily integrated into the NHS.

REGULATION AND SAFETY

The Society of Homeopaths is committed to the objective of a single register for homeopaths. As founding participants in the work of the Council for Organisations Registering Homeopaths (CORN), we believe that rigorous voluntary self-regulation will demonstrate to patients that the profession is fully accountable.

The Society supports homeopaths in autonomous practice, working to high standards, within agreed bounds of competence, in any context where homeopathy is a useful intervention.

Research has shown that whilst there may be under-reporting of adverse incidents due to the assumption that homeopathic medicines are harmless, the incidence of adverse effects in controlled clinical trials was low.

FUTURE RESEARCH

It is clear that many people of all ages are choosing homeopathy as their preferred option for treatment of allergy related conditions. Whilst an evidence-base for the treatment of allergies with homeopathy already, The Society of Homeopaths would welcome further pragmatic research in this area. Particular areas of investigation might include comparison with standard conventional treatment in terms of efficacy, cost-effectiveness, safety, patient preference and satisfaction.

REFERENCES [not printed]
Memorandum by Dr Jean Monro, Medical Director, Breakspear Hospital

INTRODUCTION

I am the Medical Director of the Breakspear Hospital, which is a private day hospital that treats patients for allergy and environmental sensitivities, run by the Breakspear Medical Group. We have treated over 14,000 patients since 1982.

The precepts of environmental medicine include detailed attention to sources of exposure to potential trigger substances, individual assessment of nutritional status, and the reduction of the total burden of physical, chemical and biological stressors, using specialised techniques. A holistic approach to treatment, the avoidance of drug therapy where possible, dietary amendment and supplementation, specialised elimination diet and challenge protocols, measurement and correction of environmentally triggered alterations in gut permeability and intestinal flora, use of proven methods of detoxification, measurement of specific biochemical pathways, and a low-dose desensitising technique are all integral to the approach adopted at the Breakspear Hospital.

Your call for evidence requires answers on different categories, as follows:

DEFINING THE PROBLEM

(a) Allergy/sensitivity explained. An account can be found on our website: www.breakspearmedical.com.
(b) Also annotated is an explanation of what is known as “the load phenomenon”.
(c) The effects of ongoing allergy/sensitivity damage are discussed.
(d) The means of assessment by challenge, elimination and rotation diets.
(e) The phenomena of bipolarity and addiction are addressed.

In my opinion, the incidence of allergy is rising because of a concomitant exposure of individuals to environmental chemicals: indoor and outdoor pollutants, drugs, and food contaminants. These can all be part of a provoking total load, which aggravates encounters with natural agents. No consideration of this is normally undertaken by medical professionals.

TREATMENT AND MANAGEMENT

Food allergy: This is traditionally treated by avoidance. However, low-dose immunotherapy has been shown to be extremely effective. Sublingual immunotherapy (SLIT) has an extensive reference base.

Chemical sensitivity: An increasing number of people report adverse effects from exposure to everyday amounts of common chemicals, for example perfume, paint, car exhaust fumes, which are tolerated by most people. The condition may develop after exposure to a large amount of a single chemical, or a low-level exposure to single or multiple agents. This is not acute toxicity, but is chemical sensitivity disorder. People afflicted often also develop adverse reactions to foods and inhaled particles.

Biochemical individuality: Genomic variations result in different responses to foods, drugs and other agents, and must be considered.

TREATMENTS

— Low-dose immunotherapy.
— Nutritional support.
— Detoxification.
— Identification of possible infectious agents.

These should all be pursued.
Government Policies

The Paris Appeal has now been signed by many international scientific key figures and by the Standing Committee of European Doctors, which represents all medical governing bodies and medical organisations in the 25 EU Member States. Amongst their nine principal recommendations are “the creation of a new medical specialty: environmental medicine”.

Chapter 5 relates to Obesity, Cancers and Allergies. Item R41 is entitled Allergy management. This stresses “. . . recognition of allergology as a medical speciality in the framework of environmental medicine”.

Section M163 states “Given the frequency and growing incidence of allergies, the complexity of etiological mechanisms, and the great number of diseases to treat specifically, the European Union and the Member States must contribute to acknowledging allergology as a fully-fledged medical specialty.”

Patient and Consumer Issues

Patients attending the Breakspear Hospital have often expressed the benefits of treatment offered to them here. We have undertaken market research surveys and an independent audit of patient satisfaction questionnaires, which have established the benefits.

Memorandum by the British Society for Ecological Medicine

1. Defining the Problem

1.1 What is allergy? What is the difference between allergy and intolerance?

Allergy is an acquired sensitivity to environmental factors or foods, provoking adverse effects. In the immediate past, the term has been limited to reactions whose mechanisms have been shown to depend on the “allergy” antibody IgE, and other sensitivities have been labeled intolerance. There is increasing dissatisfaction with this limitation because:

— The original use of the term was much broader.

— The so-called intolerances are heterogeneous and need different managements since they include intolerances with an idiosyncratic biochemical basis as well as sensitivities which behave like allergies.

— In clinical practice these allergy-like intolerances contribute to the aetiology of a wide variety of chronic illnesses including migraine, IBS, hyperactivity, asthma, eczema, arthritis, chronic fatigue, rhinitis, conjunctivitis, failure to thrive and other conditions which are “not medically explained”.

— Many of these chronic conditions respond well to allergy management: symptoms are relieved, and subsequently prevented, when the provoking trigger(s) is identified and avoided (Addendum A).

IgE-mediated allergic reactions mainly include local reactions in and under the skin, of the airways, and of the gut and the severe general reaction, anaphylaxis. They are mainly provoked by pollens, moulds, animal antigens, house dust mites, insect venoms, a few foods and a few industrial chemicals. Non-IgE mediated reactions may also be provoked by these allergens but also by others including almost any food and a large number of chemicals: they may produce similar symptoms, but also chronic or recurrent symptoms involving virtually any body system.

1.2 What is and what is not known about the origins and progression of allergic disease?

The increase in the prevalence of allergy over the last 50 years has been too rapid to be attributed to changes in the gene pool, and must be some sort of environmental effect. However, the increase in the pollenoses (hayfever etc) has not correlated with an increase in airborne pollen, pointing to some non-specific effect. Historically allergies started to increase after the start of the industrial revolution which occurred at different times in different countries. Within the UK, increases in pollenoses have correlated with increases in fine

particulate air pollution and with the increasing manufacture of and exposure to chemical pollutants. However the causal significance of this link has not been proven. Other evidence suggests that childhood infections may be protective.

1.3 Why is the incidence of allergy and allergic diseases rising? Why does the UK in particular have such high prevalence of allergy?

(a) The rate of increase in allergies is extremely worrying. If the link in 1.2 is correct, the continuing increase in the manufacture of and use of chemicals will be one factor, particularly in the UK which has a high population density and inadequate monitoring of fine particulate air pollution: pollution with relatively harmless larger particulates (PMlos) has fallen but pollution with the much more harmful ultra-fine particulates has increased: these adsorb chemical pollutants and carry them into the blood stream. Increased release of synthetic chemicals within buildings from fabrics and DIY, and decreased indoor ventilation may also be a factor.

(b) The UK has recorded inadequate levels of intake of several of the vitamins and minerals required for optimum function of the immune system: deficiencies in the foetus, infant and child may well contribute to the high rate of allergies. Disturbingly high levels of pollutants have been found in the human body, even in neonates: essential nutrients are required for the metabolism and excretion of chemical pollutants.

1.4 What gaps exist in establishing the overall disease burden for all types of allergy and what are the barriers to filling these gaps?

(a) The first gap is the inadequate training of most GPs in allergy. The second gap is the thoroughly inadequate supply of allergists of any kind all over the UK so that most patients with allergies do not have a specialist diagnosis. The third is the fact that most non-IgE-mediated allergies are not recognized as such.

(b) One of the main barriers lies in the poor training in allergies at both undergraduate and postgraduate level: resulting in many doctors wrongly thinking they know all they need to know about allergies and others being frightened of them, trying to have as little to do with them as possible. The other is the very poor recognition of the nature of non-IgE mediated allergies, even though they respond well to allergy management.

1.5 In addition to the impact on the health service, what is the overall socio-economic impact of allergic diseases (for example, absence from work and schools)?

(a) Allergies used to be rare in childhood: everyone now knows a family with one or more allergic children, and the strain that this puts on them and on the schools. In contaminated neighbourhoods some schools keep a separate room for the pupils’ inhalers.

(b) There have been marked increases in the prevalence of chronic illness in general in the last few decades and particularly of rhinitis, asthma, migraine, IBS and of “medically-unexplained symptoms”.

2. Treatment and Management

2.1 What is the effect of current treatments on the natural history of allergic disease?

(a) Most patients with allergies are currently treated either with anti-allergy drugs, steroids and other anti-inflammatory drugs, or pain killers, or with specific drugs to moderate the symptoms (eg drugs for bronchospasm). Careful management of the drug regimes helps control the symptoms (for instance in asthma) but does not help (and may worsen) the natural history.

(b) The natural history of allergies seems to be that some children grow out of their allergies naturally (although they may develop other allergies later in life), but this process is speeded up by avoidance: if trigger foods are avoided they may be tolerated after six months or a year. This may also happen in adults, where onset of allergies usually follows some form of insult and the trigger substance is
often a favourite, and frequently-eaten food.” Continued exposure causing symptoms tends to worsen the allergic state and leads to sensitivity to additional foods or environmental pollutants.

(c) Allergic patients tend to be deficient in several of the vitamins and minerals necessary for optimum function of the immune system: correcting such deficiencies seems to improve their general health and lessen their hyperactivity. Deficiencies in parents before conception and/or of the mother during pregnancy and lactation lead to poor development of the foetus/infant: the evidence suggests that this also affects the immune system, and that it can be prevented by correcting the deficiencies before conception or during early pregnancy.

(d) Specific desensitisation therapy is used in mainstream medicine to protect mainly against venomanaphylaxis: this method is risky and its use is therefore confined to specialist centres.

(e) Low dose specific desensitisation therapy is used by non-mainstream allergists to protect against pollens, moulds etc and against food allergy of both kinds: these methods use extremely low doses of allergens and are virtually risk-free. These treatments allow most patients to tolerate moderate exposures to the specific trigger(s) covered and some patients, but not all, become less sensitive overall in time. These methods are supported both by randomized trials and by audit of groups of patients most of whom had had symptoms for many years before allergy treatment.

2.2 What is the evidence-base for pharmacological and non pharmacological management strategies?

(a) For allergies, pharmacological management strategies are largely palliative, aiming to control the symptoms not the disease: the evidence-base for this is in standard medical practice. They are largely ineffectve in combating the general fatigue and lethargy which accompany allergic reactions.

(b) The so-called environmental approach aims to identify the triggers which provoke the symptoms, so that they can be avoided, or the patient protected (at least partially) using low dose desensitisation. The evidence-base for non-pharmacological management strategies is detailed in the book Environmental Medicine in Clinical Practice. Anthony HM et al. which can be obtained from the BSEM office. The evidence includes:

— double blind studies of the management of food allergy in both children and adults with a wide variety of chronic illnesses from asthma to arthritis;

— double blind studies of low dose desensitisation methods, mainly in rhinitis and food allergy;

— long term follow-up audit studies of severely-affected patients, half of whom had suffered previously for 10 years or more, and had been referred to a number of different consultants (11 in one case) without relief;

— published case studies;

— the daily experience of doctors using these methods where it is not uncommon for patients to say that after all they had been through, they would not have believed that it was possible to feel so well.

2.3 Is the level of UK research into allergy and allergic disease adequate?

No, it is not adequate. This is partly because of the individually-specific nature of allergies which does not readily fit into the standard randomized double blind format. Experiments can only be performed studying the allergens to which each patient is sensitive, and the symptoms provoked in each individual patient, and must be done during a window of opportunity unaffected by previous exposure. There is little or no publicly-funded research into non-IgE-mediated allergy, although there is considerable evidence that environmental management would reduce the burden of chronic ill-health with very large savings for the NHS.

2.4 What are the most promising areas of research into preventing or treating allergy?

(a) More accurate figures for the prevalence of allergies could be obtained by a large study based in general practice if this was designed to identify all the patients with any of the chronic or recurrent conditions which have been reported to respond to any type of allergy management, with randomized matched subsamples of the patients referred for diagnosis and treatment to mainstream allergists or other consultants as appropriate, and to allergists using environmental methods.
(b) It would be possible to test the theory that correction of deficiencies of essential nutrients during pregnancy (or preferably before conception) would reduce the incidence of childhood allergy. A study could link investigation of key nutritional factors during pregnancy using objective tests, with the well-being of the infant on delivery and the occurrence of allergies and other conditions in childhood, in two groups in one of which deficiencies would be corrected and in the other, not. Ideally this could be controlled by groups randomly assigned to standard supplementation as currently recommended or to supplementation with a wider range of essential nutrients.

(c) Cost benefit studies of environmental methods in several chronic illnesses, such as hyperactivity and serous otitis media in children, and irritable bowel syndrome, asthma, migraine and chronic fatigue syndrome in adults.

3. Government Policies

3.1 How effective have existing Government policy and advice been in addressing the rise in allergies?

We welcome the slight expansion of consultant training of allergists, most of which is concerned with IgE-mediated allergy but this remains totally inadequate.

3.2 How is current knowledge about the causes and management of allergic disease shared within Government?

As far as we are aware the DoH adheres to the general, circumscribed view of allergy. Some years ago MAAF funded a study of food intolerance which ignored important aspects of the natural history of the condition and resulted in useless and misleading results. It would be very helpful if the DoH were to fund appropriate studies large enough to establish the clinical value of management based on the wider conception of allergy.

(a) Do housing policy and regulations governing the indoor environment pay enough attention to allergy?

There has been co-operation on asthma and housing, but room for more. Encouraging the elimination of draughts helps save energy and improves heat retention but it also increases the retention of chemical pollutants which probably plays a part in increasing allergies. Government should be making more effort to reduce the volatile organic compounds released from cleaning compounds and fabrics and encouraging the use of borax as a fire retardant.

3.3 How effectively are food policy and food labeling regulations responding to the rise in food allergies?

Food labeling is improving but incentives should be given to manufacturers to establish separate production lines for peanuts so that peanut sensitive patients are not unnecessarily restricted.

4. Patient and Consumer Issues

4.1 What impact do allergies have on the quality of life of those experiencing allergic disease and their families?

The effect of allergies varies from minor to devastating. Severe peanut allergy and hyperactivity and asthma all dominate the lives of the families with sufferers and commonly lead to relationship breakdown. Many adults with severe allergy problems are unable to work, either because they are too ill or because they cannot find work in an environment they can tolerate. Their position is made worse by the fact that their condition is not widely understood and they are often treated as if their illness is imaginary, and denied benefits.

4.2 What can be done to better educate the public and to improve the quality of information that is available to patients and undiagnosed sufferers?

(a) The first group to educate is the GPs. The pharmaceutical companies spend a lot of money teaching GPs (and other doctors) about drugs, often in lavish surroundings, or with trips abroad. There is no equivalent source of funding for allergy and environmental and nutritional methods of practice and doctors have to pay for their own tuition (which is arranged by this Society) except for the occasional lectures invited by postgraduate deans etc. Some GPs actually complain to the GMC when ecologically-minded doctors get their patients better when the GP had previously failed.
(b) Although many sufferers are unaware of how they could be helped, there is currently less scope for educating the public, partly because they are in general ahead of the doctors and partly because there are so few allergists and ecologically-minded doctors at present that educating the public would be counter productive.

(c) The most pressing need is to increase the numbers of allergists, and particularly ecologically-minded allergists (such as members of this society), throughout the country. Allergists have traditionally not been widely ecologically-minded, although this is changing. Most ecologically-minded doctors are practicing privately because there are no NHS jobs for them, except for a few who manage to combine this sort of practice with NHS general practice. Few of the private doctors in this field make a good living, and their finances are now being hit by the requirements of the Health Care Commission, and will be in the future by the GMC’s revalidation requirements. There is a serious risk that they will give up the struggle to practice in a way that they know is much more effective than the standard pharmaco-therapy.

4.3 Are current regulatory arrangements, for example, those governing private clinics offering diagnostic and therapeutic services and the sale of over the counter allergy tests, satisfactory?

(a) No. Private doctors practising ecological medicine need to be relieved of some of the requirements which are appropriate for large organisations but not for one or two doctors offering a much needed service.

(b) An allergy service needs to be headed by a doctor with postgraduate training covering all aspects of allergy (such as that provided by this Society), although properly-trained nurses and dietitians can make valuable contributions. Currently doctors are much more highly regulated than complementary practitioners. When complementary therapy organisations were asked what they did, none of them claimed to practice allergy, but many of their practitioners are known to identify trigger substances and advise about diets etc which amounts to practicing allergy. It is unsatisfactory, and occasionally potentially risky for such people to practice like this without adequate training and without equipment to manage any possible emergency.

(c) There is insufficient testing and regulation of OTC tests.

October 2006

Memorandum by The British Institute for Allergy & Environmental Therapy

1. Preamble

The Institute is a professional association of some 300 holistic allergy therapists.
Members are drawn from a broad spectrum of the healing professions, both mainstream and complementary ie doctors, pharmacists, nurses, mid-wives, homoeopaths, psychotherapists, osteopaths and others.
The Institute was formed in 1987 in order to bring together therapists who were using the holistic techniques developed at the Ffynnonwen Natural Therapy Centre and Homoeopathic Pharmacy in mid-Wales.
The information presented is based on the practical experience of working with allergy sufferers using the techniques developed and refined and taught over a period of nearly 30 years.

2. Definition

The word allergy was originally coined in 1906 by von Pirquet, and was loosely defined as an abnormal reaction of the body. In modern terms this could be taken to mean “An abnormal response by the immune system—the body’s protective mechanisms—to the environment, where the body’s environment is defined as anything that can be touched, eaten, drunk, breathed or injected. Clearly this fits the holistic model as it encompasses all the activities of the immune system.

Over the years, the scientific model has come to define allergy as a condition caused by an antigen/antibody response—which may or not be life-threatening. This is activity of the specific immune system, and as continuing exposure to the allergens increases the antibody load, the condition becomes progressively
dangerous. Although different antibodies are involved, the physiology closely mimics the physiology of immunity against disease which has been closely studied since the days of Pasteur.

By comparison, food and chemical intolerance and sensitivity have been accorded, in mainstream medicine, a role of minor importance. The symptoms occur as a result of either activity of the Non-specific immune system or a genetic lack of essential digestive enzymes. These conditions are generally not life-threatening, do not involve the antigen/antibody response and are more difficult to diagnose as often a multiplicity of apparently unconnected symptoms are presented. All too often this has led in the past to diagnosis of hypochondria and unsuccessfully treated as such.

Many factors may be involved in the high prevalence of allergic disease in the UK:

- High levels of atmospheric pollution.
- An increasing dependence on pre-packaged food as increasing costs or aspirations of families lead to more working mothers with less time or ability for fresh food preparation.
- Use of plastics in food packaging leading to the pollution of foods by PCBs (Polychlorinated Biphenyls)—increasing the toxic load on the body and in particular the liver.
- Increasing use of chemical preservatives and unnecessary colourings in foods.
- Electromagnetic pollution of the environment—Power lines, Computer equipment, Mobile phones etc.
- Increasing use of “recreational” drugs.
- Increasing side-effects and over-use of prescription drugs.
- Overuse of oral antibiotics in the past causing imbalances in the natural flora of the bowel, increased levels of Candida albicans overgrowth and subsequent interference with normal digestive processes.
- The sensitivity of many individuals to the toxic and electrical effects of the over-use of dental amalgam as a restorative for damaged teeth, in spite of pressure from many dentists to use alternative materials. This material is still in use although reported evidence of its dangers has been widely reported in professional journals.
- Unnatural changes in hormone levels caused by the contraceptive pill and HRT placing pressure upon the immune system, as do increased levels of stress often in the home, the workplace, finances, cost of living, school and other areas. These all have a deleterious effect on the normal functioning of the immune system.
- In the past, Food & Chemical Intolerance and Sensitivity have been consistently misdiagnosed, in many cases due to the refusal of the scientific and medical establishments to accept the facts of its existence. As awareness increases, correct diagnosis leads to a further apparent increase in cases and additionally, one would hope, to increasing acceptance of established methods of diagnosis and treatment.

When Type 1 allergies (where the antigen/antibody response occurs) are identified, treatment is usually symptomatic and readily treated by the GP, using antihistamine, mast cell stabilising or steroid drugs. Food and chemical intolerances, although readily treatable by alternative means, present a considerable time and cost problem for mainstream medicine.

Even when treated as above, the symptoms of Type 1 allergies are, in many cases, not totally relieved and so result in lowered productivity and absenteeism in both workers and children, as not only are allergic conditions exacerbated by stress, the conditions themselves are stressful.

3. Treatment and Management

- Current treatments do nothing to reduce the incidence of allergic conditions. Treatment is concerned mainly with the relief of symptoms, rather than the prevention of development of the conditions. Prevention should be the main concern.
- The current program of vaccination of infants and children is considered by many to be responsible for the development of allergic conditions in some children and research should identify ways of avoiding this.
- If one considers the above, then one must also be very wary of the possible results of introducing an allergy vaccination program, bearing in mind that this, by its very nature would be directed at reducing only Type 1 allergies.
— Research should be directed towards ways of reducing the allergenic potential of home, work and public environmental conditions.

— Simple statistical evaluation of Alternative and Complementary methods already in use would perhaps be a starting point for the gradual introduction of these into mainstream medicine.

— Already there are effective Complementary methods for the identification and treatment of allergic conditions. These involve comprehensive case history taking, problem assessment, stress and lifestyle counselling, simple and inexpensive testing methods and low cost isopathic treatment. They involve consideration of the whole person, both psychological and physical. Incorporating these methods into GP surgeries by the training of Practice Nurses, would allow the effectiveness of these methods to be assessed statistically and would also reduce GP workload considerably. A pilot scheme would cost little initially and then would be self-financing as expenditure on drugs would be considerably reduced.

There would then be opportunities for the continuing development of already proven techniques.

4. GOVERNMENT POLICIES

It is laudable that the Government has now begun to take notice of the position of allergy sufferers in Britain. It is regrettable that this attention has been so long in coming and that in the past the Medical establishment has ignored those of its members and also those complementary and alternative practitioners who have evaluated the problem and have worked to find solutions to it in the face of relentless opposition.

— Food policy and labelling regulations are gradually responding to the demands of a general public that is very knowledgeable in matters of food allergy, and it should be recognised that the public have been educated in the main on the subject by the complementary practitioners of this Country.

— Many people have, of necessity, been able to change their living environment in order to minimise their allergies and it is useful that regulations regarding building materials seem likely to be considered. It is hoped that soft furnishings—often a cause of inhalant allergies will also be studied.

— In view of this, it is hoped that Government will understand that had it moved earlier the allergy problem would not have been as overwhelming as it now is.

— There needs, however to be caution in order to avoid the spectre of over-regulation that could so easily, and indeed so often in the past, has overridden common sense.

5. PATIENT AND CONSUMER ISSUES

— The allergic condition has, like any chronic illness, a huge impact on the sufferer. Food intolerance and irritable bowel syndrome often dominate the thoughts, regulate the patients’ activities to a great extent and call for never ending vigilance. Hayfever is easily forgotten once the season has passed. Eczema creates a constant invariable routine of treatment and bathing. The list is endless. Nor should it be forgotten that the parent also will suffer for the child.

— All information to be disseminated should be prepared from both the Medical and the Alternative points of view for it should not be forgotten that the many Complementary therapists in the Country have long experience of the consequences of the allergic condition. Perhaps the most underdiagnosed allergic condition in Britain is Coeliac Disease and Government could quickly correct this serious gap in its policy of preventative medicine by a simple inexpensive testing of children below secondary school age.

— The British Institute for Allergy and Environmental Therapy is a self-regulating organisation. As a member of the British Complementary Medicine Association, both as a teaching establishment and an association, its Members are obliged to accept the strictest standards of practice and Code of Conduct. Admission to Membership is by its own Diploma Course and it is believed that all Complementary therapists should be Members of a well-regulated Professional Association for their own therapy with access to a central body of information. It is regretted that there are many unregulated centres offering forms of allergy testing with no treatment or patient support. The sale of OTC allergy self-tests is to be deprecated as self-treatment, particularly in the field of food allergy can, without the advice of a qualified practitioner lead to dangerous under-nourishment.
I am not an allergist, nor an immunologist. I am an epidemiologist, interested in the distribution and causation of illness, and a psychiatrist, interested in the social and psychological aspects of illness. I directed a unit at King’s College London that has studied many aspects of chronic fatigue syndrome and related unexplained illnesses such as “multiple chemical sensitivity” (MCS)\(^{44}\), and I now direct a unit that researches many aspects of military health, including Gulf War illnesses. I have published over 500 professional original publications on these subjects.

We recently published a review of 37 “provocation” studies in which MCS sufferers were exposed to various stimulants in controlled conditions. The conclusions were that “persons with MCS do react to chemical challenges: however, these responses occur when they can discern differences between active and sham substances, suggesting that the mechanism of action is not specific to the chemical itself, and might be related to expectations and beliefs” (J Allergy Clin Immunol 2006: 118: 1257–1264).

This supports the strong consensus amongst clinical and academic immunologists that the phenomenon of multiple chemical sensitivity cannot be explained by allergy and/or immunological mechanisms (in contrast for example to allergic reactions to single substances such as peanuts). On the other hand, there is convincing experimental evidence that this can be explained by psychological conditioning, in which exposure to a stimulus such as an unpleasant odour becomes associated with a physiological reaction. The fact that symptoms develop only when the person is consciously aware of the stimulus (as opposed to peanut allergy for example) and that in double blind controlled tests these reactions cannot be reliably reproduced, speaks strongly to a conditioning model. Social, cultural and psychological factors related to perceptions of risk further amplify these reactions. I am not saying, and do not believe, that these symptoms are imaginary or “all in the mind”, but I am saying that social and psychological factors have more explanatory power than immunological or allergic factors.

Why does this matter? Considerable evidence shows that many (but not all) diagnoses of MCS are in reality misdiagnoses of other, often fairly straightforward, conditions such as depression or anxiety. A label of MCS not only means that such people then do not receive appropriate evidenced based successful treatments, but may instead receive treatments that do little good and in some cases considerable harm. I have in the last 20 years as a consultant seen a number of unwell patients who have received a diagnosis of MCS. So far this has only come from the private “alternative allergy” or “clinical ecology” sector. For some this has had unintended, but serious consequences for both health and bank balance. For me these have been some of the most distressing experiences of my clinical career.

\(^{44}\) “Multiple chemical sensitivity” has become a popular term, it would still be more appropriate to talk about chemical intolerance rather than sensitivity. MCS is not recognized in the WHO International Classification of Diseases.
Q545 Chairman: Could I start by asking you all what is idiopathic environmental illness or multiple chemical sensitivity?

Dr Downing: Simply, multiple chemical sensitivity is just another form of allergy that is getting worse and more common, as we see. There are reasons for that which I can go into, but it is complex and one of the reasons which I think will in due course be proven is environmental pollution and chemicals having a disrupting effect on the immune system and making all allergies worse. The obvious model for this is rhinitis which is, paradoxically, worse in towns than in the countryside and tracks better with levels of environmental pollution and small particulates than with levels of pollen. I think that exactly the same thing is happening with that as with food intolerances and with chemical sensitivities. Ten years ago, the Royal College of Physicians produced a report—it may be 12 years ago, I am not sure—that said effectively that all this stuff about food intolerances was a load of nonsense; and now your request for submissions refers to the rise in food allergy as being a fact. I think that another 10 years will probably see the same sort of shift in our perception of chemical sensitivity. I certainly do not think that it is in any way idiopathic. Idiopathic is one of those words that doctors use when they are trying to pass the buck really.

Mr Harrison: I agree with Dr Downing about the wording. Certainly I do not believe that multi-chemical sensitivity is idiopathic, which is of no known cause, but it does certainly appear to arise from either a single substantial chemical exposure or quite minor long-term exposure to chemicals. Examples of that, just a few of them briefly: people living in high pollution areas; factories; traffic; flight paths; laboratory work; farming in particular, with the spraying of pesticides and also operations in animal husbandry such as dipping of sheep; excessive inoculations in time of war, as the Gulf War Syndrome has shown; and perhaps surgical anaesthetics because in times of stress, as in a surgical operation, the patient is introduced to a number of unusual chemical gases, things they are not used to, and that may be the basis for subsequent chemical allergies to appear. Certainly much of the problem with chemical sensitivity arises in a problem with liver function and liver support is almost always required.

Professor Wessely: It is an imprecise label. People develop multiple subjective symptoms in response to perceived exposures for which there are no obvious toxicological or immunological explanations.

Dr Monro: I do not agree with that. I believe that there are explanations emerging now. There is a considerable amount of evidence that there are two principal pathways for allergies. Most allergies present at the surfaces of bodies, the whole of the outside surface and the surfaces of mucal membranes. There the gatekeeper cells—I am going to mention something because this is a scientific committee—the dendritic cells, are the gatekeepers of allergies. These are linked with some of the very fine nerve cells which are linked to the autonomic nervous system called C-fibres. C-fibres transmit information extremely fast and the information is passed into the autonomic nervous system and into the central nervous system. There are two principal mechanisms in allergy. One is the local mechanism where reactions can occur peripherally and the second is central mechanisms where the neural system of allergy is invoked. We know that the neural system of allergy can be very easily switched on by exposure to chemicals. There are receptor cites on these C-fibres which will allow responses to be perceived quite quickly. Hence there is in fact a physiological mechanism to explain a very swift onset of symptoms which can be perceived neurologically as well by individuals and often having an expression through the autonomic nervous system.

Professor Wessely: I am not an academic or clinical immunologist and I do not have postgraduate qualifications in it, I am not sure that any of us do, but those who do I do not believe would recognise that. The people in academic immunology and allergy in my institution and elsewhere repeatedly give the definition I have just given that this is where symptoms arise which do not have a recognised allergic, immunological or toxicological basis. If they did, life would be easy and we would not be here.

Q546 Lord Taverne: Apart from excessive vaccination and these multiple chemicals, do members of the panel also think that part of cause of the allergy are electromagnetic fields, phone masts, electric waves and these kinds of influences?

Dr Downing: Personally no. I do not think that that happens in the sense of people becoming allergic to electricity, but I think it is likely that electromagnetic waves add to the overall pollution effect that we are all experiencing.

Professor Wessely: On both of those things, first of all, Lord Taverne, I am not sure if you were actually agreeing with the idea that multiple immunisations is a cause of these illnesses or not.

Q547 Lord Taverne: No.

Professor Wessely: We did a lot of research on that throughout the Gulf War Illness and we showed that receiving multiple immunisations prior to the Gulf War was associated with the development of symptoms. In other words, it triggered it, but we were not able to show that there was an allergic or immunological basis to this association. We are now
in the middle of a randomised trial to see precisely what was the explanation, so you have a link but we are not convinced this was done to disturbances of the immune system. Likewise, on the mobile phones we have published a double blind trial in the BMJ a few weeks ago where we allocated randomly people who were sensitive to mobile phones but they were then given sham or real stimulation, and they were not able to tell the difference, so again people report sensitivity to the exposure but clearly whatever it is due to, it is not due to the influence of electromagnetic radiation.

Mr Harrison: On that subject, although in our work we mostly concentrate on food, and chemical and airborne pollutant sensitivities and allergies, nevertheless we still look at the involvement of dental amalgam in the mouth which also has an electromagnetic effect and also during our case histories we always look at electrical possibilities within the patient’s environment, either at work or in the home.

Q548 Chairman: Given your mention of dental amalgam, have you done any work looking at mercury and mercury leakage?

Mr Harrison: No, I have not but in the past I have had prolonged discussions with the late J G Levenson, a dentist who was an expert in the field.

Q549 Earl of Selborne: Could the panel tell us of any projects currently underway to research the mechanisms involved in environmental illness. Perhaps you could also tell us whether you think there should be further research into these issues and who should carry it out?

Dr Downing: I think to some extent we have had the answer to this question already in the previous session. The current climate in terms of funding and ethical clearance and regulation in general makes it pretty much impossible in this country, and if Professor Ernst with a team of 10 cannot manage to mount prospective clinical trials then our society with a staff of half a person is hardly likely to do so. There may be other studies going on elsewhere; I could not speak on that.

Q550 Earl of Selborne: Could you or perhaps one of the other members of the panel tell me who you think should be funded to do this work?

Dr Monro: Yes perhaps I could answer that. Dr Jaleil Miyan at the University of Manchester has shown that the neural pathway of allergy exists in his biological tests that he has done. With regard to translating that to humans we would like to be able to do further research. We have done some preliminary work and we would like to be able to substantiate that further. With regard to the comment about electrical equipment causing problems, there is in fact research which has shown that when people are put in a Faraday cage and exposed to different frequencies of very low levels they did respond with symptoms, and these were quite distinct symptoms such as provocation of asthma. So although that was a small piece of research it nevertheless does show that there are effects which should be explored. With regard to chemical sensitivity, yes, there is work but it is not being undertaken in this country, it is being undertaken in the United States. Professor William Meggs has demonstrated that there are quite a lot of mechanisms which will explain some of the phenomena of chemical sensitivity.

Professor Wessely: Academics always moan about it is hard to get research money and more should be given but there is an enormous amount done on environment and health and I do not think it is that difficult to get money for research, if you have well-designed studies with good hypotheses and good outcome measures. We have certainly managed to get research money in this area and so have many other colleagues, so I do not think it is quite as difficult as that. I think it is hard to get money for bad research and so it should be—but for well-designed studies there are mechanisms, and they do produce research grants which are carried out and published in reputable journals.

Q551 Earl of Selborne: Can you give us examples of organisations which provide funding? Are you funded by research councils?

Professor Wessely: All sorts. We get funding from the MRC, the Wellcome Foundation, we get funding from the Department of Health, the Ministry of Defence, from Leverhulme, from Joseph Rowntree. There is a variety of research organisations. It is obviously always easier in America because they just have more money than we do and so there is more going on there. That is certainly true and there are many centres looking at these issues directly across America, not just the one Dr Monro has mentioned but many others as well.

Q552 Lord Taverne: But are these research projects into environmental effect ones which look at the impact on allergies?

Professor Wessely: Yes there are. We have just reviewed 70 such papers on provocation studies, so clearly someone has paid for those and they have been published. I would go so far as to say we probably do not need any more now. I think that is a debate that is largely concluded. On mobile phones and electrical hypersensitivity there is a huge amount of studies, particularly on the Continent where these issues are much more debated. I do not believe we need any studies on dental amalgam any more, for
example, there are hundreds of studies on that, and again it is a subject that is largely closed.

Dr Monro: That is not actually the opinion of UNESCO. In the Paris Memorandum which was published in the November 2006 they said that they thought that environmental medicine should be established as a specialty and, furthermore, that allergology should be a sub-specialty of that, and they mentioned there particularly the effects of amalgams and mercury and they also emphasised the effects of pollutants, and they are calling for more research. Furthermore, the Standing Committee of European Doctors was signed up to by all 25 EU governments and the agreements that they have produced in their memorandum are signed up to by all of the professional bodies, representing doctors in each of the different 25 different countries, so in fact they are all calling for more research.

Professor Wessely: I am a member of the European Science Foundation’s Committee and several others that consider this area and I know what we signed up for and I know what we called for. Of course we called for more research, absolutely, but I said on certain questions, such as the influence of dental amalgam on health, we have not called for more research in that area.

Q553 Earl of Selborne: I wonder if we could establish where you are calling for more research. Perhaps each member of the panel could tell us the last time they submitted a grant application and who it was submitted to?

Dr Monro: From our point of view, we submitted a grant application to the Lang Foundation and they have kindly said that they will sponsor that. That was submitted last year.

Mr Harrison: The big problem with allergy, and I notice this did not emerge at the previous meeting, is that allergy is a condition of great complexity. I have mentioned various aspects of it and if you say our environment is everything we eat, everything we touch, everything we breath, everything we smell, both internal and external, then the complications begin to arise immediately, so where is research to be directed? When we work with patients, we look at foods, we look at dust, pollens, moulds, we look at the effects of immunisation, the effects of dental amalgam, the effects on the liver and the thyroid gland. Working in this complex way, I believe is the only way that we will reach satisfaction, so where one directs research is a very, very difficult problem indeed because every patient is different. There is not a patient with an allergy; there are multiple patients with multiple allergies, and it is very, very difficult to direct both treatment and research.

Q554 Chairman: Dr Downing, did you want to make a comment briefly in response to that question?

Dr Downing: I do not personally do research these days, I am too busy editing the journal and other things, but where I would like to see research directed would be at the effects of environmental pollutants in general.

Q555 Lord Colwyn: I just want to make a comment about dental amalgam as a dentist of longstanding. I have to say that amalgam probably would not get a product licence if it was produced today but if there were a direction to remove amalgams, and there are millions and millions of amalgams, the NHS would go bust overnight.

Mr Harrison: It also would be unnecessary because of course many people are not affected by their amalgams.

Chairman: I want to try and move on because we have got a lot of questions today so if you could roll your answers up concisely please.

Q556 Baroness Platt of Writtle: What is an environmental allergist and how does a person become one? Do these practitioners have to register with a regulatory body, and what qualifications must they hold?

Mr Harrison: 30 years ago when I first started looking at allergic conditions, there were no regulations, there were no therapists, or there did not seem to be very many. I began to pass on the results of my own work to alternative therapists and to health practitioners too, and after about 10 years or so it became quite obvious that regulation was important because you collected a mixture of people in your seminars, some of whom wanted to work with patients and some who did not, so then we formed an institute for the people who had attended seminars and were practising allergy work in the same way and we achieved a measure of regulation that way. We made sure that the membership were reasonably well-trained, that they had the interests of the patient at heart, and that they were insured. Now we have reached the stage where the same standards apply, and we also have continuing professional development of course. We are ourselves regulated by the British Complementary Medicine Association which I understand has a responsibility to Government. We follow their precepts and we make sure that our members follow them too. That is the type of regulation that we have. We have a complaints procedure and I am happy to say that over all the years of the institute I think two complaints, or maybe three have been on the board, all of which were dealt with satisfactorily as far as the patients were concerned.
Dr Downing: The society which I represent, the BSEM, is a society of doctors and you have to be a doctor to be a full voting member. We conduct our own post-graduate training and we are yet again in discussions towards establishing that as a diploma or similar. In order to become a member of the Register of Ecological Physicians therefore you have to be a doctor first and then to go through our training course and to conduct an audit within your practice and to present case histories and sign a code of ethics. I am not sure that makes me an environmental allergist—that is the problem I have with the question—but I hope that answers it as far as we are concerned.

Q557 Chairman: So if I am hearing you right, you have a validated qualification which is awarded by your body, is that correct, so you have an assessment process?

Dr Downing: We have an assessment process which is not yet validated but we are working towards that with the Institute of Biology.

Q558 Chairman: And Professor Harrison, you were talking about self-regulation.

Mr Harrison: Admission to our institute for several years now has been via our own diploma course. That is a course which is partly practical and partly theoretical. Currently the course has been put up to the University of Wales with a view to validation. It has been well received initially but as the mills of universities drive exceedingly slow, unfortunately, it is likely to be about another 18 months before it goes forward to the committee.

Q559 Lord Colwyn: Could it be said that the UK is taking a leading role in environmental medicine?

Dr Monro: We certainly have a society which will represent doctors in this country, but I think that there are quite a number of other countries in Europe which have got organisations which are promulgating interest in environmental medicine. In the States there has been an established training course for many, many years. Certainly in Germany there are environmental medicine hospitals, which are paid for by the federal government, under the auspices of various Krankenhaus and patients can attend there and their health insurance will pay for them. In Germany and in France and the States they have quite a number of organisations which will do this work also.

Q560 Baroness Platt of Writtle: If a patient seeks medical advice about a possible allergy what are the differences in approach between an environmental allergist and an NHS allergy specialist?

Dr Downing: So I am an environmental allergist then! Fair enough. Somebody who comes to see a member of our society with these things would be approached on a much broader basis and we would be looking at not simply the narrow definition of allergy that has been used, which is kind of falling apart these days, but is still there, which is that allergies cause IgE-mediated diseases such as asthma, eczema and so forth. We see a lot of people with a huge range of other diseases that have been shown in individual instances to have allergic or hypersensitivity mechanisms involved in them, and the link between food intolerance and arthritis would be an obvious example of that. So somebody coming to one of our clinics would be assessed in those terms and would also have their nutritional status looked at, and they would have their toxicological status considered as well, and of course we would also rope in lifestyle and psychological factors.

Q561 Baroness Perry of Southwark: I would like you to explain to us something about what I think is called the provocation or neutralisation test which is used by environmental allergists; how does it work?

Dr Monro: It is a form of low-dose immunotherapy. In your previous questioning you were asking the panel on homeopathy and they said that the doses used were very infinitesimal whereas in neutralisation techniques the doses are tested for an individual according to the individual's responses and it is a form of low-dose immunotherapy. It has been used as a sublingual form of immunotherapy and there are now some 3,000-odd papers on sublingual immunotherapy and how effective it can be. I think Dr Brostoff said that it was a technique that was approved by the European Academy of Allergy and accepted by them. Furthermore, low-dose immunotherapy has been shown to be the most effective disease-modifying form of treatment as opposed to disease-suppressing form of treatment for people with allergies.

Q562 Baroness Perry of Southwark: As I understand it, the provocation test comes first and then is followed by the neutralisation vaccines. Am I right? Perhaps you could tell me what quality controls there are for those vaccines that are used?

Dr Monro: What is used is a series of different strengths of vaccines starting with one particular strength and it is titrated as a low dose from there in strengths of perhaps one part in five, so the strengths of the initial vaccine are well known and they have been established. The dilutions are parts of that, perhaps one in 25 or one in 125 parts, just as an example, so that when one knows the original strength one can calculate what the strengths of the others are. The point about it is that immunotherapy
has been shown to be beneficial. I can quote from a paper from *Nature Reviews Immunology* in October last year which says: “It will prevent the onset of new sensitisations to different allergens, reduce the development of asthma in patients with allergic rhinitis caused by inhaled allergens, and it is disease modifying rather than palliative.

Q563 Baroness Perry of Southwark: Where did you say that article appeared?
Dr Monro: That is from *Nature Reviews Immunology*, volume six, October 2006.

Q564 Baroness Perry of Southwark: I was going to ask about a double blind study of the provocation tests, which I am still not quite clear about. You have talked a lot about the immunisation programme but I am not quite clear what the provocation test is. I wanted to press you really on the study that was published in the *New England Journal of Medicine* in 1990 where they said that the provocation test had no value in identifying food sensitivities. Has there been any study afterwards specifically on the diagnostic test?
Dr Monro: Yes, there have been and I have a dossier of information about it. That paper was by Jewett and it was critiqued by a number of people who actually practised provocation neutralisation. He did not actually practise it, he is an orthopaedic person, but the point is that the critique has shown that the techniques that he was recommending were not entirely valid.

Q565 Baroness Perry of Southwark: So the provocation test is what, giving somebody a dose?
Dr Monro: It is giving a dose of allergen which is at a particular strength that I have mentioned and then that can provoke symptoms in a person which can be nullified by a weaker strength.

Q566 Baroness Perry of Southwark: So how many provocation tests would you have to have before you could identify what it was that the patient was allergic to?
Dr Monro: Whatever the strength of solutions it is that is being used, say wheat diluted to a fifth of a standard concentration, that can be used as provocation. The next weaker dose could be used as a treatment, so it is a series of different strengths.

Q567 Baroness Perry of Southwark: How do you find out which allergen the patient is reacting to? Would they have to have 20 or 30 different allergens given to them as provocation?
Dr Monro: They may have to but quite often if one has a history of a problem in an individual—and that is where the skill of the environmental physician is used—you identify the things that you suspect might be a problem and that is the item that is tested, and you might have three or four items in an individual or you might have ten.

Q568 Baroness Perry of Southwark: Since that *New England Journal* article in 1990, have there been any research reports showing that the 1990 report was wrong, that these provocation tests do work, and can you give us a quote?
Dr Monro: Yes I can, I have got a dossier of them but, in addition, as I say, since then there has also been a vast literature on sublingual immunotherapy, which is part of the provocation testing technique, which shows that low-dose immunotherapy is very effective, and I am happy to provide the Committee with the relevant documents.

Mr Harrison: I agree with the validity of the provocation test certainly but we use a different type of testing. We use the type of testing beloved of Professor Corrigan. We use muscle testing, we use kinesiology. The test is comparatively short and it can be anywhere between 20 and a couple of hundred allergens. The case history taking has to be long. The remedies that are used and that are produced in our own pharmacy are dilutions of one in 100. In other words, they are homeopathic centesimal dilutions going up to the 30th centesimal potency; sometimes to the 200th and sometimes higher, but usually the 30th is adequate, and so we are way beyond the level of actual material in our remedies; we are looking at energy medicines rather than anything else. The test is short and more time is probably devoted to the case history.

Q569 Chairman: Again I am going to shorten you because Professor Wessely has been patiently waiting to make a comment.
Professor Wessely: The Jewett test in the *New England Journal* was one of a large number of double blind provocation studies and what these show is that where the blindness is maintained thoroughly, in other words neither the patient nor the doctor is able to guess or work out what the provocation is, they give consistently negative results, no better than chance alone. Where either the doctor or the patient is unblinded, they give positive tests. It is for that reason that the provocation tests are not used to diagnose sensitivities.

Q570 Baroness Perry of Southwark: I am grateful for that. Could I just return to the difference between the neutralisation process that Dr Monro is talking about and conventional sublingual therapy which we have certainly seen practised for example in Germany and elsewhere. What is the difference between the two?
Dr Monro: The difference is simply that one uses in a neutralising technique a series of different solutions and one uses the solution which produces no adverse effects as a treatment, the strength can then be increased. It is perfectly safe to do sublingually because there are known to be very few what are called mast cells in the mouth and under the tongue so that a person can be given a treatment very safely without the likelihood of adverse effects. So the neutralisation technique is to find a strength which gives no symptoms and then you can increase the dose thereafter sublingually in a form of low-dose immunotherapy.

Q571 Baroness Perry of Southwark: So it is different from the sublingual therapy which is used in conventional allergy treatment?
Dr Monro: It is not entirely different. As I say, one can use one of the strengths and then build it up so that in fact it becomes the same thing.

Q572 Chairman: Could I just clarify, would that technique apply to something like peanut allergy?
Dr Monro: Yes it has been used for peanut allergy but it is not commonly used and there have been only two reports of sublingual immunotherapy causing any major effect, and that was when it was done in a rush desensitisation for peanut allergy.

Q573 Lord Colwyn: This is a question for Dr Downing. In your evidence you said that allergic patients tend to be deficient in several of the vitamins and minerals necessary for optimum function of the immune system; correcting such deficiencies seems to improve their general health and lessen their hyper-reactivity. I would agree with that statement, namely that possibly zinc and vitamin C are some of the major offenders. Can you give us an answer on what is the evidence for this statement—and you are going to have to do it in about 60 seconds!
Dr Downing: It is a good job that I prepared a written response which gives a number of things. The short answer is, yes, there is quite a bit of evidence but that environmental allergies, as we are now calling them, are no different from the rest of allergy in that respect, it is true of all asthmatics and allergics. 45
Lord Colwyn: Are you aware of any control trials that have been undertaken which have been published and peer-reviewed?
Dr Downing: On treatment?

Q574 Lord Colwyn: Yes.
Dr Downing: Somewhat more limited.

Q575 Lord Colwyn: To support your claim about vitamins and minerals?

45 Please see supplementary evidence.
more importantly, referred by GPs. As far as the Government is concerned, it is already regulating the preparation of homoeopathic medicines. The distribution of them should not be open to the normal aspects of commerce because, for instance, putting allergy neutralisation remedies on the shop shelf would be entirely irresponsible—no doubt very attractive as a money-making proposition but totally irresponsible—because people would just go and help themselves, dip into them, take this or that and waste their time and money. How the Government would regulate homoeopathically prepared medicines further, I am afraid that is beyond me. I do not think they could manage it.

Dr Downing: If you are talking about doctors running clinics of this sort, then it is hard to see how we could be more regulated, quite honestly.

Q578 Lord Haskel: It is the clinics and the treatment clinics which they provide that we are concerned about.

Dr Downing: Yes, a clinic run by a doctor of that sort would come under the terms of the Health Care Commission and therefore also the National Minimum Standards. A number of us have either gone through the process or are going through the process at present, and I am myself, and I have to say that it has been challenging but I think it has been valuable and enabled us to improve what we do and the service that we provide.

Q579 Lord Broers: But are you required to do that?

Dr Downing: Yes.

Q580 Lord Broers: To register with the Health Care Commission.

Dr Downing: Yes.

Mr Harrison: We ourselves are not. Our members have to rely on the regulation that comes from the association as a whole. We have to rely on ourselves to put the regulations in place. I have been a qualified pharmaceutical chemist for 50 years and I am headed by the Pharmaceutical Society, I cannot put a step out of place, and I have to ensure that our members toe the line, and I am pleased to say that they do. They would be removed from our register immediately if they cause problems. We are open to listen to patients who have been to therapists who are members of our association so the patient has a direct line with which they can communicate and get answers.

Dr Monro: I was just going to say with regard to doctors, we have the Health Care Commission, we also have GMC validation, and also we have to do CPD accreditation with them. Yesterday, or perhaps today, there is a new five-year appraisal for doctors that is being instituted. With regard to the products that we use the neutralising vaccines or the low-dose immunotherapy vaccines the Medicines and Health Care Products Regulatory Agency is involved in supervising those so there are all the regulations as far as doctors are concerned, and indeed the care standards people are getting a more standardised format for their rules of interpretation now.

Q581 Chairman: I think we need to finish here. I just think it would be very helpful if in one short phrase you could each tell us how your private clinic services communicate with the patient’s GP what has been happening?

Dr Downing: We send a letter direct to the GP and any other doctors after first consultation and after any one of which there is a significant event and after other ones. The patient has a health dossier and there will be a summary of the consultation.

Dr Monro: The same pertains in our facility. Patients’ doctors always receive letters. Patients are allowed to say whether or not they want their doctor to receive information and the responsibility then rests with the doctor in the facility as to how they handle that. Our practice is always to give a report to the patient to hand on to their doctor if they should decline to have a direct communication.

Mr Harrison: Where patients are referred by their doctor, then automatically the doctor receives an assessment of the patient’s condition, the treatment administered, and the subsequent treatment recommended. Many patients who are self-referred do not wish communications to go to their doctors. Nevertheless, one does sometimes, unfortunately, find other conditions that are present and then the patient is asked for permission to refer to the doctor, and then of course the doctor gets an explanation of what has been found and how and why and one hopes then that the patient will go back to them.

Q582 Chairman: Professor Wessely?

Professor Wessely: I do not do private practice.

Chairman: Fine. Could I thank you for coming today. If there is additional information that you would like to give us as a Committee please do write in and it will be considered as part of your evidence. It will be helpful if the references that you have referred to could be sent in to the office, in particular the paper that you prepared for us today, Dr Downing; that would be most helpful. Thank you very much indeed.
**Evidence for Vitamin Deficiencies in Environmentally-Sensitive Patients**

*Clinical Ecology* VI(2) (1989)

**Serum Zinc in a Series of Allergy Patients**

Maberley D J and Anthony H M.  

**Bronchial reactivity and dietary antioxidants**

Soutar A, Seaton A and Brown K.  

**Dietary fats and asthma in teenagers: analyses of the first Nutrition and Health Survey in Taiwan (NAHSIT)**

Huang S L and Pan W H.  

**Vitamin A status in children with asthma**

Arora P, Kumar V and Batra S.  

**Serum vitamin levels and the risk of asthma in children**

Harik-Khan R I, Muller D C and Wise R A.  

**Levels of coenzyme Q10 in asthmatics**


**The role of selenium, zinc and antioxidant vitamin supplementation in the treatment of bronchial asthma: adjuvant therapy or not?**

Ricciioni G and D’Orazio N.  

**Dietary intake in patients with asthma: a case control study**


**The influence of the dietary intake of fatty acids and antioxidants on hay fever in adults**

Nagel G, Nieters A, Becker N and Linseisen J.  

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**Supplementary memorandum by Mr Don Harrison, Principal, British Institute for Allergy and Environmental Therapy**

I am grateful for the opportunity to offer additional material to the Committee as a number of the questions that I was not asked to answer at the meeting are within my sphere of interest and knowledge. I am a member of the Royal Pharmaceutical Society of Great Britain, having a degree in pharmacy; a graduate Member of the British Psychological Society, with an honours degree in psychology. I have worked in community pharmacy, holistic medicine and homoeopathic pharmacy since 1954. I trained extensively in physical therapy, psychotherapy, kinesiology, use of the Vegadevice, Bowen therapy and NLP, and have worked for the past 30 years as an holistic allergy therapist and homeopathic pharmacist, during which time developing holistic techniques for allergy identification and treatment. As Founder and
Principal of the British Institute for Allergy and Environmental Therapy, I believe that if I briefly describe the work of the Institute this will answer, in context, many of the questions that were raised by the Committee in relation to alternative and complementary therapy.

During the development of the techniques used by members of the Institute in the identification and treatment of allergic conditions, a number of testing techniques were evaluated. These included the tests commonly used in NHS allergy clinics as well as the Vega test and Applied Kinesiology (Muscle testing).

It was found that, of these, Applied Kinesiology was the most simple, inexpensive, comfortable and accurate test in the hands of a trained practitioner, and the most easily understood by the patient, including children.

Treatments were developed along homoeopathic/isopathic lines, and these treatments are matched with the results obtained from the testing procedure. The remedies used are prepared using the techniques of homoeopathic pharmacy, the starting point being a sample of the offending allergen in each case, usually prepared and succussed to a dilution of 100^30.

The difference between a homoeopathic and an isopathic remedy is not one of substance but one of prescribing. Homoeopathic medicines are prescribed following an examination of the symptoms presented by the patient, and an attempt is made to match those symptoms to the “symptom picture” of the remedy according to the Materia Medica whereas Isopathic remedies are prescribed by identifying the causative agent and matching the remedy to this as an oral immunization.

Following the initial treatment, a re-test and consideration of changes in symptomatology indicates the progress of treatment and following the re-test further treatment is given if required, dealing with the offending allergens in a logical progression, the aim being to normalise the patient’s response to potential allergens.

Because allergies are caused by a number of different physiological reactions, and are exacerbated by stress, by dietary insufficiencies of vitamins and minerals and genetic absence of certain enzymes, attention is also paid to correct functioning of glandular systems, the effect of mercury amalgam, residual bacteria, viruses, yeasts and other parasites and a number of other factors. The patient is encouraged to make beneficial lifestyle changes if necessary in order to reduce both physical and emotional stress.

The Institute is a group of some 300 like-minded therapists drawn from the medical, nursing, pharmaceutical, osteopathic, chiropractic, homoeopathic, herbal, nutrition and other health professions, many dedicated to allergy work, but some who practice allergy work in addition to their original orientation.

As an estimate, at least 2,000 patients are treated annually.

Admission to the Institute membership is by Diploma Course and examination. The members are regulated by a code of ethics based on that of the British Complementary Medicine Association, and all carry professional liability insurance. There is a complaints procedure available to patients, who have easy access to the Institute if needed. The Institute has been in existence since 1987 and has dealt with only three complaints in that time, all minor and all satisfactorily resolved.

Patients are mainly drawn from those whose mainstream treatment has been less than satisfactory, are either self referred, or referred by their GP.

A system of Continuing Professional Development is in place.

It is believed that the cost of treatment as outlined is affordable by most patients and that the total cost, which may be funded by health insurance, is usually of the order of £100 to £150 and represents a fraction of the cost of allergy treatment as undertaken by the NHS.
INQUIRY INTO ALLERGY WITH REFERENCE TO SKIN DISEASE: CALL FOR EVIDENCE

1. Defining the problem: Several skin diseases have an allergic basis or an allergy-associated component. The most common can be summarised as follows:

**Allergy in eczema:**

(a) **Diagnosis:** in a patient with eczema (dermatitis), it is often difficult to distinguish contact dermatitis (allergic or irritant) from other types of eczema. In fact, pure contact dermatitis is uncommon—almost always constitutional and other factors are involved. This is one reason why people with skin disease are best assessed by a dermatologist as the specialist with a full education in the diagnosis and management of skin diseases.

(b) **Patient pathway:** A Department of Dermatology normally should be the first point of referral for patients with eczema, for the reasons mentioned above. It can be difficult to differentiate atopic eczema from contact dermatitis—indeed the two not uncommonly co-exist. Departments of Dermatology provide a holistic approach to the management of the eczemas including allergic aspects related to the skin, often using clinics led by specialist nurses.

**Latex allergy:** All dermatologists who deal with contact dermatitis are competent to manage latex allergy and will be called on to do so regularly. In many hospitals the dermatologist is the first port of call for latex allergy. Several dermatologists have written the latex policy for their hospital, with collaboration from other specialties including allergists and immunologists.

**Urticaria and angioedema:** All dermatologists are trained to manage these conditions and, in most hospitals, it is the dermatologist who mostly treats patients with these diseases.

2. Treatment and management: Patients with more than mild skin disease are best seen by a dermatologist since:

(a) **Training:** The dermatologist is trained to diagnose, investigate and treat all types of skin disease including occupational aspects.

(b) **Facilities:** Departments of Dermatology have the facilities and support for the full range of investigation and therapies that are required to treat skin disease.

(c) **Specialist clinics:** Most large Departments of Dermatology have a consultant who specializes in the diagnosis and management of contact allergic conditions related to the skin. They are trained to do more than patch testing. Activities include:
   (i) Patch testing primarily, but also . . .
   (ii) Prick testing, and frequently, the . . .
   (iii) Interpretation of specific IgE tests

In addition, all dermatologists treat atopic eczema and will be familiar with the IgE-mediated problems seen in many patients with this condition. This will be particularly the case for dermatologists who specialise in paediatric dermatology, as IgE-mediated problems can be especially problematic in children.
3. Government policies

**Allergy Networks/Centres:** Dermatologists with an interest in allergic problems in skin disease would be pleased to be members of a network of specialists who treat various allergic diseases. Dermatologists recognise that other specialists may be needed in the management of patients with skin disease that has an allergic basis, eg allergists, immunologists, gastroenterologists and respiratory physicians.

**Current debates on provision:** There is presently much change in the way that services for patients with skin disease are being managed. Generally, the management of more than simple allergic problems related to the skin is a specialist activity that would be difficult to organise in a care-close-to-home setting. For example, the performance and interpretation of patch testing and prick testing requires a lot of training and experience. Hence the management of patients with this type of problem should continue to be based in secondary care.

4. Patients and consumer issues

**Referral pathways:** Dermatologists are best placed to manage patients with more than mild skin disease, with referral to other specialists in allergic problems as necessary. Some patients with atopic eczema who have severe IgE-mediated problems require to see an allergist. It is a matter of ensuring that the right patient gets to the right specialist with the right problem.

24 October 2006

**Examination of Witnesses**

Witnesses: Mrs Margaret Cox, Chief Executive, National Eczema Society, Professor David Gawkrodger, Honorary Treasurer, British Association of Dermatologists, Dr Clive Grattan, Dermatology Consultant, Norfolk & Norwich University Hospital, and Dr Shuaib Nasser, Consultant in Allergy & Asthma, Addenbrooke’s Hospital, examined.

Q583 Chairman: May I thank you for coming today to give evidence to this sub-committee of the Science and Technology Select Committee. The proceedings will be webcast today. I am Lady Finlay and I chair this Committee. All members of the Committee have declared their interests on a separate document, so we will not be going through a declaration of interests in relation to different questions today. I would like to begin by asking you if you would introduce yourselves to the Committee and then we will proceed with our questioning. It would be very helpful if you would speak up because, even though there are microphones, the acoustics in this room are not always the easiest. So, if you could speak clearly, that would be much appreciated. Let us begin with you, Professor Gawkrodger.

Professor Gawkrodger: My name is David Gawkrodger and I am a consultant dermatologist in Sheffield and Honorary Professor of Dermatology. I have been the President of the British Contact Dermatitis Society. I have an interest in contact dermatitis and occupational skin problems. I am also the Treasurer of the British Association of Dermatologists.

Mrs Cox: I am Margaret Cox and I am the Chief Executive of the National Eczema Society, a registered charity which exists to support people who have eczema. I also have eczema myself.

Dr Nasser: I am Shuaib Nasser and I am a consultant allergist in Cambridge and I am a full-time NHS consultant at Addenbrooke’s Hospital. I am also the Chairman of the Standards of Care Committee of the British Society for Allergy and Clinical Immunology. My interest is in all aspects of allergy and asthma.

Dr Grattan: I am Clive Grattan and I am a consultant dermatologist. My base hospital is the Norfolk & Norwich University Hospital where I see allergy and I see general dermatology. I also work one day a week at St John’s Institute of Dermatology at St Thomas’ Hospital as part of the cutaneous allergy group where I am Head of the urticaria clinic.

Q584 Chairman: I wonder if perhaps—and this will be principally for the two dermatologists here—you could describe to us the main forms of allergic dermatological disease.

Professor Gawkrodger: It depends a little on how you define allergy but, taking into account what I think the remit of this inquiry is, I would classify the allergic skin disorders as being atopic dermatitis, contact dermatitis, urticaria and drug eruptions. There are other skin diseases which have an immunological basis but I think they are probably not generally regarded as being allergic.

Dr Nasser: I agree entirely. It is important though to recognise that many patients who present with atopic dermatitis often appear to have endogenous constitutional behaviour to their disease that appears to bear little relationship to allergy and furthermore urticaria, which is my special interest subject, is often an internal problem as opposed to an allergic
problem and whilst allergy may cause urticaria, there are many instances when it does not.

Q585 Chairman: Dr Nasser, do you wish to add anything to that?
Dr Nasser: The only thing that I would like to add is angio-oedema, which is a subset of urticaria, is another skin condition which presents slightly differently and can occur in association with urticaria or in isolation and indeed may result from a drug-related disorder.

Q586 Chairman: Am I correct in thinking that you are the lead person on the urticaria guidelines for the British Society for Allergies?
Dr Nasser: Yes. We have just completed guidelines which are due to be published soon. I should also add that Clive Grattan on my left is the lead person on the urticaria guidelines for the British Association of Dermatology, so there is a little bit of urticaria expertise here.

Q587 Chairman: Are those guidelines being written in parallel and in conjunction to make sure that they are completely compatible?
Dr Nasser: We have certainly had some input from Clive and I know that Clive has written the editorial for the guidelines.

Q588 Baroness Platt of Writtle: May we ask when they are going to be published. Are they going to be published before our report or after?
Dr Nasser: Before, I am sure.

Q589 Chairman: Would you make sure that we have a copy of those as they will be helpful.
Dr Grattan: The British Association of Dermatologists’ guidelines were published in 2001 but a revision is currently under way and will be published soon.

Q590 Chairman: Mrs Cox, in relation to the question about the main forms of allergic dermatological diseases, is there anything that you would like to add?
Mrs Cox: Only one thing, which will I think be a consistent theme for me, and that is that, for the patient, one of the main challenges in this area is in fact knowing what you have.

Q591 Chairman: It has been suggested to us as a committee that there is perhaps less credence given to allergy in relation to urticaria and atopic dermatitis or eczema in this country than happens in other parts of Europe where these patients are principally seen by dermatologists. I wonder if you have any comments on that. Perhaps you would like to begin, Mrs Cox.
Mrs Cox: I do not think that on an evidence base I could say whether it is right or wrong that the UK is more or less inclined to see these diseases in dermatology than allergy, although my personal perception specifically by reference to communications, for example, with my opposite numbers in the US equivalent group is that such is indeed the case. My perception again as far as a patient is concerned is that there is a tendency to get either into one track, be it the allergy track, or into another track, be it the dermatology track, and that possibly in some cases what we are lacking is an overlap in the middle.

Q592 Chairman: Do you feel that there is sufficient credence given by dermatology in the UK to the allergic nature of some skin diseases?
Mrs Cox: I think that it is becoming increasingly accepted by the dermatology community, particularly perhaps those who are working with children in paediatrics, that there are cases where allergy or allergy-related issues are if not the whole story at least part of it.
Chairman: Would you clarify for us the difference between atopic dermatitis, contact dermatitis, atopic eczema, urticaria and angio-oedema.

Q593 Lord Colwyn: And may I ask on top of that, is a differential diagnosis easy or is it difficult? It sounds impossible to me.
Professor Gawkrodger: Usually I would say that it is really quite straightforward to diagnose atopic dermatitis when it presents in children. If a child develops eczema affecting the skin folds of the elbow, behind the knees, on the neck or on the face, it is usually quite obvious that it is atopic dermatitis. It can be a little more difficult in adults who present for the first time with eczema. I think that diagnosing and sorting out dermatitis in adults, say hand dermatitis or facial dermatitis or foot dermatitis, is quite a complicated business and that is where consideration of different allergic-based phenomena may come in because you may need to consider contact allergy in addition to a background of atopy which is a type of endogenous or internal eczema, and other factors as well including external environmental factors.

Q594 Chairman: Dr Grattan, do you wish to add to that?
Dr Grattan: In relationship to urticaria, which has not been covered by Professor Gawkrodger, the diagnosis is often relatively straightforward to the public, the primary care physicians and the specialists, but the exact type of urticaria and therefore its cause and treatment may be elusive and this is where there is a need for a specialist with insight.
Q595 **Lord Rea:** If you look at atopic eczema, is there always a trigger factor or do you suppose that there is one even if you cannot discover it, or does it sometimes come out of the blue for no particular reasons?

**Professor Gawkrodger:** Atopic eczema is one of those conditions which can be very easy to diagnose or quite difficult. There are many, many different things which feed into it and partly there are strong constitutional or genetic factors, so inheritance is often a strong thing. It is associated with other disorders such as asthma or hay fever rhinitis and some people do have a previous history of these things. If somebody develops an eczema in adulthood, they may have a past history of eczema as a child which cleared up and then something comes along, say they develop hand dermatitis, and, in those sort of instances, it would be important to look for some triggering factor which may be occupational, so they may be exposed to some environmental factors that have brought their eczema out and that could be wet work or exposure to a cold or hot climate and there can be other things such as stress and allergy for example contact dermatitis, but there may be some internal factors as well and it is quite well recognised that, for example, in students who are undertaking examinations, their eczema may get worse at the time of their exams because of stress and stress makes them rub their skin which brings out the eczema. Having said that, even despite looking for triggering factors and investigating for allergic problems which may include patch testing and also blood tests for immunoglobulin E levels and specific immunoglobulin E levels, you do not always find the triggering factor in every case.

Q596 **Chairman:** How often do these conditions coexist in patients?

**Professor Gawkrodger:** Do you mean asthma, hay fever and eczema?

Q597 **Chairman:** I was thinking of the different skin manifestations such as urticaria and eczema.

**Professor Gawkrodger:** I think I will let Clive answer the one about urticaria.

**Dr Grattan:** Usually, urticaria is a stand-alone disease but, in children with atopic eczema, it is possible for them to react with urticaria to allergens including foods and maybe animals or plants, so there is overlap. Most patients who present to hospital clinics with chronic urticaria—and this implies continuous disease for at least six weeks—have a stand-alone disease.

Q598 **Chairman:** How often do children with eczema have other manifestations of allergy?

**Dr Grattan:** I will ask Dr Nasser to supplement what I am going to say, if I may. My own experience is that it is quite a small number. I see a number of children with eczema every week and the parents are often concerned that allergy is driving the condition and that allergy is causing specific problems over and above the eczema. I think that the number of times I can confirm that is probably no more than 10 per cent, but that is a personal view and remember that this is a population of patients referred to a dermatologist rather than an allergist.

**Dr Nasser:** The first thing that I would like to say on this issue is that eczema should really be regarded as a symptom rather than a disease with many underlying causes of which allergy is one. So, you can have patients with eczema who are completely non-allergic and do not have any allergenic triggers and others in whom allergy does play an important role, and it is important to try to tease out that group because if you can get them to avoid certain allergenic foods or aeroallergens, then you can improve their symptoms. In terms of overlap, we know that one of the first manifestations of allergic disease (and by that I mean food allergy, asthma and hay fever) is in fact eczema and I regard the surface of the skin as a portal of entry for allergic sensitisation. So, it is not just the forerunner, it is actually an important underlying factor leading to food allergic sensitisation and also asthma and hay fever. So, there is a large overlap and certainly patients presenting to an allergy clinic are much more likely to have these overlap diseases.

Q599 **Lord Taverne:** Coming back to an earlier question regarding how treatment and diagnosis of dermatitis compares with other countries, Mrs Cox said that she had some comparison that she could make with the United States. Can any of you throw any light on how we compare with the continent?

**Professor Gawkrodger:** One problem that we have in the UK is that we have far fewer specialists—that is not just for dermatology; there are far, far fewer specialists in allergy for example—than most of the countries in Europe. Germany has several thousand dermatologists and the same in France and Italy. We only have 500 consultants in dermatology and far fewer consultants in allergy. In Germany, for example, a number of dermatologists have more than one qualification, so they have a qualification in dermatology and they are also qualified in allergy as well. I think that the combination of these two things, the fact that they are more widely qualified in Germany and there are many more of them, perhaps 7,000 dermatologists in Germany compared to just 500 in this country, perhaps means that they are more prone to investigate patients with some eczema and urticaria than the average dermatologist might do in this country. Having said that, I think that it might
also be true to say that British dermatologists might have something to learn from their continental counterparts in perhaps taking a wider interest in IgE-mediated allergy than they presently do.

Q600 Chairman: If I may follow on from that, how adequate are the services to enable allergic triggers to be diagnosed amongst patients? Is there a cohort of patients there who currently are not accessing the appropriate diagnostic services to detect an allergic trigger to their skin diseases?

Dr Nasser: The answer is “yes”. There are very few specialist allergy centres in this country as you will be aware from previous hearings. There are something like six full-time specialist centres dealing with allergic disorders and perhaps only 30 full-time equivalent allergists compared to a couple of thousand in, say, Germany. In terms of being able to access an allergic diagnosis for your eczema, you are actually very unlikely to be able to achieve that and eczema is a very common disorder as are all the other allergic diseases. Food allergy is increasingly common as is hay fever and asthma. It is not just the milder forms, but in fact the more severe forms of these disorders that are seen increasingly. So, it depends where you live whether you can access these services. There are some dermatologists who are interested in both aspects and Clive Grattan is an example. So, there is a considerable overlap but there are many dermatologists who are not able to access allergy services at all.

Q601 Chairman: Mrs Cox, would you like to answer that from the patient perspective.

Mrs Cox: I would agree wholeheartedly that, from the patient perspective, where you live makes a huge difference and that many patients are not able to access an allergy related service for their eczema. I would also add that, in consequence, what is tending to happen, particularly with parents of children with eczema, is that they are guessing around allergy, they are frequently guessing that it is diet and they are tending to embark upon do-it-yourself diet avoidance which in many cases is probably not going to impact upon the eczema but might well impact on the overall well being of the child and meanwhile the eczema itself remains untreated.

Q602 Lord Haskel: May we move on to the environment and ask you what environmental factors contribute to the development and exacerbation of diseases like atopic dermatitis, eczema and urticaria and whether there are any environmental measures that we can take to prevent these disorders developing.

Professor Gawkrodger: That is really quite a complex question. When it comes to the environment, there are a number of interactions between the skin and the environment because the skin is really the first barrier of the body and the immune system, so the skin is actually there to protect you from the environment but it is there to be damaged by the environment as well. If you have any sort of skin disease, then there are certain environmental factors that may make it worse. The exact factors that might worsen almost any sort of skin disease might be different. If you think about atopic eczema and you just consider what external environmental factors might be playing a part, then you have things that are non-specific triggers such as wet work, wind, cold, heat, dryness and other environmental things like that, and you have frictional things which may be rubbing of the skin or rubbing of frictional materials against the skin, and you also have chemical allergy as well, chemicals that come into contact with the skin and which will often aggravate patients’ eczema. I saw a first-year veterinary student yesterday who had to leave her lesson because contact with a horse within minutes aggravate her eczema, so much so that she was unable to stay, and it had happened to her on a number of other occasions. There are many factors that can aggravate eczema. In a proportion of patients inhaled allergens, for example animals and house dustmite, are important allergens. Also, in the environment, I suppose you could add infection. Certainly infection will aggravate eczema and that is something that is often not appreciated especially in primary care.

Dr Grattan: I think it would be worth at this stage making clear that atopic dermatitis and allergic contact dermatitis are completely separate
conditions and the replies you have had to some extent merged those two illnesses together. Atopic dermatitis may have a genetic component that allows people to develop it in addition to asthma and hay fever and there may be environmental triggers and factors as we have heard. Allergic contact dermatitis on the other hand can happen to anybody. I do not believe that there is an underlying genetic predisposition. Also, it depends on the concentration and prolongation of exposure to the chemical allergen whether or not sensitisation and an allergic skin disease develops. I think it is important to separate those two and discuss them separately.

Professor Gawkrodger: I do not entirely agree with you there in that an awful lot of people who will be developing an allergic contact dermatitis actually have an atopic background. I think that you have to look at the patient in the round and, when I conduct my contact dermatitis clinic, I want to know the atopic status of the people I am seeing. In addition, I think that there is a genetic predisposition towards being sensitised to chemicals in terms of allergic contact dermatitis. I think that some people become sensitised and some people do not. There are genetic factors which I would say we do not fully understand that are playing a part.

Q603 Lord Haskel: What measures can we take to prevent these disorders developing? We can just simply avoid food allergens or possibly house dustmites, but there are a number of things which we cannot avoid in the environment such as fragrances, cleaning fluids and this sort of thing. Is there anything we can do to prevent this such as the pre-testing of products and that sort of thing?

Professor Gawkrodger: There is European legislation on this matter and I would refer you to the European legislation on chromate in cement which is particularly important for hand dermatitis in construction workers. The chromate sensitises people and they develop a chronic hand dermatitis, and there is some evidence that reducing the amount of available chromate in cement by adding ferrous sulphate has actually reduced the incidence of that. There is European legislation on the amount of nickel in jewellery and there is some evidence that that has reduced the evidence of nickel allergy which may be associated with certain types of dermatitis. In addition, European legislation on the labelling of fragrances or labelling of the ingredients in cosmetics has come into play and that has been very useful because we can advise patients whom we diagnose as being allergic to certain things to avoid these things. I would share your concern about our wider exposure to things like fragrances and it is particularly worrying in children’s products where children are being exposed now to a lot of fragrances and we do not know what is going to happen in, say, 10 years time. Another area of concern is hair dye. That is a chemical called paraphenylene diamine which is virtually the only chemical which will actually dye hair. It is present in up to six per cent concentration in hair dye and, with the increased frequency of hair dyeing—up to 70 per cent of women and up to 20 per cent of men actually dye their hair—and with younger and younger age groups of people dyeing their hair for fashionable reasons, allergy to hair dye is quite a concern and I think probably warrants further inspection as to whether there are alternatives and whether it is actually safe. On a European-wide basis, certain preservatives which may produce a contact allergy have been banned because they have caused too many problems. I think that legislation can be helpful in limiting contact with problem chemicals.

Q604 Lord Taverne: With the very widespread fashion for hair dyeing, has there been an equivalent increase in the number of allergens?

Professor Gawkrodger: It appears that there have been. I cannot quote you the publication off the top of my head. The problem with paraphenylene diamine is that you can get very severe reactions. You can get severe swelling of your face and neck requiring you to have treatment with systemic prednisolone to get it down. I believe that there has been an increase. I cannot quote you the exact paper but one of the problems is the severity of the reaction.

Q605 Lord Haskel: What about non-clinical things like air conditioning which we are all subjected to? You mentioned that infections were a cause. Can we do anything about the quality of the air or something like that?

Professor Gawkrodger: When it comes to the area of air conditioning, it is difficult to say whether it causes problems with their skin. I do ask people about that and I think that sometimes, if you have a tendency to get dry skin, excessive air conditioning may actually make your skin worse, but it has not actually, as far as I am aware, been very well researched.

Dr Grattan: May I expand a little on the hair dye sensitivity prevalence. There is some information on that and it is contained within a document which I believe has been submitted to this Committee and is therefore before you. I can read it if you wish.

Q606 Chairman: Are you referring to the BMJ editorial with all the references in it?

Dr Grattan: Yes and there is a further document which has been produced by my colleagues I believe at St John’s Institute of Dermatology which contains that information.
Q607 Chairman: Yes, thank you. Dr Gawkrodger: There is one other area of avoidance which has been a success story and that is powdered latex gloves for healthcare workers. It was recognised some years ago that having powder within latex gloves appeared to be linked with the increasing incidence of latex allergy and, since powder has been banned, at least in Germany and I think thoroughly discouraged in the UK, the incidence of latex allergy is falling. The investigation into latex allergy does also illustrate the overlap between allergic contact dermatitis and urticaria which Professor Gawkrodger was talking about and I separated them out for simplicity only but, as an example, someone who reacts to a rubber glove may react to the natural latex protein with an allergic mechanism which is Type I and relates to eczema, asthma and hay fever, or to the chemicals used to cure the rubber and then that would be the Type IV mechanism which would be diagnosed by patch testing, so there is an overlap of dynamics for the treatment of patients and their condition.

Q608 Chairman: Mrs Cox, would you like to come in at this point? Mrs Cox: Looking at this in an overarching way, I suggest that there is a tendency for us to hugely underestimate the importance of our skin as our barrier to the outside world and a need for people to have a better understanding of the need to protect their skin and, to the extent possible, not to go into total avoidance of everything but to be sensible about what they put on their skin and perhaps, more importantly, their children’s skin and not to be tempted into thinking that everything which is promoted as being “good for your skin” and “good for your baby” is actually good for either.

Q609 Lord Colwyn: Some of us went to Germany to take some evidence—unfortunately I had to miss the trip—and there we saw the dermatologists do what is described as an allergy work-up for atopic dermatitis and urticaria. Can you tell us whether all dermatologists do this in the UK and, if they do not, why do they not? Professor Gawkrodger: I am not sure what the work-up was. Are you able to say what it was?

Q610 Chairman: We heard from the allergy clinic there that they go through an exclusion process actively looking for allergens. Professor Gawkrodger: I think that is probably not common practice in the UK. Certainly in my department and with my colleagues, I think when it comes to somebody with, say, atopic dermatitis, we will take a history and I think that the history is the key thing. We will ask whether there are any triggering factors and I ask people if they think that there are any foods involved. It depends a little on the severity of the eczema. If it is somebody with mild eczema that can be easily controlled, I think that we will not probe too deeply. If it is somebody with more severe eczema, we will certainly look for whether there may be a contact dermatitis complicating the picture, in which case patch testing would be part of the work-up and, in my department, we do actually patch test people with atopic eczema to aeroallergens. I certainly would take blood investigations for immunoglobulin E and I might actually look for some food allergies if the patient had given a very strong history of food allergy. I think I might be going beyond what the average dermatologist would do there because I have a particular interest in allergy and the skin. As to why British dermatologists do not do such a major work-up—and I would agree that they do not in most cases—I think that perhaps part of the answer is pressure of work with there being only 500 dermatologists and another aspect is also availability to undertake allergic investigations particularly for prick-testing which is quite a time consuming investigation—that is where you prick in the allergens into the arm—but maybe also that there is a trend for British dermatologists not to regard an allergic input into the dermatitis in the same way as people do in perhaps Germany in most cases.

Q611 Lord Colwyn: How is it in Norwich? Dr Gawkrodger: I also have an interest in skin allergy and I think that one of the limiting factors that I experience and many of my colleagues experience is offering patients sufficient time. Certainly, a full consultation may take at least 30 minutes and for more sophisticated allergy problems 45 minutes. The structure of clinics often precludes allowing that amount of time, and from history flows the investigations and I would direct at problems that I identify from the history as opposed to giving a battery of tests to everyone. Mrs Cox: Could I add that what we are hearing here is experience in relation to secondary care and in fact hugely the majority of patients with atopic eczema will be seen in primary care and, in that environment, very few, if any, will have any allergy issues investigated at all and fairly obviously time is a huge factor. Chairman: We have spent quite a lot of time on this first bit of questioning and we now need to speed up. I will now move to Lord Taverne and ask you to keep your answers concise and we will be able to move through all the other questions that we have.
Q612 Lord Taverne: How many people in the United Kingdom currently suffer from atopic dermatitis, atopic eczema and urticaria and how has the incidence of these diseases changed over recent years?

**Professor Gawkrodger:** With regard to atopic dermatitis, at the present time, about 20 per cent of the children have atopic eczema and that is an increase compared to about 50 years ago we suspect, although really good studies previously were not actually done. Of those children, I would say that approximately 50 per cent will grow out of it in their teens which leaves you with 10 per cent of adults who will have atopic eczema to a greater or lesser extent, and it may be very mild in terms of just some dryness of the skin or it may be very severe, it varies. I will let someone else answer about urticaria.

**Dr Grattan:** Dealing with atopic eczema, there are some studies that show a threefold increase in the last 20 years or so and there is a Welsh study which in 1973 showed a five per cent incidence of atopic eczema amongst 12-year olds and by 1988 that had gone up to 16 per cent. There are other international studies and there is a very good study, the ISAAC, the International Study of Allergy and Asthma in Childhood, which looked at both cohorts, and they found a 22 per cent prevalence of atopic eczema. So, we know that these diseases have increased enormously in the last 15 to 20 years and I would certainly go along with the fact that many of these patients do not have resolution or they do not grow out of their symptoms into adulthood although the severity of the condition may have improved.

**Dr Grattan:** The prevalence of urticaria is effectively unknown because there are no good studies that looked at this. Estimates range from as high as 30 per cent of the population of a country being affected by one form of urticaria or another over their lifetime to as low as one per cent, and good data are needed. I cannot tell you if the incidence has gone up. It may have but I do not know.

Q613 Lord Taverne: Who records the number of people suffering from these diseases?

**Professor Gawkrodger:** Nobody records them officially. Any sort of study is a research investigation.

Q614 Lord Taverne: The Department of Health said that there are currently problems regarding the data collection of allergic diseases and they hoped that the introduction of a new nomenclature system, which they elegantly describe with an acronym called SNOMED, would enable allergy to be classified more specifically when clinicians enter data on to patient records. Do you think SNOMED will enable the prevalence of allergic skin diseases to be more accurately recorded?

**Dr Nasser:** Maybe I can talk a little about that. I have certainly come across SNOMED but it is at an embryonic stage so it is not yet being used. The principle is that every allergy patient has a diagnosis recorded, but it is important that the correct diagnoses are placed into the system in the first place which can only happen if the doctor is appropriately trained in allergy.

Q615 Lord Colwyn: May we move on to some of the treatments now. Can you give any common treatments such as antihistamines and corticosteroids that are used and say whether you think these actually cure anybody.

**Professor Gawkrodger:** With regard to atopic dermatitis, the treatment will depend on the severity of the condition and also where you are seen. If you are seen in general practice with mild eczema, I think that first of all you would be offered moisturiser emollient which is a cream which can help to treat the dryness of the skin which is one of the primary symptoms along with itching and also emollient for the bath or for showering with. If it were more than just mild eczema and non-responsive to an emollient, then the plan would be to move on to a topical steroid of which there are different strengths from mild to moderately potent to highly potent and it is usual to start with a mild one such as hydrocortisone and move on to a stronger one if necessary. Any infection that is present, which is not an uncommon thing, should be treated as well. If the patient does not respond at that stage, the usual thing is to refer on to secondary care and there they may try a stronger topical steroid for a longer period of time, perhaps considering other things that might be involved and that is where considering other allergic problems might come in. There are other topical treatments apart from topical steroids and these are called calcineurin inhibitors, and they do not have the same side effects as topical steroids, things like tacrolimus. If people do not respond at that stage, probably another thing that happens is that the team will look at the compliance of the patient, so is the patient applying his/her cream properly, and it is very important to look at that. This is a common reason why patients do not get better and it is where nurse practitioners are useful at improving patient care. If these topical treatments do not work, then it is on to systemic therapy which is quite a big step because you are on to quite potent immunosuppressive drugs which can have quite serious side effects but which can be very helpful for people with the very most severe types of eczema.

**Mrs Cox:** Clearly, I would not disagree with that but again I would like to remind everyone that in fact most eczema patients are seen in primary care. Certainly in my experience referral out of primary
care into secondary care can be very hard to achieve. I do agree that compliance with topical treatments is not always too good but there are several reasons for that, one of which may well be, particularly in the primary care environment, that nobody has really had the time or possibly the expertise to show the patient or the parent how to apply them in the first place.

Q616 Lord Colwyn: Are there many patients who do not respond to these treatments? Are you able to give a rough percentage? I know that it is difficult because there are varying degrees of the illness. Professor Gawkrodger: I could not give you a figure but I would say that, in all of our clinics as consultant dermatologists, one of the most regular things we see is people on systemic treatment for their eczema, so there is a quite a lot of them, but I cannot say exactly what proportion of people with eczema as a whole have to have systemic treatment. It is certainly a minority.

Q617 Lord Colwyn: Can you say something about allergen immunotherapy. Professor Gawkrodger: I cannot myself.

Q618 Lord Colwyn: Can it be used to treat atopic dermatitis or urticaria? Dr Nasser: That brings us on to curing the condition and that is really what your question is aimed at. We have heard about lots of pharmacotherapy and the question that arises is, are there any allergens first of all that you can avoid which may improve symptoms and other than irritants, are there any chemicals that you can avoid as this aspect of the management is also very, very important? One of the things that patients eventually come to realise is that, when the eczema is severe, it is very difficult to improve, but, when it is good, it is easy to maintain its status. So, it is important that patients understand that. One of the things that we try to do as allergists is to identify underlying causes in the proportion of patients who have an allergic cause, and these may be aeroallergens or food. Certainly that can lead to a reduction in the pharmacotherapy, some of which have very severe side effects. You asked a question earlier about the difference in management in different countries and the simple answer to that question is that there is no education in English or British medical schools on allergy, so there is no curriculum on allergy and that is why our general practitioners have very little understanding of the subject, and I think this is a very important point. Immunotherapy is not effective in eczema on the whole. I know that people have tried immunotherapy for eczema but, as far as I am aware, the results have not been terribly good, unlike for rhinitis or for some studies in asthma.

Q619 Baroness Platt of Writtle: What you said just now about no curriculum position for training doctors was very interesting, but is that perhaps one of the most important things that ought to happen? Dr Nasser: The most important thing. I am glad you picked it up. It is probably the most important thing that should come out of the Committee’s findings.

Q620 Lord Colwyn: Do the treatments vary with children and how does the school environment deal with this? Mrs Cox: In the school environment, as so often happens, truthfully it is hugely variable. Issues that are commonly experienced by children with eczema in school tend I think to stem from a failure to take eczema terribly seriously combined with the fact that it requires frequent topical treatment which of course can be very difficult to achieve particularly at the younger age.

Q621 Lord Rea: I wonder if you could deal a little more with the training of general practitioners. How do you think this training could be improved either as undergraduates or perhaps as postgraduates? In primary care, what proportion of patients is referred to specialists in allergy or dermatologists and which? Dr Nasser: The first thing I would say is that, if you look at the curriculum for most undergraduates, there is hardly any teaching on allergy and there is certainly no structured teaching. It may be given as part of an asthma lecture, for example on one slide, but there is certainly no structured teaching in allergy and there are so many other demands on the curriculum at the moment in terms of communication skills etc that some important aspects of the curriculum do not actually make it into training. Unless that is remedied, we are not going to get general practitioners who understand anything about allergy at all. The second aspect of the question I think is the postgraduate training and, because there are so few allergy specialists in the country, there is no one to undertake teaching. Certainly in our area in the eastern region, we undertake quite a lot of teaching and I suspect that our general practitioners are better educated than in any other parts of the country, but that is something that cannot be rectified unless there are centres with allergy specialists. What was the last part of your question?

Q622 Lord Rea: The question of whether to refer to dermatologists or allergists if somebody has atopic dermatitis and urticaria.
Dr Nasser: I would say that only a very small proportion of patients get referred. There are increasing pressures in primary care not to refer patients into secondary care and these are pressures that have come on in the past six to 12 months because of cost, and because of the great debt that PCTs find themselves in. My wife is a general practitioner, so I can talk about this subject—and certainly there are internal pressures to refer as few patients as possible to hospital.

Q623 Lord Rea: As a former GP, my problem was that there were difficulties in referring people to allergists because there was a very long waiting list, six months or more, and it was easier to refer to a dermatologist something which perhaps appropriately should have gone to an allergist.

Dr Nasser: I am sure that is right. The waiting lists are coming down but, unless you have an allergist in your locality, you cannot refer patients.

Q624 Earl of Selborne: I want to come in on this rather familiar story but a very depressing story that Dr Nasser was spelling out that patients see GPs and indeed nurses, dieticians and the people at the frontline, the people to whom most patients are referred, and do not go much further and yet, as you point out, the knowledge of GPs and indeed others is really very poor. Addressing the curriculum at undergraduate level is not going to solve the problem, is it, or not for a generation or two? Would you have any radical thoughts as to how this great omission could be addressed? What structure would you like to see put in place to allow GPs, nurses, dieticians and other people like that to get a grasp of these issues?

Dr Nasser: I would say two things. The first is that we have to look long term and sort out the problem from the beginning, so that has to be thought of as an important aspect of introducing allergy training into the undergraduate curriculum. So, we must think long term. In the shorter term, I think what can be done is that we must educate our primary care physicians and the way in which you do that is by conventional means but, unless you have a local allergist, you cannot do it. So, the best short-term solution to that would be to increase the number of trainee physicians in allergy in order to create more centres that are able to deliver teaching. There are large parts of the country that will have very little exposure to an allergy clinic. So, in the short term—and by that I mean four or five years—you can achieve that simply by increasing the number of trainees but, in the longer term, I think it is essential that allergy, which is one of the most frequently encountered illnesses in general practice, is entered into the undergraduate curriculum.

Q625 Earl of Selborne: If you are going to increase the provision of training to GPs and others, does that imply that you have specialist clinics or does it imply a peripatetic training which goes round to the GP practices?

Dr Nasser: I think a bit of both. I would be supportive of both things. There is so little knowledge in primary care that we should do both.

Q626 Lord Taverne: Since we have a shortage of teachers who can train, is this a case where we should import the expertise from abroad, if we can get it?

Dr Nasser: I would not be a fan of that. I think that we should develop the expertise within our own trainees. Certainly it could be a short-term measure but again we have to think long term about this.

Q627 Chairman: Is there an adequate use of modern education methods such as e-learning and distance learning in the subject?

Dr Nasser: Yes and I am sure that that is something that could be employed. The question is, how effective would that be simply because I think that the most effective training is from seeing patients and, unless it is ingrained from the very beginning that allergy is an important aspect of many disorders, for example asthma and atopic dermatitis, then it is unlikely to succeed. E-learning is certainly taking off. I do not know how effective it is.

Q628 Chairman: Do any of the dermatologists want to comment on the effectiveness of e-learning?

Dr Grattan: I would be happy to comment but may I steer the discussion back a little to the education of GPs in dermatology. Although dermatology is on the undergraduate curriculum, it is often allocated a relatively short period of time and there is no compulsory postgraduate training of general practitioners in dermatology that I am aware of. However, they do get education on rotational training schemes when dermatology is included as a specialty. My own experience is that they find this extremely valuable. This might be a way forward with allergy if allergy were to be included on GP vocational training schemes where that expertise is available.46

Chairman: Would you like to comment on that, Mrs Cox?

Mrs Cox: I believe that there is some limited availability of postgraduate training in dermatology but I would agree with the overall point, namely that, on the whole, when you go to see your GP with atopic

46 Most departments of dermatology in the UK offer programmes of postgraduate education for General Practitioners for the purpose of CME (continuing medical education) credits but only some GP’s will have the opportunity of a formal training in Dermatology as an element of their Vocational Training and this should be encouraged.
eczema, you will be extraordinarily lucky if your GP has had any significant training in dermatology and even luckier still if that training is anything remotely recent.

Q629 Baroness Platt of Writtle: I am just thinking at what level the people who do the training would need to have a qualification. I understand that GPs are having CPD, it is part of their on-going qualification; could the allergy skills be included there? How do we train the trainers?

Professor Gatekrodger: I think when it comes to training GPs and specialist registrars, all consultants are trainers so there is no problem; any consultant has to train a registrar and can train GPs.

Q630 Baroness Platt of Writtle: But there is a shortage of them?

Professor Gatekrodger: I think perhaps one of the points that could be made there is that there is not enough attention given to time set aside for training in consultants’ job plans because consultants’ job plans have now been squeezed and squeezed to reduce the amount of time there for training people—and for research, I might add—and to increase the proportion of the time spent in clinics and seeing patients, which is where the target-driven ethos that now pervades the NHS comes into play. I would like to just support the views of my colleagues here in saying that GPs need far more training in dermatology and allergy than they currently get, and there is no doubt the best way of getting that experience is for specific training posts for general practitioners to include an element of dermatology and allergy within the training.

Q631 Lord Colwyn: Do you think the GMC might ever make it compulsory as part of CPD to do certain aspects of medicine?

Professor Gatekrodger: Training is regulated by something called PMETB—the Postgraduate Medical Education and Training Board—and the exact components of training are determined by that with influence from the Royal College of General Practitioners.

Chairman: I want to move on with some of our questions now. Lady Platt?

Q632 Baroness Platt of Writtle: Patients suffering from latex allergy often experience difficulty in obtaining medical care due to the contact with latex-containing articles such as gloves or vial stoppers. What information is available to these patients when they enter hospitals, health clinics—and I had better add or GPs’—and how could awareness of the potential risks be improved?

Dr Nasser: Well, latex allergy is actually one of the success stories and it is an example of where Government and Department of Health intervention has actually improved matters. In Cambridge we have had a written hospital latex policy with patient leaflets for at least six or seven years and we have seen a decline in the number of referrals of patients who are essentially health care workers, but also people in other industries, and the number of referrals has come down considerably. The main reason for this is the written policy and also the fact that we got rid of powdered gloves many years ago. Up until recently the National Patient Safety Agency identified that up to 40 per cent of health care institutions did not have a written latex policy and they have now made it compulsory for every health care organisation to have a written policy, which I think had to be done within the last few months. I am sure that this will further reduce the number of people with latex sensitisation.

Q633 Lord Selborne: I wanted to ask about occupational diseases. Could you tell us what proportion of patients suffering from skin allergies have developed their disorder due to conditions at work? Perhaps you could tell us what occupations are most commonly affected by allergic dermatological conditions and what could be done in the workplace to prevent the development of these disorders?

Professor Gatekrodger: Firstly, with regard to the proportion of patients that have developed their skin allergy from occupation, it is not known. The number of patients who have occupational skin disease, which is almost all dermatitis, is just over 100,000 per year by an estimate from the EPIDERM Unit at Manchester University. Of those, up to 50 per cent will have a contact allergy as part of their problem. That is about the best figure I can put on it. The commonest occupations to figure there—and I think it is best to look at the proportion per occupation—one of the highest ones is hairdressers. Hairdressers are a particular problem because they have very poor access to occupational health services and they work in very small firms and the message about good hand care, avoidance of allergens (of which there are several in the hairdressing industry) and also sensible glove use does not get through as well as it should. Of the other industries, the ones that appear in the top five include the chemical and petroleum industry, the construction industry, health care workers and people working in agriculture. As regards what can be done to prevent it, I think there are a number of things and some are legislative, as I mentioned before, for example the limiting of chromate in cement is an important thing, and getting the message through about being careful when handling toxic chemicals because very commonly people handle
chemicals in an inappropriate way and they do not wear the appropriate personal care equipment, and better education of the workforce can go a long way to improving matters there. Also I would agree that there should be the proper use of the correct type of gloves. Perhaps also people who may be inclined to develop eczema, perhaps people with an atopic eczema past history should not go into certain occupations where they are likely to develop problems, for example hairdressing, which has got a lot of wet work involved in it, tends to make people with a past history of atopic eczema develop severe hand dermatitis which then means they have to leave the job.

Q634 Lord Selborne: It is interesting, is it not, to reflect that where you have got a large, structured organisation such as the hospitals you get the success stories which we have just heard about with the latex, and then you refer to the small businesses of hairdressers or farmers, where presumably it is much harder to impart this information. Do you think that there are any other success stories? Is for example the National Hairdresser Day which we have heard about likely to impact on this problem, do you think? Professor Gawkrodger: I get the impression that the hairdressing industry is taking the message on board about better hand care and more sensible use. They are a very difficult group to reach, but I think the Health and Safety Executive have got a project on this in mind and I hope that it will make a difference.

Q635 Lord Rea: We have heard about the Centre for Occupational and Environmental Health at the University of Manchester which records the incidence of occupational dermatological diseases as part of the OPRA and EPIDERM projects. Would you perhaps spell out what those acronyms stand for? I gather these projects have been criticised because you perhaps spell out what those acronyms stand for? Professor Gawkrodger: The OPRA scheme is the reporting scheme for occupational physicians and the EPIDERM scheme is the reporting scheme for dermatologists. Yes, the problem about these schemes, as you mention, is that they are selected reporting. In both schemes there is a core group of reporters who report every single case of occupational skin disease that they see, but then also there is a sampling group who only report for one month every year, so the figure of the number of people who have an occupational problem is a figure that has been produced by multiplying a number of other figures, and so it is an estimate not a firm figure. Another problem with the scheme is that it both under-estimates and over-estimates. It under-estimates because there is general under-reporting and under-recognition of occupational skin problems, but it can also over-estimate the importance of an allergen because you only have to have suspicion that it might be involved to report it, and it does not need to be verified by somebody who knows the answer. I think the biggest problem about the gross under-reporting of occupational dermatitis is the problem that general practitioners cannot recognise properly, because they are not educated sufficiently, when occupation is playing a role in somebody’s skin problem. It is not recognised enough. What you can do about it is a very difficult thing to answer. I think the best way of getting a really pure answer to it—and it is really a research question—is to take a defined population out there in the community and look at it in great detail by people who can truly recognise and investigate for an occupational skin problem and then somehow translate the results you get on a national basis, but that has got problems as well.

Q636 Lord Rea: There is a problem in distinguishing objectively whether allergic disease has an occupational origin or not. I believe that the Health and Safety Executive has suggested that there should be standardised criteria introduced which might help measure the trends in these diseases.

Professor Gawkrodger: Yes, at the moment the way we say whether we think somebody who is exposed to a certain chemical whether that chemical is an occupational chemical or not, is once you have shown on patch-testing that they are allergic to it, once you have demonstrated the allergy, then we say are they exposed to it, and if they are exposed to it we more or less say, well, in that case we think it is playing a part. I agree that a better definition of the situation would be helpful.

Q637 Lord Taverne: Can all dermatologists adequately treat patients suffering from a disorder with an occupational cause or is there a need for a small number of subspecialists?

Professor Gawkrodger: All dermatologists are trained in contact dermatitis and that will include some training in occupational skin problems, so if it is a relatively straightforward occupational skin problem, such as somebody is allergic to rubber chemicals in rubber gloves or latex or to chromate, then it should be within the capability of the average dermatologist. If it is a rather more complex case, then it may not be and it may require somebody who is specifically trained and has specific expertise in occupational skin disease, of which there are a number of people in the major centres, so I think if you take the major centres in the UK, the big cities
with the large departments, you will find one person there or sometimes more than one person who does take a specific interest but you are then only talking about 20 or so individuals. I personally do favour that because the subject of occupational skin disease is becoming more and more complicated and I think it would be the best way forward.

**Dr Grattan**: I would support everything that I have heard and I think that specialist groups who have particular experience in occupational dermatology and patch-testing should be promoted and encouraged. The subject of dermatology is becoming more diverse. Skin cancers are becoming more common. Practitioners are being asked to do more things than ever before and there is a future risk of training skills in, say, patch-testing and occupational dermatology becoming diluted by the requirement to do other aspects of dermatology, so even having centrally funded posts that recognised the importance of this would be helpful.

**Q638 Lord Taverne**: In the case of occupational asthma, a Group of Occupational Respiratory Disease Specialists (GORDS) convened regularly by the Health and Safety Executive aims to develop a standard of care document for diagnosis. Would it be useful to have a similar document circulated for dermatitis?

**Professor Gawkrodger**: I am not aware of the document on asthma, but I certainly would agree that better definition of the problem and greater awareness would be helpful.

**Q639 Lord Taverne**: Dr Nassar is perhaps aware of the GORDS approach?

**Dr Nassar**: I am and like with any written guidelines it is always helpful to have a set of standards because you can then compare the incidence of a particular disease from one year to the next knowing that you have used the same set of standards, otherwise you have many practitioners up and down the country using perhaps different standards so I guess that would be helpful.

**Q640 Lord Selborne**: I was going to ask about research and we have already heard as an aside that research and training have been squeezed by cost-cutting. Could you tell us what research is currently being carried out into atopic dermatitis, eczema and urticaria in the United Kingdom and who carries it out? Is it declining?

**Professor Gawkrodger**: The major funder of skin research in the UK is the British Skin Foundation. I did check with them last week and over the last nine years or so they have funded 139 projects of which 12 were on atopic eczema and 10 were on dermatitis. When it comes to funding I could not see any that were funded on urticaria. When it comes to the major funders like the MRC or the Wellcome I am not aware at the present time, although I have not checked with them specifically, that they are funding any research on atopic eczema or other aspects of dermatitis. I do feel that it is an under-researched area. One problem that we have in dermatology is that funding for research in dermatology comes quite a long way down the pecking order in comparison with funding for cancer and cardiovascular disease, for example, and there has been erosion of the university bases. University departments of dermatology have been merged into larger departments and in some cases the departments have actually closed. The two major departments in Liverpool and Glasgow have actually closed over the last 10 years, so academic dermatology has been under a big threat generally.

**Q641 Lord Selborne**: Do you think that there is adequate international collaboration on the research?

**Professor Gawkrodger**: Certainly major research groups do look to collaborate internationally, particularly within Europe. I think that generally speaking there is insufficient research on the subject of eczema and atopic dermatitis, even at an international level.

**Dr Grattan**: The situation with urticaria is even worse than you have heard for atopic dermatitis. There is little active research in the UK and internationally less attention is paid to urticaria than other diseases of similar prevalence. This does have consequences for me as a clinician advising patients who come to me often from all over the country to the tertiary referral clinic at St Thomas’. They want to know why and they want to know what to do and I often have to respond by my instincts and my experience but not by written evidence, so I often have to treat patients with unlicensed remedies that have not been fully evaluated. There is a major need for better research and recognition of the importance of this subject.

**Q642 Chairman**: Is that because there is nobody interested in taking the lead or is it because there are people who are interested in applying for funding but just not getting the funding?

**Dr Grattan**: I think it is probably lack of interest in people taking the lead as a whole. We have many pressures on us to accomplish service work and I think that funding is perhaps an issue. I can give you my personal experience very briefly that I have now an allergist from abroad who is working with me and will be for three years, doing what I hope will be a very useful and enlightening series of projects, but she is funding herself to come and work with me and I
have to give my time outside my service commitment to support her.\textsuperscript{47}

\textbf{Q643 Chairman:} Mrs Cox, do you want to comment?
\textit{Mrs Cox:} Really I agree with everything I have heard. From my perspective, the National Eczema Society, along with several other of the patient support groups in dermatology also seek to fund medical research. One of the challenges that we are finding, in addition to the obvious one that we too find it hard to raise funds, is that in fact it can be increasingly difficult to find appropriate projects and centres to fund, so I think we have a chicken and an egg.

\textbf{Chairman:} Thank you.

\textbf{Q644 Lord Colwyn:} Do you think that the allergy specialism is an unattractive career pathway for undergraduates, leading to postgraduate study?
\textit{Dr Nasser:} I think for undergraduates whenever I have taught allergy in Cambridge it has always been very well received and with great interest. For postgraduates there are so few training positions that it is difficult to answer the question, but certainly when we advertised for a trainee specialist registrar we had lots of applicants, but there are so few training positions available. I do not think it is necessarily an unattractive proposition but I think it is important there are jobs they can go into once they are trained. So that is the way to make it more attractive.

\textbf{Q645 Chairman:} I just want to finish up with two questions which are quite unrelated. The first one relates to cosmetics where the label “hypoallergenic” is often attached to cosmetics, bed linen, all kinds of items. I just wonder if you have any comments about what it actually means, and whether it is meaningful?
\textit{Dr Nasser:} I will start with that. I do not know anything about cosmetics but I understand that hypoallergenic simply means “less likely to cause an allergic reaction”. With that I will pass over to colleagues.

\textit{Professor Gawkrodger:} I think it is meaningless basically. There is no regulation of the term “hypoallergenic”. What may have happened if it says “dermatologist tested” or something of that sort is that in one of a small number of testing centres in the UK a dermatologist in conjunction with a testing organisation has actually patch-tested a number of individuals with different skin types, including people who say they have got sensitive skin (which is a sort of syndrome where people say their skin reacts easily to chemicals, it does not necessarily imply allergy), and people with this sensitive skin have not reacted in a very high proportion to the tested product and that is what it really means when it says “dermatologist tested”. I look at a lot of these preparations and what is in them when it says “hypoallergenic” and I see a whole list of things which I know can cause allergy, so I am rather cynical about the label of “hypoallergenic”.

\textbf{Q646 Chairman:} Mrs Cox?
\textit{Mrs Cox:} My personal view is that both the term “hypoallergenic” and “dermatologically tested” for somebody who has an allergic skin disease are hugely misleading, and I can tell you from personal experience that you can put either on atopic skin and react massively.

\textbf{Q647 Chairman:} My final question to you goes back to education—and I have to redeclare an interest which I have already declared—at Cardiff University where the distance learning course is educating over 400 GPs every year and those GPs are in the Royal College of General Practitioners’ Special Interest Group, forming the GPSIs (GPs with a special interest) across the country. In five years there will be more than a further 2,000 of these. Do you have any comment as to how these GPs, whose education has been evaluated, are being received by the dermatology community, given that the Royal College of GPs has certainly embraced their development?

\textit{Professor Gawkrodger:} This is a major medical and political question at the present time and one of the driving factors for it is the wish of the Department of Health to see more dermatology and other specialties delivered closer to the patient’s home. The actual regulations for being a GP with a special interest are being defined at the moment by the Royal College of General Practitioners and other organisations and so there will be certain criteria that these doctors will need to fulfil to take on that role. As regards the view of the British Association of Dermatologists, we are not against the idea per se. I think we recognise that not all dermatology can be delivered by dermatologists, there just are not enough, so some care has got to be delivered by GPs with a special interest. Most skin care at the moment, as you know, is done by general practitioners not by dermatologists. What we are concerned to ensure is that the GPSIs are actually integrated into the local schemes so they actually work with secondary care doctors and are not a separate organisation. As long as they are integrated with the secondary care so that people in secondary care know what they are doing.

\textsuperscript{47} The apparent lack of interest in research into urticaria is due to many factors, including the diversity of presentation of the disease, the relatively small number of doctors with a special interest in it, the time pressures on clinical posts that prioritise service work, training and clinical governance, the lengthy approval process for research projects through ethics and research committees and the current lack of new treatments for urticaria under development by the pharmaceutical industry.
know their capabilities and they know what can be offered in a hospital environment, then that should safeguard the patient to receive good-quality care because it is the quality of care that the patient gets that is the key theme to this. The patient must not be disadvantaged by being seen by a GPSI compared to being seen by a consultant, and if the patient requires to be referred on to another specialist or to see a consultant dermatologist then they have got to have that available to them. So long as these safeguards are in place then the British Association of Dermatologists is happy to support the scheme.

Mrs Cox: A couple of points. The first is clearly I welcome the fact that there are GPs who are receiving additional training in dermatology through the distance learning courses. However, I do have from a patient’s perspective some concerns around the way patient services are already being delivered in a lot of places across the country in that while there are of course some excellent GPSIs, as things currently stand, there are also people fulfilling that role with very limited education or requirement for CPD. I have yet to hear a patient say that they would prefer to have a lower quality of care closer to their home. I think on balance what a patient would like to have is an appropriate level of care. I am not at all convinced that that is currently what they are getting. I am genuinely worried that if we destabilise secondary care in dermatology any further that is what they are bound to get because we will then go back to the position where there is nobody to train people in the future.

Q648 Chairman: Do you want to add anything, Dr Grattan?
Dr Grattan: Little; I think it has been well said. I would just observe that distance learning courses will produce a qualification and a certificate but that does not necessarily translate into clinical care that has been supervised and audited, and that is the second part of the education.48

Chairman: Can I thank you for coming today. If there is additional information that you would like to give to us as a Committee, then please feel able to send that in. Your comments have been very helpful and you will be sent a transcript from today’s proceedings. Thank you.

48 The training and supervision of GP’s with a special interest in Dermatology in Secondary Care is a requirement for achieving and maintaining acceptable standards of practice. Whilst an expanded base of practitioners competent to deal with dermatology problems in the community should be in the interests of patients it is essential that Primary Care Trusts and Practice Based Commissioners do not fund GPSI posts in Dermatology and Independent Treatment Centres at the expense of Dermatology specialists in Secondary Care. These posts should be expanded rather than reduced to meet the wide needs of patients with skin disease, including allergy.
Memorandum by Professor Jonathan O’B Hourihane, Professor of Paediatrics and Child Health, University College Cork, Ireland

Nearly half of the population are now vulnerable to developing allergic conditions, including food allergy. Allergic conditions are usually chronic and low intensity but have a significant impact on quality of life of both the patient and their families, whose lifestyle may often be very restricted. The prospects of unexpected allergic catastrophe or anaphylactic death are real issues for many families and should not be underestimated. Similarly the seasonality and short duration of high intensity symptoms may not be elicited by a casual medical enquiry. Many modalities of treatment that are still common are very outdated and put sufferers at significant risk of side effects, when modern, safe treatments are more effective but not widely available.

Food allergy is widely thought of as merely an early step on the “Allergic March”, where eczema and food allergy merely precede rhinitis and asthma. This is to underestimate food allergy’s critical impact on health and quality of life of affected children and its potential to cause fatalities, usually in older children and adolescents. However there are few or no known lifestyle factors that are uniquely associated with food allergy and it must be considered therefore in the context of known or suggested risks for allergic diseases. Biparental atopy is now common and appears to be a strong predictor of allergic disease in offspring. Allergen avoidance while pregnant is not effective. Being first born is linked with higher allergy rates. Housing conditions/location and parental occupation are also influential eg lower allergy rates in farming families in Germany. The role of mode of delivery (vaginal delivery or caesarean section) is controversial. Changing weaning practices and the impression that organic or exotic fresh food is better for children than traditional staple foods may be linked to the appearance of allergies to foods that would have appeared bizarre to previous generations.

Memorandum by Dr Mark Rosenthal, Consultant Respiratory Paediatrician, Royal Brompton Hospital

There is an increasing demand from the public for allergy services. This has stemmed from partly a modest true increase which may be stabilising (Thorax, 2007; 62: 91–6), the comparatively recent recognition that certain infant symptoms may be manifestations of allergy, a greatly increased public awareness, and all fuelled by the rare but well publicised deaths from food allergy. This has been compounded by a large amount of lay literature much of which is non-evidence based. There is a large body of scientific data and clinical trials testifying to the value of, for example, desensitization for hayfever and venom allergy. However, there are a large number of “complementary” medicine services from the clinic to the high street advertising allergy testing services almost all of which are unproven; examples being hair testing and passing magnets over the body. These represent a danger to the public—for example, we have seen children lose weight as a result of completely unnecessary exclusion diets. There is also the danger which I have seen manifest in otherwise sensible consultant clinicians that almost any symptom in a child can have an allergic dimension placed on it.

Allergy is following a well known pattern of medical inventions. Having been comparatively ignored in the past and under-diagnosed, under-researched and indeed under-funded, there is now tremendous (over)-enthusiasm, possible over diagnosis and a surge in interest and funding. In a few years the pendulum will swing back to an extent so that allergy takes its rightful important but not cuckoo like place in the spectrum of childhood disease.

Disentangling the true facts from misinformation and hype is naturally problematic. Allergy suffers from a lack of detailed understanding; for example why do 95 per cent + of milk (and egg) allergic children grow out of their allergy whilst only 15 per cent of peanut allergic children do so; and why do the overwhelming majority of children not have food allergy? Apart from tree/grass hayfever and bee/wasp venom allergy desensitisation, the rest can only be prevented and managed given the current state of medical knowledge. Does infant avoidance of risk foods especially peanuts reduce or increase food allergy later is the subject of a large study at its earliest stage. There is no formalised allergy training programme for doctors in the UK certainly in
paediatrics and perhaps it should have greater prominence. Is the tremendous increase in prescriptions for adrenaline injection devices (1/80 children in Manitoba, Canada carry one) serving children well and protecting them or merely leading to social difficulties and greater family anxiety. Out of countless prescriptions I have written over the last 12 years for such devices only one has ever been used.

This committee has assuredly chosen a minefield to walk through.

Examination of Witnesses

Witnesses: Professor John Harper, Professor of Paediatric Dermatology, Great Ormond Street Hospital, Professor Jonathan Hourihane, Professor of Paediatrics and Child Health, Cork University Hospital, Dr Warren Hyer, Consultant Paediatrician and Paediatric Gastroenterologist, Northwick Park and St Mark’s Hospital, and Dr Mark Rosenthal, Consultant Respiratory Paediatrician, Royal Brompton Hospital, examined.

Q649 Chairman: I am Lady Finlay, I am chairing this Sub-Committee and this is our tenth public hearing in our inquiry into allergy. I would like to welcome you as witnesses today and, also, members of the public who have come for this session. There is a note declaring the interests of Members of the Committee, so we will not be going through declaring our own interests during the session. We would like to go through and ask you questions, and it would be helpful, because we have a lot of things we want to cover, if we can try to keep answers fairly tight so that we can move on. I hope everyone will contribute to the session. I wonder if I could start by asking you each just to introduce yourself and then I will go into questioning.

Professor Harper: I am Professor John Harper from Great Ormond Street Hospital and the Institute of Child Health in London.

Professor Hourihane: I am Professor Jonathan Hourihane, from the University College, Cork in Ireland.

Dr Rosenthal: Dr Mark Rosenthal from the Royal Brompton Hospital in Chelsea.

Dr Hyer: I am Dr Warren Hyer, from Northwick Park and St Mark’s Hospital in northwest London.

Q650 Chairman: Thank you. I wonder if you could start off by telling us how the prevalence and clinical spectrum of allergic diseases differs between adults and children.

Professor Harper: I am a paediatric dermatologist, so my take on this subject really relates mainly to atopic dermatitis, or eczema, in association with allergy. Eczema is a major part of my work. The prevalence in children ranges from 10 to 15 per cent, and there have been some studies approaching 20 per cent. So it is a very common problem. It is primarily a clinical issue in childhood, particularly children under the age of five, but the predisposition to developing atopic dermatitis, or eczema, does not really go away. Something like 10 per cent of adults still get eczema from time to time, and in a smaller percentage, maybe around one per cent, this is quite severe. So eczema is right across the whole age range, and is primarily a problem of children. I do not know whether you want me to develop further, but the prevalence seems to be increasing which has been documented in a number of studies. It is a worldwide problem with some countries having a much higher incidence of eczema than others.

Professor Hourihane: I am a paediatric allergist, so my particular interest is in food allergy. There is data to show the prevalence of peanut allergy in the United Kingdom has trebled since 1996 from 0.6 per cent to 1.8 per cent, which is one in 55 children. Other food allergies are less common in older children but the burden of allergic disease with food allergy is borne by the pre-school child, and it may be that up to 6 or 8 per cent of pre-school children will have experienced an allergic reaction to food by the time they go to school. There is attrition of this prevalence to about 2 per cent in adults with food allergy, and I think the other witnesses will talk about asthma. The issue about food allergy being a minor problem which then evolves into asthma appears, maybe, not to be correct any more because the allergies that children are having now are the ones that are known to persist into adulthood. So we may see a hardcore of up to 3 per cent, I imagine, with serious allergies, like peanut and shellfish, etc.

Dr Rosenthal: I am a respiratory paediatrician and, therefore, my slant is on asthma as well as food allergy. Certainly asthma has increased quite a lot over the last 50 or 60 years, but is probably plateauing-off as a recent study has suggested, or possibly even falling. I agree that the concept that asthma is allergic is far too simplistic as asthma covers a very wide spectrum of conditions whose final common pathway of symptoms are very similar. Therefore, it would be a mistake to say that asthma was an allergic condition only.

Dr Hyer: Specifically to answer your question about why it is different to adults, I see this as a paediatrician who serves the population as well as a paediatric gastroenterologist. The difference with my children compared to adults is children often suffer many different manifestations of atopy. So if they have peanut allergy they may have very severe
eczema. If they have peanut allergy their asthma is a greater risk for a life-threatening event. There are much more multi-organ issues in childhood than there are in adults, where it may be that only one manifestation of atopy will persist. As a consequence, the workload that has come forward to a simple district general hospital has been suffocating in its volume of children with complex, multiple allergies, who may just start with eczema, and it may be very severe eczema, and persist with potentially very serious restrictive multiple food allergies as they get older. I think this is a big difference and has been well-documented in good quality, prospective studies looking at the natural history of these children with very complex multiple food allergies.

Q651 Chairman: Thank you very much. I wonder if you could also explain something else to us. The conditions such as asthma, rhinitis and eczema can have allergic and can have non-allergic etiological backgrounds. I wondered whether the balance of allergy, and true allergy, that it plays in these conditions is different in the childhood population to the adult, whether allergy is more difficult to diagnose in the childhood population and whether the balance of importance of allergy on life is greater or lesser in children than in adults. I do not know if you are able to answer that.

Professor Harper: In relation to eczema, I think that we need to recognise that a proportion of children with eczema also are susceptible to allergy. You can certainly have children with eczema who do not have allergy as a major problem but a proportion do, and this can be very difficult. The data as to what percentage that is is variable depending upon which age groups are looked at and how they define eczema. It is complex because we do not understand the relationship between eczema and allergy very well. In those that do suffer with allergy as an issue, allergic reactions can be a major factor in making the eczema worse. So you need to address that almost as a separate issue. This is a situation that is mainly seen in children, and as they go into adult life several of these common allergies, like cows’ milk, become better tolerated and only a few allergens persist as a significant problem in adult life, such as peanuts and, maybe, kiwi fruit.

Dr Hyer: In relation to food allergy, food allergy, as you have already heard, is principally an issue for pre-school children. So its relationship to eczema, for example, will mean that allergens and food allergens are more likely to be associated with that. We know that children with severe eczema, for example, carry a 50 to 60 per cent chance of having significant food allergy. That data is not supported in adult practice. So if you take, for example, eczema, from my perspective, you can see that food allergy has a significant role in a significant proportion of children. That has been validated by international data and that is not concurrent with what happens in adult practice, so there must be a skew to greater allergic phenomena in children.

Professor Hourihane: Part of your question was: is it more difficult to diagnose allergies in children. It is if you have got nobody to make the diagnosis.

Dr Rosenthal: I would say, from an asthma perspective, that allergy in the sense we are discussing it, is the cause of a relatively small proportion of asthma in childhood. There are a lot more important environmental or other precipitants of asthma than allergy.

Q652 Lord Haskel: Professor Harper said that some countries have a higher prevalence of eczema than others. Is there any pattern to this? Is it less developed countries or more developed countries?

Professor Harper: There is data. I do not know how reproducible this data is but there are studies that show a lower incidence in developing countries compared to more Westernised countries. Also, migrant populations; those coming from developing countries to the UK or the USA are more likely to develop eczema. It is really complicated. It is not quite clear what these environmental factors are but it does seem that Westernisation is relevant in some way.

Dr Hyer: We know that the prevalence of allergic diseases differs even within developed countries, and certain parts of Australia and certain parts of Europe carry a much higher prevalence, of which the UK (certainly from within the ISAAC study) does not favour well; we have some of the highest prevalence of allergic disorders than anywhere else in Europe. Professor Hourihane may be able to validate that.

Professor Hourihane: What I would like to say is that in less Westernised parts of the world, such as Western Africa, they can eat peanuts at the age of six or eight months without ever developing peanut allergy. So maybe it is related to the environment, the nature of the food allergen and its timing of introduction. Peanut is not the problem all the way around the world that we have the perception it might be in the UK.

Q653 Lord Taverne: A recent article by the International Study of Asthma and Allergies in Childhood found there was a rise in the prevalence of allergy symptoms, particularly in the 6–7 year-old age group. I find the picture rather confusing: I heard Professor Harper say that across the whole age range there is a prevalence of eczema increasing; from someone else that asthma was, perhaps, falling; there is more multi-organ allergies in children, and Dr Mark Rosenthal’s statement that we have here
suggests that there has been a modest true increase but it may be stabilising. Do you see an increase at the moment, particularly amongst children? If so, what is the reason for it and what can be done about it? Professor Hourihane: You may have heard from other witnesses in previous sittings about the hygiene hypothesis, which appears to be the most plausible or most robust of the explanations. I think there is not much more to say. That is what we think is the reason. It appears that allergic conditions are the price that a small proportion of our population pay for the way the entire population lives.

Dr Hyer: Just so it is not focused on the 6–7 year-old, which is the outcome from the ISAAC study, there are numerous studies (and there are at least seven studies in the UK) which looked at the prevalence of allergy and which validate that it happens across many age ranges, and not just limited to the 6–7 which was reported in that specific study. That data can be looked at throughout the UK, it can be looked at throughout Germany and many other parts of Europe. So I think it is important not just to assume that there is a rise in one specific age group.

Q654 Lord Taverne: Are there signs of a plateau? Stabilisation?
Dr Hyer: There will be a bias for how data is validated and the quality of the data collected because, of course, allergy is quite trendy and people may over-report. From a clinical perspective, I have had to change my practice in a district general hospital because I can no longer practise paediatric gastroenterology without tackling allergy. This was not the same issue 14 or 15 years ago when I started my training. The prevalence of peanut allergy is such that it has now reached, as we heard, around about 1 in 55. The allergy to agents such as tree-nuts and to fruits and pollens did not exist in my practice 20 years ago. I have kept my eyes open during that time, and I do not know whether it has plateau-ed but I have certainly seen it rise.

Professor Harper: We can make these clinical observations and you can ask why, but there are many unanswered questions. We really do not know the answer. It is interesting that Professor Hourihane mentioned the “hygiene hypothesis”, and that actually is all it is, a hypothesis; that is, cleanliness and the lack of exposure to viruses and bacteria may make you more susceptible. However, the opposite is not true; if you actually have children who are exposed to infection there is no evidence whatsoever that this reduces your risk of allergy or atopic dermatitis. In fact, there are many papers on infection in early life triggering eczema and asthma. So it is a hypothesis.

Dr Rosenthal: I might slightly demur on that one in that there have been good studies from Germany, Switzerland and Austria showing the effect of being pregnant and attending to farm animals and whether the child after birth also got into the barn, and their risks of having asthma at the age of seven was reduced almost to zero compared to other farmers whose wives, when pregnant, did not go into the barn or have contact with animals. So exposure in early life certainly affects something, though why does remain completely unanswered. So you can see from the various answers that this is a highly complex problem of which we only know a very tiny amount.

Dr Hyer: There will be more than just the hygiene hypothesis to account for this. People have looked at diet, polyunsaturated fats, cereals, grains, the way food is prepared, breastfeeding practices, nutrition during breastfeeding. All of these—in fact, Gross National Product of your country can also predict your risk of atopy. There are such complexities that the hygiene hypothesis alone is a very valid hypothesis but it is made so much more complicated than that.

Q655 Lord Taverne: It has already been mentioned, but I was going to ask, whether early viral or bacterial infections predisposed infants to the development of allergies.

Dr Rosenthal: If you take studies of American day-care inmates, so to speak, they will have far more viral illnesses and virus-associated-type wheezing episodes, which currently are not defined as asthma but their risks of having asthma at the age of 11 is reduced as a result. So this can be argued in many directions, but the studies from the southern states of America are quite compelling in that regard.

Professor Hourihane: There is similar data from Scandinavia about early entry to day-care, which is part of the social contract in those countries where mothers go back to work and children go into state-run day-care. The children who go into state-run day-care before six months, compared to those who go in after a year or 24 months, have lower rates of asthma and other allergic conditions. So it is guilt by association. It is very hard to prove that any particular—I do not know how we would prove—viral infection in infancy prevented allergy. However, there are data regarding children who have either been vaccinated against measles or had wild measles, in Guinea Bissau, and those who were vaccinated—i.e. they did not have the wild-type infection—had higher rates of allergies than those who had had measles and survived it. So it is a trade-off between surviving measles or not.

Q656 Viscount Simon: The “allergic march”/progression (whatever you like to call it) describes the march from mild allergies, such as rhinitis, to more
severe conditions. Is there any particular age at which children typically are most likely to develop these more serious disorders, and is there anything that can be done?

Dr Hyer: It depends what you mean by “more serious”. I would say that multiple food allergy in a child under one or severe eczema which impacts on your growth in a child under one is, perhaps, more serious than asthma that is looked after by Mark that is older. I would fight that corner. People progress through different manifestations of the allergic march at different rates. For me, the burden of workload is the preschool child who has multiple food allergy, but as I continue my clinic as they get older many of them became tolerant to the most significant foods, which are milk and egg; they may remain allergic for life to foods such as peanut, which may amount to a serious risk, and then as I continue running my clinic I inevitably end up running an asthma clinic or a rhinitis clinic as they get older. People do progress through symptoms. The preschool child may lose their original food allergy, but I am not clear that I have a specific age where the threat is greater. I consider the preschool child at significant risk.

Professor Harper: I would like to make an important comment. I do not like the term “allergic march”, personally. I know it is used in the literature a lot but it is often misused; it is a very loose term and people understand it in different ways. It seems to me to assume that there is a progression: that you develop eczema, then you develop your hay fever and then you develop your rhinitis. I think, these are all individual diseases which are associated and, perhaps, aggravated by allergy, and that they vary from one child to another. There is a time difference; the onset of eczema is primarily in early infancy, under one, and then perhaps the peak of asthma onset is a bit later and then the onset of rhinitis after that. However, it is time-related rather than necessarily a progression in an individual. The ultimate point here is: is it progressing in such a way that it becomes more severe? I am not sure that is true. There are genetic factors as to why some children are born with severe eczema and asthma and rhinitis, but it is not a progression from one of these disease entities to another.

Dr Rosenthal: There is a danger of moving from the particular to the general. There is a very good study from Cambridge which looked at food allergy events and looked at the risk of progression to a more severe event subsequently, admittedly following intervention by training and advice, etc. Certainly in children the risk of progressing to a more severe event was virtually zero.

Professor Hourihane: However, it is not the case that they move from a benign condition of eczema to a more severe condition of food allergy. Food allergy and eczema are there in infancy and rhinitis is what develops after several years of exposure to allergens. The perception that the diseases become more severe is because the burden of death due to allergies is in adolescents and teenagers, whose approach or response to their illness puts them at risk; they ignore the warnings, they take risks, or they eat in places where they may not be sure of the provenance or safety of the food. So the severe illnesses start in childhood and persist, but the responses of individuals to the conditions may alter their risk through life, as for any other condition that an adolescent may have to suffer.

Q657 Viscount Simon: It is a common belief that most children grow out of asthma and allergy, but am I right in thinking that this may not be true particularly with regard to food allergies?

Dr Hyer: There are food allergies that persist. The simple ones that resolve, like cows’ milk and the egg, not all but many children will outgrow. Those with multiple food allergies sometimes do not and there is a significant burden of children who have multiple food allergies who are not outgrowing them. That means that there is a cohort coming through to adulthood, potentially, who have a one-in-50 chance of having a severe adverse event were they to face peanut. So in answer to your question, some of the food allergies you do not outgrow. There is information still to be gathered—remember, we are seeing a rise in the prevalence of peanut allergy—but at the moment these ones seem to persist.

Professor Hourihane: I have been told twice within a month by two families that they wish their child had cancer instead of food allergy because there is a cure for cancer.

Q658 Chairman: You commented earlier on about the absence of the ability possibly to diagnose accurately. How much do you see that as a problem amongst children and then, moving on into adulthood, that the actual allergic nature of their disease has not been adequately diagnosed?

Professor Harper: It is also a perception by many doctors in different specialities, because this range of conditions can present to a whole number of different specialities and they each have different protocols of management. It all needs to be much more co-ordinated, with a greater awareness for potentially aggravating factors, whether it is eczema or asthma and so on, and to investigate allergy. That is what is important, and to be able to have the facilities to be able to do that. There is a need for awareness right up from general practice to specialist.
Q659 Lord Colwyn: Would children stand a greater chance of outgrowing an allergy if they were on a totally restrictive diet which prevented any taking-in of that food? Or would they stand more chance of outgrowing it if they carried on eating it and slowly acclimatised themselves to it?

Dr Hyer: A wonderful question and there will be many different answers to that. We know that in terms of primary prevention the best tool is to breast feed. Breast feeding is not a mechanism by which you are not exposed to allergens; you are exposed to hundreds—thousands. The advice of the Department of Health, for example—and this is particularly controversial and will cause much concern—about not having peanuts to eat in the first three years of life if you are at risk may not be what happens in the rest of the world. So when you compare that with data in Israel where the prevalence of peanut allergy is so low, is it because they are weaned on to sweets and crisps that contain peanut? We do not really know the answer to that, and this is being addressed by studies which are funded studies at the moment. We know that breast feeding helps. We know that if you have severe eczema you may benefit by going on to a hypoallergenic feed when weaned and not being fed cow’s milk formula, but because of the diagnostic difficulties that you so kindly mention, selecting which patient should take on which avoidance pattern is very complicated and sometimes managed in general practice but really ought to be managed at a specialist level, whether it be at an allergist level or an organic-specific consultant who can take on that question. It is very complicated and very individual because the diagnostic test difficulties that you have alluded to requires judgment which is not available in general practice.

Professor Hourihane: I would rarely put children on total elimination diets. I would say it happens, maybe, once every year to eighteen months. There are other ways. The major allergic manifestation is usually eczema under the age of one and failure to thrive with gastro-intestinal symptoms. So an integrated approach and the holistic management of these things is the key. Elimination can be appropriate but it is extremely limiting on the family; it makes the child unadventurous in new situations, socially isolated and it should not be undertaken except under specialist care. So we are not in favour of such elimination diets being started in primary care before being assessed by an allergist, because, for one thing, they may be nutritionally unsound unless they are properly supervised and they may be promoted or persisted with for far too long after the allergy has gone away. As we have heard, milk and egg allergy go away in the first four or five years of life. I am encountering now, in Ireland, where there is an even less developed allergy service than in the UK, children of nine or 10 who are still on elimination diets for a reaction that they had in the first year of life. Their social wherewithal is very limited.

Q660 Lord Colwyn: It is a sort of do-it-yourself immunotherapy?

Professor Hourihane: We would not advise that. There is the risk of an extreme allergic reaction which may be augmented by a period of elimination. That has been well-described in the dermatology literature, particularly by Tim David from Manchester. So avoidance and then casual reintroduction has caused problems.

Dr Hyer: This is, surely, effectively, an argument that these children (and the numbers are not small; we are talking about 2 per cent of all children have cows’ milk protein allergy of some form) need to be seen in services outside primary care with access within a few weeks of the diagnosis. Some of these children are three months and they cannot wait 12 weeks on a waiting list; they may have failure to thrive; they may be breastfed and the mother does not know what other foods to give this child; they are told to over-restrict unnecessarily and you can see that this ultimately impacts on these children, not infrequently they will end up on the ward; they will be admitted because they just could not get into a service. Perhaps this is an opportunity to think about the access of this group of children who, ultimately, will represent an allergic burden for many more years, because they do need specialist care. It is not just about whisking out a few foods and doing-it-yourself at home.

Q661 Lord May of Oxford: We have actually covered much of the ground of the question I was going to ask, which would have been: against the background of a lack of understanding of what is actually happening and causing the rise, what, if any, consistent advice is or should be offered to pregnant women and mothers of young children regarding allergy prevention? Is there any consistent advice that is recommended that be given? If so, what do you think of it and do you think it is well-founded?

Dr Rosenthal: The Cochrane database on this aspect of prevention or food avoidance in pregnancy or lactation has been revised more often than any other Cochrane database, and the conclusion remains entirely the same: that there is no evidence—definitely no evidence—in terms of food avoidance during pregnancy, and during lactation possibly. Therefore, is it scientifically well-founded? It is scientifically well-founded only to the extent that nobody still has any idea.

Professor Hourihane: Could I read out what the current European Academy of Allergy and Clinical Immunology guidelines for this are? “The dietary
recommendations based on present knowledge: all infants, no special diet during pregnancy or for the lactating mother; exclusive breastfeeding preferably for six months, on the basis of WHO advice, but at least four months. If supplement is needed conventional cows' milk formula is recommended." So there are no particular dietary restrictions for the general population. “Avoidance of solid foods preferably until six months but at least four months.” Further recommendations for infants who are at high risk of allergic disease (so they would have a father, mother or sibling with allergies) are that if supplement is needed extensively hydrolysed formula is recommended until four months, and after the age of four months high-risk children can be nourished like non-high-risk children. The important point is there is no particular advice for pregnant mothers.

Professor Harper: This is a really important question that one is always asked. I see a child with eczema and allergy and the mother is wanting further children saying: “What can I do? What should I do?” The policy we adopt is that just described by Professor Hourihane. As I said before, these children are seen by such a variety of different specialists—it could be gastroenterology, it could be general practice, it could be a paediatrician, dermatologist or allergist, and so on—and advice does vary. It seems to me that particularly among gastroenterologists there are doctors who maintain that mothers should be on a diet, but there is very little evidence to support this approach. If you look at published papers there are some papers that say it is good and there are some papers that say it is not helpful. At the moment, there is no evidence that mothers should go on a diet at all.

Q662 Lord May of Oxford: In the first instance, that people are more likely to see their GP than a specialist, who may well have particular views of a good or, alternatively, peculiar kind, to what extent do you think GPs are well-informed about this?
Professor Harper: I think this is crucial to everything here: and that is better education at primary practice. You cannot send every child with a potential allergy to a specialist—that is just not on—but what you can do is give better education all the way through the medical system from whence they first go to a doctor.

Dr Hyer: No.

Q664 Lord May of Oxford: Do you not think they should be?
Professor Hourihane: Clearly.

Q665 Lord May of Oxford: That is not postgraduate education, that is just basic practice.
Professor Hourihane: I would declare an interest: my wife is a GP and if you went into any GP’s surgery the list of guidelines on their desk is taller than their computer. It is an impossible position to be put in. We need to be able to deliver targeted specific advice or accessibility in a way that is accessible for them, at a time when they need it as opposed to when they are meant to be doing their reading. They need to have it immediately available in some way that they can—I do not know—Google it, for another word, on their desk, or Prodigy, or the other systems that GPs have for information: “what do I need to do with a child with eczema?”

Dr Hyer: We are all vaguely missing the point. A very significant proportion of these parents will not be seeking advice from the medical profession, and they may be seeking advice from complementary care which may not be following these guidelines. The paediatric gastroenterologist will follow those recommendations. These are well-established recommendations that have also come out of working parties that have worked with the World Allergy Organisation. It is good, solid advice but it is not current advice if you are one of the 25 or 30 per cent of mothers who will take their small child with eczema to a homeopath, a complementary physician of some kind, who will, not uncommonly, over-restrict a child’s diet. We should not kid ourselves; actually, primary care is only one route that you access advice on what to do with your child’s incurable skin condition. There are a not insignificant number of children in my care who have significant failure to thrive or social impairment because of restrictions imposed by non-medical resources.

Q666 Lord May of Oxford: This opens the door to a much larger question, which is the extent to which non-evidence-based medicine should be being purveyed within the NHS.
Dr Rosenthal: We would all have to go home now!

Q667 Lord Soulsby of Swaffham Prior: We have been talking about breastfeeding. Is there any transfer of either sensitivity or tolerance actively or via lymphoid cells incolostrum, for example?
Professor Hourihane: It is certainly true that any allergen that a mother ingests—whether it is a food allergen or anything else—will be found in breast milk shortly afterwards. You can find peanut allergen
in breast milk within 20 minutes of a mother eating it, and the variability of that goes from within 20 minutes to up to eight hours later. So it is not often the case that you can say if it is not there in the first hour it will not have happened. 0.5 per cent of breastfed infants have cows’ milk allergy even though they have not been exposed to cows’ milk and that is due to intact milk allergens expressed in breast milk. We are talking about the tail end of a curve here because all children are exposed to those allergens that a mother expresses but we are talking about the vulnerable, high-risk child who then develops symptoms on the basis of that.

Q668 Earl of Selbourne: I want to come back to Lord May’s question about the help that GPs might get from this Committee in its report and the structure. We come back, time and time again, to the cases, as you have already reminded us, where it is impractical to suggest that children, in the main, can see a specialist; it will be the GP who is expected to be able to deliver advice and diagnosis. We have also been told, time and time again, that there is very little postgraduate training, and absolutely nothing at undergraduate level—we have been told this is 20 minutes, or so. What I would really like to hear from you is what precisely you would like us to say which needs to be put into the hands of a GP which would allow him or her to be more effective in the diagnosis and treatment of allergies in children.

Professor Harper: In simple terms they need to have formalised basic training in allergy and to make sure that there is good communication with their local allergy specialist, and all the other specialists that relate to this group of disorders. There should be protocols of management and that guidelines are agreed nationally. In the past, allergy, at all levels, has not been taken seriously enough. There is now a lot of background science to allergy and a lot of formulated ways of managing these children. I think that GPs should have CPD training specifically for allergy, if they have not already had it.

Dr Hyer: This has been looked at by the Royal College of Physicians. They produced a report, which I am sure you are aware of, about three years ago. There is an issue that it is not taken seriously by general practice and one of the big pitfalls as a child with eczema is that the GP may say: “Look, it is just not related to food” and they carry a 50 per cent chance of being wrong, because we know the relationship between food and eczema, potentially. This then produces a further barrier between the patient and the GP. There needs to be a realisation that it has to be taken seriously; these are real diseases, they are not made up by homeopaths; they are real disorders. GPs, therefore, need to have a resource that they can access for advice. That means there needs to be specialist allergy services which are recognised nationally, and not just a few units stuck in the south-east of England with nothing west of Bristol. Access to colleagues is a way round your suggestion, number one, and a realisation that allergy does have a role, not in all, but in some children with complex profound atopic disease.

Q669 Lord Rea: As a former General Practitioner I would like to put the view that most postgraduate education and keeping up-to-date received by GPs comes from exchanges with the specialists to whom they refer their patients. Certainly it was the case with mine; a good relationship with a local consultant and good letters back from the consultant, with non-patronising, postgraduate education included in the text, is a very good way of doing it. However, the problem is that there just are not enough allergy specialists for GPs to refer their many patients that they might like to.

Professor Hourihane: We will need to grow some allergists to populate the regions where there are not any, and we cannot do that until we have proper centres of research and training for allergy itself. The NHS responds very well to standards and the Australia College of Allergy (I forget its particular acronym) has developed standards for management of anaphylaxis in the community which are very accessible. Off the top of my head, one of them is that no person should have more than one episode of untreated anaphylaxis during their lifetime. That is quite a simple thing; it should happen once and then you should have enough training and support so that it never happens again. All children who have had anaphylaxis should be seen within one month. Those are accessible, understandable, achievable targets if we put the resources where they should be.

Chairman: I think that takes us very neatly on to Lady Platt’s question.

Q670 Baroness Platt of Writtle: What are the priorities for research with regard to the primary prevention of childhood allergy, and who is carrying it out in this field at present?

Professor Harper: Perhaps I could start. There is minimal research in eczema. It is an area that I have a particular interest in. We have a research team at Great Ormond Street, but there are very few other places that are doing proper basic science skin biology research on eczema and why this condition makes children susceptible to allergy. We need to know more about the basic biology of what is happening to children who get inflamed skin with eczema, and why—address the question—are they more susceptible to allergy, because a lot of the allergy is actually through the skin. I just want to make one point because I know all these facts are
being recorded, and it is wrong of me to disagree with my colleagues, but it does highlight the lack of research and the lack of good knowledge. Food allergy is important but there is a wide spectrum of allergy, not just foods, but inhalant allergens and environmental allergens. Food allergy is not 50 per cent of children with severe eczema; it is probably more like 10 per cent. Nevertheless, it is an appreciable number that must not be overlooked. If we understood more about why children with eczema get allergy, maybe we can address that, but there is a lot of research that is needed focused on atopic dermatitis.

Q671 Chairman: We, particularly, too, want to look at primary prevention rather than research into established disease. You are talking about prevention in children with eczema. I wonder if others of you have comments on that.

Professor Hourihane: In high-risk groups, defined as having a sibling or a parent with allergies, intervention, such as the delayed introduction of solids, appears to be effective. On a population basis it is very difficult to see if that advice will be effective because intensive investigations in isolated populations are not effective, so bombing their bedrooms and making their rooms hypoallergenic and very austere do not work for house dust-mite sensitisation—removal of pets, etc. On a population basis it is very hard to know what is the primary thing we need to know, but interventions regarding early or delayed weaning and selective weaning with low-risk allergenic foods is probably more of a plausible way in the first year of life with primary prevention. On the role of breastfeeding, I think, we need to maintain the excellent breastfeeding rates in this country and try to get them up to the levels they have in Scandinavia, where they have support groups for women who cannot breastfeed, whereas in Cork we have support groups for women who try to breastfeed. So we need to switch this round to make this a breastfeeding culture.

Dr Rosenthal: The question I always ask myself is why do most people not have allergy? How do they learn immunologically to tolerate antigens and foreign proteins that are presented to them? What distinguishes 98 per cent of the population from 2 per cent of the population, because until you know why that happens you cannot prevent it in the 2 per cent of the population. On the studies from Israel, as Dr Hyer has said, why does everybody in Israel stuff peanuts down their throats, from birth virtually, and never have a problem, and yet we in the UK have a comparatively large problem? Bear in mind that the eating of peanuts has become much more common in the last 40 or 50 years with a rise in allergen, but in Israel it seems to have no effect. So until that sort of thing can be disentangled then primary prevention is not actually possible because avoidance does not seem to work. Saturation in certain cultures appears to work and why is it different? That is where the research should focus.

Dr Hyer: In answer to “Where should it be done”, it should be done in established departments of allergy in university departments who can manage sensible, prospective studies, and it should not be done by small, little observational studies done in little parts of the country. There needs to be a clear idea about how we are going to look at primary prevention because we do not really know where to target, as you have already heard. That probably should be left to university departments or specific tertiary allergists to work with primary care and work out which studies will answer where primary prevention works.

Q672 Earl of Selbourne: Could you tell us how the typical treatments differ between adults and children for conditions such as asthma, rhinitis, eczema and food allergies?

Dr Hyer: I do not think they do.

Professor Harper: There is not a lot of difference, in terms of managing eczema, between a child and an adult, except to respect the paediatric aspects; that in a child the surface area of the skin has a higher proportion to weight than in an adult and therefore absorption through the skin is relevant. We are very aware that what we put on the skin might be absorbed into the blood, but the principles of treatment are very similar, both for children and adults, and most children can have their eczema treated adequately with topical therapy.

Q673 Earl of Selbourne: Are there some medicines which you have to be more careful with than you would with adults, such as anti-allergic medicines, antihistamines and corticosteroids?

Professor Hourihane: If they are used appropriately. We use them down to very young ages, and Professor Harper would do the same. Appropriately managed they are very useful. One of the things I would like to get on record is the fact that we should not be using first generation antihistamines in children just because they are sedative to decrease their itch; we should be treating the itch and then they will be able to sleep. We should be using modern medications at appropriate doses with appropriate frequencies, and that goes for corticosteroids, immunomodulatory therapies, such as tacrolimus and pimecrolimus, as well as anti-asthma medications.

Dr Hyer: I would argue that the treatment is different in children for food allergy because it does not exist in adults. I work in an adult hospital, which is a big gastrointestinal service in North London called St Marks. They do not need any food allergy services.
So the treatment is different. You need specific food allergy services for children which you will not need in adults. Why is it necessary? Because you need a multidisciplinary approach with dieticians; you do not have over-restricted diets; you want reliable ways of investigating children and interpreting the results correctly and not with prejudice, and that is a different treatment package to that which you get from adult practice. This requires dedicated services.

Q674 Earl of Selbourne: Can I ask Dr Rosenthal: he has given us an interesting paper and near the end of it he refers to the tremendous increase in prescriptions for adrenalin-injection devices—EpiPen, and the like. You hint that perhaps they are being over-prescribed. Is there a danger in this? You ask the question (and you do not actually answer it) that there might be an issue as to whether they are leading to social difficulties and greater family anxiety. Would you like to answer your own question on that?

Dr Rosenthal: The answer covers all the subjects from defensive medicine through to clinical practice. There is no doubt that over the last 10 to 15 years the prescription of these devices has rocketed, although I actually say I do not know how many I have prescribed but only one has ever actually been used. Whether I am just lucky, I do not know. In quite a lot of it there is a cost in the sense of social cost: Johnny goes to party, but Johnny has to bring EpiPen, antihistamines and all the rest of it. It may, of course, truly be necessary but it is not a free lunch in that respect, and one has to be careful that the management of the condition is not worse than the problem and only equals the problem. There has been, though we still wait with bated breath, no court case of which I am aware of the non-prescription of such a device leading to not preventing some tragedy and being sued as a result. So in terms of the criteria for when you should prescribe them, there is very little laid down and everybody has their views—they are much more rigorous in America than, for example, here. As I put in the statistics, one in 80 children in Canada carries an adrenalin device, which is extraordinary.

Professor Hourihane: I am afraid I do not find it extraordinary at all when the prevalence of peanut allergy is even higher than that. In almost every one of the consensus documents about who should carry adrenalin, if you have peanut allergy you should carry one. So, if we do the maths on this, one in 55 children has peanut allergy but only (from Australia in 2004) one in 500 children had an EpiPen. So to even increase the number of EpiPens just to provide for the single condition that is peanut allergy we would need to increase the number of EpiPens by a factor of more than six, just to cover the single allergy that peanut represents. I want Johnny to go to the lunch rather than not go to the lunch. If he has to bring a bag of equipment that he does not need to use that is a different matter; that can be left outside. We want these children socialising normally with the extra caution that comes with an appropriate adrenaline kit. We do not want them to ever have to use it but we want them to have it available if they ever have to use it.

Dr Hyer: You have heard two differing opinions. As a practising paediatrician this is a real challenge. I could give an adrenalin pen to every child who comes in with a food allergy that might pose a life-threatening episode. It is not just peanuts; it is tree-nuts, and it is potentially milk in smaller children. Every day I get three or four ‘phone calls from a parent and it is perhaps one of the commonest questions that is raised. There are guidelines out there; there are Australian guidelines, there are American guidelines, but actually what to do in this country is still not clear. It is a real shame for this honourable Committee not to have clear guidance from the four of us, because we do not know yet exactly who should carry them. This therefore becomes an individual decision with a patient which cannot be made, probably, in primary care safely. These patients deserve to sit down and have a sensible diagnostic process taking place where they find out which nuts they can and cannot have, see a dietician, have an emergency protocol and then, if they still feel it is necessary, receive the adrenalin pens. This was a practice that was put into place by the McEwan group and other colleagues who have looked at packages of care. That cannot happen in general practice. So, in answer to your question, we need to have a relationship with our GPs, so that if they ‘phone us and say: “I do not know whether this mother needs an adrenalin pen”, this is a decision that may last for five or 10 years, or a lifetime. Surely, these patients deserve a consultation with either someone like Mark or myself or anyone who has the specific interest and skills to make that decision with a parent. My plea to you is that it is not just leaving it for general practice to do. This is a question that was raised before. If you have a child you are weaning and you are breastfeeding, with severe eczema, even if general practice can manage it, perhaps it is wrong to expect them to do so. We have the expertise, we can help at least on one consultation and share that burden with the GP. The same argument happens with adrenalin pens. There are differing opinions; there is no fixed protocol a GP can follow; the practice must change from one patient to another. It is unfair to leave that specifically unsupported in general practice to do, and we should seek the people who have an expertise, whether it be a respiratory doctor or an allergist, to work out who should have
those pens before the whole population walks round with them.

**Q675 Lord May of Oxford:** Is the procedure that you recommend that which is followed in Australia or not?

**Dr Hyer:** I have just come back from a sabbatical working in the allergy services at Melbourne Children’s Hospital, which is probably one of the best established services around the world. There is not absolute clear consensus. There is rapid offering of adrenalin pens because they meet the criteria of distance and inability to access hospitals as they may, for example, in Ireland, but they certainly would not if they were living within Chelsea. These are very individual decisions, but the primary care is not the same in Australia as it is in this country. Access to hospital specialists is not the same, and the need for adrenalin pens is different for whether you live in a suburb round the corner to the Royal Children’s Hospital in Melbourne or whether you live in Wogga-wogga in the outback. These people make individual decisions and we must make individual patient decisions in this country, based not in primary care, about who should be carrying adrenalin pens.

**Q676 Lord Soulsby of Swaffham Prior:** Can we turn to immunotherapy? Is immunotherapy widely practised in this country? Is it as effective in children as in adults? A rider to that is, is there danger in using immunotherapy for that allergen, do not have the criteria that you must not have asthma precludes quite a lot of them. Also, it is quite an onerous injection regime, so getting a younger child to have it is very unlikely. People, therefore, have to be positively begging me before we undertake it. I am, personally, still very chary about it because most of the time non-immunotherapy treatments for this sort of thing are effective, and it is only the hardcore minority which you need to progress to that stage.

**Q677 Chairman:** Our Sub-Committee visited Germany and there we saw immunotherapy being used to a much greater extent than in this country, with a much lower instance of risk than the old experience from this country, which was out in primary care, which is where the problems were arising when patients were given these injections in primary care, a long way away from any kind of resuscitative centres. I wonder if you have any comment on that discrepancy between the German therapeutic practice, where they are reporting quite a major benefit?

**Dr Rosenthal:** In relation to my customers, so to speak, I have to wait a long time before somebody comes up who qualifies, at least in my view, but maybe I am being too austere about this. If I was going to be cynical about the American viewpoint, it is very lucrative pastime.

**Professor Hourihane:** I do not think that pertains in the UK because of the structure of the health service. The NHS is the laughing stock of Europe for its absence of immunotherapy for allergic diseases—briefly. The regulators are stuck in a 1986 mindset and need to get over that, and move with the science. Professor Kay’s group and others have driven this to areas which show that it is safe, effective and its impact is comparable to simpler medication, which is much more expensive. The issue for children, my Lord, is: is there some way that immunotherapy can prevent (the favourite term) “the march” or not? It appears that mono-sensitised children who are allergic to just one allergen, if they are treated with immunotherapy for that allergen, do not have the promotion or diversification into other allergies. So it appears that children may be the key group in which we should be doing this.

**Q678 Lord Soulsby of Swaffham Prior:** It is an interesting comment that progress stopped in 1986. Maybe we should take that on board. At what age could you start immunotherapy in childhood?

**Dr Hyer:** From a food allergy perspective and from a practising clinician, I am frustrated that I do not have the access to immunotherapy that I would like to try and see if I can reduce the burden of atopic disease, although nor am I also convinced yet about its therapeutic benefit. That needs to be taken on and introduced to see whether it works within this country. There is one wonderful immunotherapeutic
agent which is under-utilised in this country, which is called breastfeeding. The Select Committee also need to remember that if postnatal care was improved in this country and the prevalence of breastfeeding rose we would already have our own biological immunotherapy, at least for some foods, that may offer significant benefit. I do not know if that is a fair comment.

Q680 Chairman: Is there an onus then on midwives and health visitors to understand allergy better? Professor Hourihane: They are very powerful intermediaries of medical advice. The advice the Government gave about peanut avoidance was much more commonly adhered to if it was received from a midwife than from a family care doctor or an allergist, if you happen to have seen one. So they are very important people. They also have got to stop the habit of giving individual bottles of milk to children just to keep them quiet while the mother rests on her first night, lying in. There are a key target population for training.

Q681 Lord Colwyn: We have covered some aspects of training already this morning, and it has become clear there is not a lot of postgraduate training available, although I think in previous evidence we did hear that it has been suggested that in group practices specific doctors might be allocated the job of being particularly interested in allergy. Literally, all my own training in medicine and later in dentistry consisted of was training in how to deal with allergic reactions to substances that we had introduced into the patients at the time. Can you tell us what training programme there is for paediatric allergists and is it an attractive career path for a doctor?

Dr Hyer: In answer to the last bit, if you look at the recent applicants by paediatricians for clinical training programmes and specialists in areas of speciality for the year three registrars, (in other words they have got about three more years to go) allergy is one of the most popular specialities to go into. It is now a credible paediatric resource and so it is popular. For the training I would have to refer to Professor Hourihane.

Professor Hourihane: We need to have centres that can do the training where they can give the whole experienced complement of dermatology, gastroenterology, asthma and immunotherapy. It has always got to be in centres where this can be done and then these people need to be diffused out into other regions following training where they would then be able to interact with primary care. It needs to be in a place where everything can be done.

Dr Hyer: Whilst you are being trained in your allergy I think it is true to say that if you take on other specialties, particularly paediatric gastroenterology, you cannot really do it unless you have had some allergy training, such is the burden of clinical work that will come to you from food allergy. The training programme for juniors needs to be modified to take into account that there is a specialty of allergy and that it will impact on their clinical practice and they need to be trained in it. That is going to require training centres—proper tertiary units with specialist supervisors in paediatric allergy and specialists who can train you in respiratory complications such as asthma—and those need to be in place.

Q682 Lord Colwyn: Does the Certificate of Completion of Specialist Training in Allergy involve paediatric training as well as adult allergy training? Professor Hourihane: No, I think I was the first paediatric allergist to go through the CCST scheme and I have got a CCST in general paediatrics and immunology because allergy was not a recognised specialty at the time in paediatrics, and it remains so.

Q683 Lord Colwyn: How do paediatric allergists work with adult allergists and organ specialists to ensure long-term care for patients as they grow older? Professor Hourihane: Paediatricians are very good at organising transitional care. It is well-established for cystic fibrosis and asthma and other chronic respiratory conditions. There has not been the evolution of paediatric allergy clinics on a broad enough scale to say that there is a logical and well-defined structure of transitional services. In Southampton, we transferred patients to the adult services with an overlap of appointments. We did not share clinics but we co-ordinated appointments. It is a real risk that the children who have been carefully supervised with food allergies will then become the adolescents who leave all their kit at home and go to restaurants at risk, so care of adolescents with significant allergies as well as significant asthma or cystic fibrosis could be better co-ordinated.

Dr Hyer: When I finish with my patients at 15 I do not have anywhere to send them. I know who my paediatric allergy colleagues are, but I do not really have access to strong adult allergy services. The numbers are small because, as we have said, food allergy is principally a phenomenon of the pre-school child, so it mainly fits within the remit of paediatrics, but I do get 16-year-olds turning up to my clinic who have oral allergy problems with pollen et cetera who want to know where to go because I cannot see them any more, and I do not think I have anywhere to send them yet.

Q684 Lord Colwyn: So are there particular difficulties for specialised paediatric allergy services in district general hospitals?
**Professor Hourihane:** They do not exist in district general hospitals.

**Dr Hyer:** What happens in district general hospitals is what is happening here. I am an organ-specific specialist, I deal with the gut, and invariably I have to deal with food allergy. I got myself trained. I trained myself in Australia in order to get the training that I really needed, and I do not mean that in a derogatory fashion and I am sure my colleagues would understand that. I had to do that because of the demand for services and the referral patterns. I think that probably answers the question. In a district general hospital we are not allergists, we are organ-specific consultants who have to do allergy with different passions, so I would be passionate about my food allergies and less passionate about my asthma, but hopefully as a paediatrician I can deliver the whole package. That may not be true in adult practice where if you have got food allergy you go to an adult doctor and he may not be an adult gastroenterologist and he may not be able to help you with your eczema.

**Professor Hourihane:** I would say that allergic conditions are diseases that live in the community and are looked after by professors in university hospitals, and that is not a reasonable model of care.

**Q685 Lord Rea:** How long does it take for a consultant in any of the specialties in which allergy plays a part to get a sufficient body of knowledge in allergy to consider themselves well-trained as an allergist in their particular field?

**Professor Hourihane:** There are European standards of training which say that they should have four years of specialist training or so. If you take the British model of higher specialist training, that is two years as a registrar and then three years of higher specialist training and many people who would go into what are niche areas would do primary research at that stage, so it is at least five years as a registrar with maybe a couple of years for higher degrees.

**Q686 Lord Rea:** What I am talking about is somebody who has already got a consultant post in their particular area but wanted to establish an expertise also in allergic manifestations of their particular specialty.

**Professor Hourihane:** There is a specific allergy MSc course in Southampton which can be taken in a modular fashion and that can be done at certificate, diploma or full MSc level over the course of four years. So there is postgraduate training available but it is very unavailable!

**Dr Hyer:** If you ask how long does it take: I have had to train myself and I do not know how good I am because I am only trying to do the job, no-one has validated it, I just have not made mistakes. You will need to ask Dr Rosenthal his opinion on how long he has had to do it as a respiratory doctor, but I think it has taken me several years of clinical practice and close liaison with my colleagues who are allergists within London to get a feel for what I am doing. Just as GPs get back a reply from a consultant, I get responses back from my colleagues and so I know how to step forward. I have many shared patients with for example Professor Harper so I have learnt how to address some of his practices as well. It has taken me a long time. If you put it in a training programme the minimum you would need, for example as a gastroenterologist, if you want to practise it at a hospital level, is six months doing allergy, to meet the burden of work that comes to you in a district general hospital.

**Q687 Lord Rea:** Would a general practitioner be able to enrol on the MSc course?

**Professor Hourihane:** Yes, it is multi-disciplinary.

**Q688 Lord Taverne:** Just following that up, with the general practitioners being so ignorant about allergies and being in such a crucial position to refer people, there are many pressures on their time to get up-to-date on all sorts of different developments. What would be the minimum education and training they would need in the diagnosis or recognition of allergy? What sort of base model would they have to get and how long would it take them to get it? It does seem to be a rather desperate situation when they know nothing and the training courses appear to be so long.

**Professor Harper:** It should be incorporated in part of the core training. Not just for general practice, but in thinking about my own specialty—dermatology—there is very little provision, even nowadays, for incorporating adequate allergy training in becoming a consultant dermatologist. I think it should be done at core level. If there are already general practitioners who are out there practising, then they would need to attend courses, or undertake an MSC if they had a particular interest, but perhaps one particular person within a general practice who had a particular interest in allergy could take it on.

**Dr Rosenthal:** To be completely pragmatic, given the number of hours that GPs are compulsorily required to be educated, I would have said four hours in a year would get you a fair way up the learning curve.

**Dr Hyer:** What you are asking them to do in those four hours is learn to recognise allergy because you are going to have colleagues who will take it on. I am being a bit controversial here, but I do not expect a GP to diagnose and manage a young child who may be at risk from multiple food allergies. I think thischild has a degree of complexity that validates him seeing a specialist in hospital so those four hours are
principally about recognition and sharing treatment, but I still think there is a role for the hospital doctor in actually seeing them. If you had two hospital admissions with asthma and they have multiple food allergies, surely they merit seeing Mark or another specialty or a general paediatrician to address that? I do not know if the others agree.

Professor Hourihane: I agree.

Dr Rosenthal: I agree, the principle of the training is to recognise the problem. Management is a separate issue but you cannot do management without recognition.

Q689 Chairman: I would like to just finish by asking one short question to each of you and that is whether we know what the burden is of misdiagnosis or wrong diagnosis amongst allergy in children in this country?

Dr Hyer: I can tell you from my own audit that 50 per cent of my new referrals to my allergy services, I can tell them they do not have an allergy and send them away.

That is a significant saving bearing in mind that 10 per cent of all GP prescriptions in this country are based on some kind of atopic or allergic role. I can stop that in 50 per cent of the patients where they are alleged to have food driving their atopy, overcoming some of the myths. I also believe if you make the right diagnosis you can help prevent hospital admissions and complications, etcetera. You are quite right; you can reduce the misdiagnosis if you offer the right service.

Q690 Chairman: Did you want to add anything?

Dr Rosenthal: My biggest worry is the consumption of what might be called fringe diagnostic things or “high street quackery” that may make an erroneous diagnosis of allergy and lead to dangerous management practice.

Q691 Chairman: Are systemic steroids appropriately used in children?

Dr Rosenthal: It depends who is doing the using. That is not the question I expected. All medicines have to be treated with respect, but the failure to use systemic steroids where appropriate is as big a problem as using them when they are not appropriate.

Professor Hourihane: I would say that an integrated allergy service spends more time normalising a diet rather than restricting a diet, and we take the worries of allergic disease off families by showing them or proving to them that they have not got the allergy. Effective management to address the allergic components of asthma can decrease hospital attendance by 55 per cent and medication use by 60 per cent, so there is an enormous added bonus to the NHS to invest in allergy services.

Professor Harper: We have heard that eczema is often the presenting feature so many of these children are referred to dermatologists and the severe ones often to me. It is both ends of the spectrum. I think very often allergy is under-rated and perhaps missed but there is also a drive from the parents themselves who have initiated a diet or been given advice from friends, family or someone in the high street, so it really is a subject that needs to be more expertly managed.

Chairman: Could I thank you all for coming today and for all the information that you have given us. If there is any additional information that you would like to submit to the Committee, we would receive it as part of your evidence today so please feel able to send anything in. You are very welcome to stay and listen to the next session. Thank you.

Examination of Witnesses

Witnesses: Ms Joy Winks, Chair, School Nurses Forum, Royal College of Nursing, and Ms Sarah Day, Independent School Nurse Representative, School Nurses Forum, Royal College of Nursing, examined.
really have an effect. They may be missing a lot of school either because of bad management or because their condition is not under control. Again management is down to trying to plan care. In independent schools we are fortunate enough to have a large number of school nurses actually attached to schools so we can liaise closely with parents and things are much easier whereas with the state school nurses we are signing up one nurse to 14 schools so they cannot work quite so easily.

Q694 **Chairman:** Is enough being done to help children manage allergy, particularly hay fever sufferers? I am thinking of the examination season. Is there anything that the Government should be doing centrally for such children?

**Ms Day:** I just look at it, having listened to our professionals speak, we work down on the ground level and if the management is not coming from higher up then at ground level we are picking up the bits and pieces. You could say that, no, the management is not as efficient as it could be and we have to work with the resources we have.

**Ms Winks:** I do feel that the school nurse, as a health professional in school, and one of the very few health professionals in school, is ideally placed to help schools and head teachers and staff deal with these children, but, as Sarah says, there are not enough of us on the ground as health professionals in schools.

Q695 **Baroness Platt of Writtle:** We are told that because the season for hay fever is the exam season children with hay fever quite definitely are achieving considerably less than their fellow students. What do you think ought to be done to combat that problem?

**Ms Winks:** I think the variations are huge. In some areas a child will be allowed to sit an exam at a different time or consideration will be taken of the fact that they have taken medication and in another area that does not happen. There is no consistency and I think that is the major problem. Listening to the four allergists previously it is obvious that there is a problem with standardisation.

Q696 **Lord Haskel:** There was a study published in 2003 showing that children with peanut allergy suffered a poorer quality of life and they had higher anxiety levels than those suffering from, for instance, insulin-dependent diabetes. What is being done to reassure food-allergic children and their parents about their safety while they are at school?

**Ms Day:** I would say, yes, there probably is a greater level of anxiety because we do seem to have diabetes more under our control and yet the evidence you have heard with allergies is that there is a problem with actual diagnosis or getting hold of specialist treatment. Again, the anxiety levels from parents being unable to access specialist treatment means that they will turn to alternatives where they can pay and access the facilities. Obviously I am talking about those who can afford to pay for those services, and in the independent schools we do see alternative medicines being used quite a lot. To reassure them again from our point of view in independent schools, they have a nurse on the premises, so that is reassuring to them that we do have some knowledge and are able to care and look after their children while they are at school.

**Ms Winks:** The burden of our practice in the state side is on training and supporting school staff in dealing with the allergies so we will have things like school agreements, whole-school training, protocols, and individual care plans for children and it is a very individual thing. A child in a huge comprehensive school will maybe carry their medication with them and for a child in a small primary school it will be kept in one place and all we could do is support and train, but again it is not a standard across the board because of the numbers.

Q697 **Lord Haskel:** Is there any conflict between the Government’s current Transforming School Food initiative and the needs of food-allergic children?

**Ms Winks:** There is some writing about the conflicts. They are going to provide nuts instead of chocolate and things like that. I do not feel that I can comment particularly on that, I have not read any papers or anything about it, but it would obviously be a conflict if that arose.

Q698 **Lord Haskel:** Can you deal with it just by common sense?

**Ms Winks:** A lot of it is common sense certainly. Again we have heard the experts saying that to deny all contact is not good so there is not even a consensus of opinion there.

Q699 **Viscount Simon:** How are children with asthma and anaphylaxis monitored during school hours?

**Ms Day:** They are managed mainly on an emergency basis. The children all have a care plan so that we know what they need to do in the school day and you hope that it goes well and you deal with any emergencies. Again, in independent schools they have access to nurses and boarders are obviously monitored by the school nurses, maybe with peak flows for asthma, who can look at skins for eczema and rashes and refer easier. This is a problem again for the state schools who do not have health care professionals on a daily basis.

**Ms Winks:** It is exactly the same, as I said before, that there will not be a nurse on site in the majority of the mainstream schools and so it is about training the staff and helping them, supporting them, making sure that they have the knowledge and the skills. There
was an Audit and Healthcare Commission report about how schools deal with obesity in February last year, and I know obesity is different but it is still a health problem and the heads there recognised that they do not have the knowledge and the skill to deal with that and teachers said in that report that the lack of health professionals in school was a barrier, and it is exactly the same for the allergic children; it is a barrier at ground level.

Q700 Viscount Simon: What is the role specifically of the school nurse and teacher when there is an allergic emergency? How do they cope?
Ms Winks: The nurse in the mainstream state schools will not be present.

Q701 Viscount Simon: Teachers?
Ms Winks: So the teacher and the staff in the classroom or the dinner ladies, whoever is actually present, will have been taught and trained and practised with a dummy EpiPen, if it is an EpiPen, or knows that the child had an inhaler and they will follow the child’s individual plan.
Ms Day: I would probably say a high degree of anxiety at each emergency, whether it be for the teacher or for the nurse because it is a life-threatening condition, and you have the protocols and you have your training but it is not something that you are dealing with every day and, like everything, there is a high level of anxiety to get them to hospital care as quickly as possible.

Q702 Lord May of Oxford: What actually is the incidence of these sorts of happenings because you have just heard Dr Rosenthal talk about—or in fact maybe I read it in this—the countless EpiPens he has prescribed and he is only aware of one of them being used. What are we talking about here with people having to use an EpiPen at school? Once a year, once every few years, once a month?
Ms Winks: In my experience I have never known one used and I am from a large city.
Lord May of Oxford: This is a not irrelevant problem.

Q703 Lord Rea: In fact, do you feel that school nurses are sufficiently well-informed on how to deal with emergencies?
Ms Day: I would say probably on emergency training as nurses if we are giving vaccinations we are expected to have anaphylactic training every year. However, there are not any standards that I am aware of across the nation as to the exact amount of training we should have so it varies again from individual nurse to an individual area as to what training you are actually getting. At the moment accessing funding to training is a problem both across the state and independent sector.

Ms Winks: Virtually across the nation at the moment school nurses are not being allowed to go on training, even the training for their specific degree course, for their professional training; places have been cut.

Lord Rea: This is rather different from the evidence we have had.

Lord May of Oxford: It is just as well they are not using the things that they need to be trained for that they are not being trained for, is it not?

Q704 Lord Rea: We heard evidence from Mr Wells from the Department for Education and Skills that “any nurse who administers an immunisation in a school setting will receive anaphylaxis update training on an annual basis. That is a requirement of their own continuing professional development.” Is this an aspiration or reality? Who provides the training?
Ms Day: Where you can get it from.
Ms Winks: Some primary care trusts provide the training in-house and that is why we still get it. I am fortunate that I come from a city with a children’s hospital and so we access the allergists for our anaphylaxis training, but it will be done in-house so, yes, it is right we do have to do it and anybody administering vaccinations will have that training, that is standard, but it will be in-house.
Ms Day: Again, as independent school nurses we do not have any line management or medical management as such so we are having to buy into services all the time for training. Obviously each nurse is accountable but it can be a problem to try and access into the training courses depending on where you are.

Q705 Lord Rea: Could you explain again what you mean by “buy into”?  
Ms Day: We have to pay for our training so that we can practise because we do not come under the NHS, we are employed by the schools.

Q706 Lord Rea: So it is the Department for Education and Skills who pays?
Ms Day: Yes, our school environment will pay for our training.49

Q707 Lord Colwyn: But when you give a vaccination I assume you know which ones are slightly risky and which ones are not?
Ms Day: With any vaccination anyone can react at any time to anything. Obviously there are protocols and guidelines for vaccines but anybody having a vaccination could react at some point, in theory.

49 Following the evidence given by Ms Day, the Royal College of Nursing wished to clarify this statement. The Department for Education and Skills is not responsible for training, but nurses employed by local education authority schools may get funding from the DfES. For further information please see the supplementary evidence from the Royal College of Nursing.
Q708 Lord May of Oxford: I gather that in 2005 the Department for Education and Skills produced a guidance document for schools—and they are very good at producing documents—called “Managing Medicines in Schools and Early Years Settings” suggesting that children with particular medical needs should have an individual health care plan. Who actually draws these plans up and do you think that the following through to make sure that all staff are aware of them is as it should be?

Ms Winks: No, it is not as it should be. There are again huge variations across the country. From my own experience of school nurses it is in their core programme which is agreed with the Education Committee that we do other care plans and we do that and the schools will have a process for staff knowing which children have got care plans.

Q709 Lord May of Oxford: Do you think the document itself is satisfactory? I spent five years, in a curious way, as a civil servant and I found some of the things quite useful and some of the things were a most tremendous waste of paper and effort (although it did provide employment)! Do you think this particular document is a good and useful one?

Ms Winks: It is useful but I do not think it was ever meant to be used in its entirety otherwise you would waste an awful lot of time and paper. Because it is an individual care plan you are expected to pick out the individual parts of it. A health professional is definitely at an advantage when you are trying to pick out what is necessary.

Q710 Lord May of Oxford: How aware are parents of this and what sort of interactions do you have across the range of parents, who I imagine can range from those who are insufficiently concerned to those who are excessively concerned?

Ms Winks: We totally work with the parents; we have to, they are the experts in their children.

Q711 Lord May of Oxford: What is your experience of doing that? Does that seem to you to work well on the whole?

Ms Winks: Like I say, there is a huge variation. We will have to do home visits on some to get the care plan done. Others will come into school willingly or meet at a health centre. Obviously if a parent is not going to help you with it, you can end up looking at the child protection side of things because there is a need for that child to access school, so you need to work in partnership with people from education and other areas.

Q712 Lord May of Oxford: But on the whole you feel this thing is working okay, this particular bit of the whole thing?

Ms Winks: There are huge variations. It will be working very well in some places and not in others. They may not know where to find it on the bookshelf in some schools.

Q713 Chairman: How much is the influence of the parents’ use of complementary practitioners outside the NHS impacting on your drawing up of care plans with the parents?

Ms Winks: If I have to say in the mainstream state side it is not something that I have come across or something that I have heard nurses up and down the country talking about.

Ms Day: I think in the independent side you go with the parents and if you are finding that that treatment is not working, as a health professional you can recommend other areas or perhaps turn back to the medical side and advise them where to go, so that is more on an advisory state but it is a question of managing. The problem as well, as we have heard before, is the communication down from specialists. We rely on the parents. We are not jumping straight to their GPs or straight to a specialist practitioner and we find it very difficult to access perhaps all the right information on which to make a validated care plan for the children. In boarding schools as well with an increasing number of overseas students obviously communication there is a real problem. We have language barriers as well as cultural differences and whereas we might say that the instances of peanut allergy are not high they do have a lot of rhinitis and hay fever and other allergies which we are trying to manage.

Q714 Lord Selborne: I would like to come back to EpiPens, which we talked about in the earlier session as well. You have already told us that they are very rarely used in your experience or the need rarely arises, but we are also advised that they are prevalent and they are widely prescribed, so there must be quite a lot of them knocking around the schools and there is not a school nurse in the maintained sector, so it is going to be the teacher ultimately on the rare occasions when it is used who will have to supervise it. We have been told by the Government that there is no reason why the teacher should not deliver these EpiPens. Do you think that this is appropriate and do you think they are stored appropriately in the school environment?

Ms Winks: There is absolutely no reason why anybody should not administer it if they actually are there. There will be a protocol for somebody staying with the child and somebody going and fetching the EpiPen if it is held in a certain place. There is no reason at all why a teacher should not administer it, but then there is no reason at all why a dinner lady or a caretaker should not administer it either. It will depend on who is at the scene at the time. As for
storage, it varies hugely. In small schools they tend to be kept in one place and the staff know exactly where to go and they send a runner. In a huge comprehensive on different sites you cannot possibly do that, so the young person is usually encouraged to carry it with them.

Q715 Lord Selborne: Are there national guidelines which would be easily available?

Ms Winks: The Anaphylaxis Campaign do issue some guidelines and they can offer training, if people can afford to buy it, so there are some but it is only from the charity, the Anaphylaxis Campaign. As far as I know, there are not any national—

Q716 Lord Taverne: Can I come back to your earlier answer. You say you have never actually known of a case in which it has been used. That is over how many years and with how many schools?

Ms Winks: I have been a school nurse in Sheffield, in a large city, for 15 years and we had very few EpiPens when I first started, in fact it was not something that we encountered, and gradually over the years we now have a lot of EpiPens.

Q717 Lord Taverne: So how many schools would that cover? In 15 years you have never known one used?

Ms Winks: There are 70,000 school children in Sheffield.

Q718 Lord Taverne: Over 15 years they have never been used to your knowledge?

Ms Winks: No.

Q719 Lord Selborne: I wonder if Sarah Day can tell us whether you think in the independent sector they are more prevalent or less prevalent.

Ms Day: I have a school of 400 pupils and six have been prescribed EpiPens, and that is various ages. The youngest is five with an EpiPen up to the oldest being 18, mainly for nuts, but also for a bee or wasp sting for one of them. None of those have actually had anaphylaxis to then be prescribed an EpiPen at any time. That comes to the attitude that sometimes it can get a bit like asthma where they do not carry their EpiPens with them because they do not know what it is like to experience something, so perhaps we are prescribing when they do not need it, I do not know. Or maybe it is better to have something there for emergency rather than nothing at all. I would like to suggest something because if you think about it you have schools which have got all these EpiPens flying around everywhere, and it is the same with Ventolin inhalers, which you may know are for asthma emergency care, and if every pupil with asthma and anaphylaxis are prescribed then the schools are loaded with drawers full of inhalers and EpiPens which need to be accessible; there is no point in locking them away otherwise they are not accessible. Because they are a prescription-only medicine there is also an issue that you cannot have a stock, so for our premises where there is a school nurse or even in the state school it would be good to be able to have an EpiPen and a Ventolin inhaler for emergency use but we cannot because they have to be on a prescribed basis for a prescribed patient. I think that is something that could be looked at for schools in order to prevent a lot of expense to the NHS on prescriptions and it would be quite a simple thing to enable schools to do.

Ms Winks: Wherever there is a medical practitioner or nurse on site then you could do that, but it would be a different ball game for a teacher to be making a decision to use a stock bottle of something.

Q720 Lord Selborne: We have heard from the Anaphylaxis Campaign that they have suggested that generic auto-injectors should be available in schools where there are severely allergic children, and that would be available for any child who might need a second dose. In the light of what you have told us I suspect that you would feel that that is unlikely to be needed on the whole.

Ms Day: It is the question of unknown, is it not? We may not have experienced it but other people have and every year a child dies from either anaphylactic shock or asthma.

Q721 Lord Selborne: You think it would be a good idea?

Ms Day: I think it has to be there and it is being able to recognise the symptoms in an emergency and that this child needs treatment straight away.

Q722 Lord Selborne: How long does an EpiPen last in storage? Can you keep it indefinitely?

Ms Day: No.

Ms Winks: They do have dates on them.

Ms Day: 18 months to two years max.

Ms Winks: It will be a part of your protocol to check.

Lord May of Oxford: I can see that being a tension with the manufacturer who wants a short date.

People do over interpret the dates on these things and from my understanding of the functioning of the EpiPen I am at a bit of a loss to see why there is a date of 18 months.

Q723 Chairman: Do we know the evidence of when it actually does deteriorate?

Ms Day: I do not know.

Lord Colwyn: I have an EpiPen in my medical equipment and I have to replace it every 18 months or two years.

Lord May of Oxford: I am asking a different question.
Q724  Lord Colwyn: It is expensive. In these days of increasing litigation doctors tend to over-prescribe rather than under-prescribe and I think your idea of having a school store of asthma inhalant and an EpiPen is a very good idea. I am surprised that you cannot do that, I did not know that.
Ms Day: No you cannot. It is a prescription-only medicine so it is a different legal issue.

Q725  Chairman: It was the Anaphylaxis Campaign who also told us that they felt the Government was not adequately training school nurses, so it is developing a training programme which has been piloted around the UK. Do you think it is necessary for them to do this and that there is indeed a need for them to do this nationwide?
Ms Day: It certainly would be good to have a standard nationwide.

Q726  Baroness Platt of Writtle: The Government have also told us that it is the responsibility of the head teacher to assess and monitor whether teachers or support staff are capable of dealing with allergic emergencies. Do you think that is appropriate and is this monitoring being carried out?
Ms Winks: I think the head teacher obviously has the ultimate responsibility for the children within the school but they would not have the knowledge or the skill to be able to say that people are adequately trained. They would be looking to be working in partnership with somebody from the NHS and obviously the school nurses at the moment are virtually the only medical people that go into the schools, and so we are the link between the school and the specialist and anybody who is training.
Ms Day: The head teachers are academic. I work in an academic environment all the time and there is a lack of understanding about the medical and the educational side. To put the emphasis on teachers and head teachers all the time to meet government health targets is very unfair. They have enough to worry about with the academic side. I think there is a lot more we can do to help.

Q727  Baroness Platt of Writtle: What further training is needed for school nurses, teachers and—as you have mentioned several times—dinner ladies, in the management of our allergic children? You have also mentioned cuts?
Ms Winks: Obviously I am going to say that if we had more school nurses we would be able to do more on the public health side. Anaphylaxis is not the only aspect. We are quite high on the Government's agenda. We are in most of the documents to do with public health in schools—extended schools, teenage pregnancy, obesity, all those things—and at the moment we just do not have the capacity. The RCN did a survey, which I think you have, to say that whereas the Chief Nursing Officer's review said that there should be one school nurse for every comprehensive and its cluster, the survey shows only one to 14 schools, and that is qualified school nurses.

Q728  Lord Rea: I was just simply going to ask what is the overall deficit in school nurses compared to the establishment that there should be? Do we have any information on this?
Ms Winks: The only information that we have is the Royal College of Nursing survey that was done which said that a school and its cluster (which would be one and maybe five primary schools) should have one whole-time full-time school nurse, and the evidence is that there is one to 14.

Q729  Chairman: Thank you very much indeed for coming up today. I know you sat in during the earlier session. If there is any additional information that you would like to send into the Committee, then please feel free to do so and it will be considered as part of your evidence. You will also be sent the transcript for you to look through and perhaps correct if you feel that you have been inaccurately transcribed. Thank you again for coming.
Ms Winks: Thank you very much for inviting us.

Supplementary memorandum by the Royal College of Nursing

Training budgets

Committee members were interested in the annual anaphylaxis training that school nurses receive and inquired about who has primary responsibility to provide training for school nurses. Whilst it is the responsibility of each individual PCT to ensure that school nurses receive their statutory training requirements the RCN has concerns that, as posts remain unfilled due to financial deficits, many specialist nurses such as school nurses are finding it difficult to be released for essential training updates. A recent RCN survey showed that almost a quarter of school nurses were unable to take time off to undergo further training, with a lack of career progression proving a problem for three quarters of nurses.
In a survey undertaken by the RCN in October 2006 we found that 83 per cent of nurses believed training has been reduced or cut as a result of financial pressures in the NHS and over 38 per cent of nurses had study leave cancelled. Whilst these figures apply to the entire nursing workforce reports from our school nurse members reveal that financial deficits have impacted on school nurses accessing the training that they require.

**Emergency Medication Stocks**

Our Independent School Nurse representative, Sarah Day, made a recommendation during the evidence session that schools could keep an emergency stock of inhalers and epi-pens instead of holding an individual supply for each child. This was suggested as an alternative to schools holding a large supply of individually prescribed medications which by their nature need to be easily accessible. However, as medication such as ventolin inhalers and epi-pens are prescription only medications, required to be prescribed to an individual, it would prove difficult in the current environment for schools to hold a stock supply of emergency medication.

The current difficulty is that medication is prescribed on a patient specific basis and once this has been done it would be illegal to use prescribed medication for someone else. To enable school nurses to prescribe and administer from an emergency stock of medication they would be required to train as independent nurse prescribers or work under a clinical management plan as a supplementary prescriber for each child. This would mean that a smaller emergency stock of medication could be kept on site and a school nurse could prescribe the medication to the child in case of emergency. This could work very effectively in the independent sector or in special schools where there is generally a registered school nurse on site. However, in the state system where there is not a registered school nurse permanently on site, it will continue to be necessary for a stock of emergency individually prescribed medications to be kept on school premises for administration as per the Department for Education and Skills guidance on managing medicines in schools and early year’s settings.

*April 2007*
ABOUT YORKTEST

YORKTEST Laboratories Ltd is a specialist provider of food allergy and food intolerance testing, direct to the general public, and has helped thousands of people find relief from chronic health conditions during the past eight years. It uses a food-specific IgG food intolerance test to identify food intolerances which could be the cause of an individual’s ill health symptoms. This particular method was subject to scientific scrutiny in a recent clinical trial which was published in Gut Journal. A clinical research study is also due to be published shortly in the International Journal of Nutrition and Food Science.

YORKTEST has worked hard to scientifically validate its testing services and has a number of ongoing collaborations with patient groups (Allergy UK, Action Against Allergy, IBS Network, Migraine Association) and clinicians in order to further explore the area of food intolerance. There is no doubt that the mechanisms involved with food intolerance are not totally understood. However, there is very clear evidence which supports the fact that food intolerance can cause negative health symptoms and relief can be found from these symptoms once the offending foods are removed from the diet.

The area of food intolerance, as with many areas deemed “complementary” health, suffers with a negative image. Many providers of such services, some mass available on the high street, do not use scientifically validated or clinically proven tests and are therefore unlikely to offer their customers any relief from negative health symptoms nor do they provide any health benefit.

YORKTEST is keen to differentiate itself from the non-scientifically validated service providers.

YORKTEST holds three SMART awards from the DTI, both ISO9001:2000 and ISO13485:2003 Quality Management Certificates, and the Food Allergy and Food Intolerance Testing Services they offer are fully compliant with the European In Vitro Diagnostic Directive 98/79/EC Annex III, Section 6 (self-test) which includes the Design Examination by the Notified Body (UL International). YORKTEST also holds the Queen’s Award for Enterprise: Innovation. Despite these accreditations YORKTEST often finds itself grouped with the less reputable organisations and still finds resistance from GPs or clinicians whose patients are interested in exploring YORKTEST further. YORKTEST understands this attitude as there are many examples of non-reputable providers. However, the lack of regulation (or the lack of policing of the existing regulations) could actively be preventing people from finding relief from their ill health symptoms because of the lack of differentiation within the industry.

Q: What impact do allergies have on the quality of life of those experiencing allergic disease and their disease?

Food intolerance, as with all types of allergy can have a negative impact on an individual’s quality of life. Many people who turn to YORKTEST have suffered with chronic conditions for many years and have found very little relief.

Chronic conditions can result in time off of work, numerous visits to the GP, and costly prescription medicines or OTC medications. From a personal perspective many people find that chronic conditions can negatively affect their social lives or ability to participate in sports or other activities.

The all encompassing nature of many chronic conditions means that people often turn to private services in an attempt to relieve their symptoms which seem unaffected by traditional methods and treatments. People simply become desperate and are keen to try anything which offers hope. However, it is important that this “hope” is regulated in order for people to identify whether it is false or has some scientific basis.
Q: Are current regulatory arrangements, for example those governing private clinics offering diagnostic and therapeutic services and the sale of over the counter allergy tests satisfactory?

— The MHRA, an agency of the Department of Health, is responsible for regulating the safety, quality and performance of self-test kits. The transposition of the European IVD Directive 98/79/EC (IVDD) and European Medical Device Directive 93/42/EEC (MDD) into UK law was enacted by a statutory instrument which in turn updates the 1987 Consumer Protection Act—and as such is criminal legislation. Food Allergy and Food Intolerance tests and testing services clearly provide information regarding pathological/physiological conditions and thereby are included in the IVDD definition of in-vitro diagnostics.

— During 2004 the MHRA and the Notified Bodies jointly decided that, not only IVD products, but also IVD testing services, supplied direct to end users (consumers) without the involvement of a healthcare professional are designated as “self-test” thereby requiring Notified Body (eg LRQA, UL, SGS) audit of the technical files, and approval prior to registration and placing on the market.

— Direct to consumer “self-test” testing services have had to be in compliance with the IVDD, including successful Notified Body audit and approval, since 7 December 2005.

Despite these laws and regulations being in place to (supposedly) protect the consumer, there are many providers of such services who do not use scientifically validated or clinically proven tests and are therefore unlikely to offer their customers any relief from negative health symptoms nor do they provide any health benefit.

YORKTEST would welcome more regulation in this area and believes that it is a vital step in the provision of allergy services. In addition to the commercial implications YORKTEST believes quite strongly that the consumer requires protection in this area. It has been identified by the Government that allergy is an unmet need in the UK. The Government is struggling to cope with patients suffering from classical allergy symptoms; food intolerance isn’t even on the radar. Many people frustrated by their symptoms seek help from sources such as private testing services. These individuals are often desperate to find relief having suffered for many years with chronic conditions. The lack of regulation combined with a lay person’s inability to differentiate between these services means that the consumer often pays large sums of money to organisations which are in no way scientifically validated.

Examination of Witnesses

Witnesses: Dr Gill Hart, Technical Director, YorkTest Laboratories Ltd, Mr Richard Gutowski, Head of Compliance and European Business for Medical Devices, MHRA, Ms Helen Young, Executive Clinical Director and Chief Nurse, NHS Direct and Mr Andrew Dillon, Chief Executive, NICE, examined.

Q730 Chairman: Could I start by welcoming those who have come to give evidence to us and members of the public who have come here today for our 11th public hearing of the inquiry into Allergy. There is an information note in which all members of the Committee declare their interests so we will not be repeating those today because they are on the record already. I wonder if I might start, I am Lady Finlay, I chair the Sub-Committee inquiry and I wonder if I might start by asking you to introduce yourselves and then we will go into the questions. During the questions it will be really helpful if you can keep your answers as tight as possible because we have got a lot of questions that we want to ask you, it means that we can get through them, otherwise we will have to stop. The other thing is that the acoustics in this room are not very good, so please speak up and speak clearly, this is being webcast. Please start, Dr Hart.

Dr Hart: I am Dr Gill Hart. I am the Technical Director at York Test Laboratories Ltd and I am a biochemist with expertise in the development of diagnostic tests.

Mr Gutowski: I am Richard Gutowski from the Medicines and Healthcare Products Regulatory Agency which is an executive agency in the Department of Health and I have responsibility for compliance issues relating to medical devices.

Ms Young: I am Helen Young and I am the Clinical Director and Chief Nurse for NHS Direct which, as the Committee will know, is the telephone, web and digital television service for the NHS.

Mr Dillon: I am Andrew Dillon and I am Chief Executive of the National Institute for Health and Clinical Excellence.

Q731 Chairman: Thank you very much indeed. I wonder if I could start by asking you what types of allergy self-testing kits are available to the public and where they can be obtained?

Dr Hart: I can just speak about the services that York Test provide. York Test provide an allergy screening test, which is an IgE test for allergy, direct to the public. The public have a sample taken, a full blood
draw by their GP or phlebotomist, the sample is posted to us and we run it on a test in our laboratory. In addition, we provide a service for IgG testing, a service direct to the public, again a sample kit is sent out to the general public, they provide the blood sample, post it back to the laboratory and we provide the results. We are very aware that this is a huge responsibility in that we do not provide the consumer with healthcare professional involvement and we have taken this very seriously, so much so that we have put our testing services through the same route as would be applicable to a self-test kit which was on the shop floor in Boots and we have put it through that regulatory procedure which I can tell you more about later.

Q732 Chairman: Mr Gutowski, do you have anything to add to that?
Mr Gutowski: Yes, I have. The majority of allergy test kits are called skin prick tests and the substance in the test kit is inserted into the body to produce a reaction and these kits are in fact regulated as medicinal products.

Q733 Chairman: They are not self-tests, are they?
Mr Gutowski: No, they are medicinal products and they are prescription only medicinal products, so they are not available to the public unless the GP initially writes a prescription, but, in the main, they are used in testing laboratories either in general practice or in hospitals. There are allergy test kits which are regulated as medical devices, and I will come onto the distinction later because I think there is a separate question on that, and these are in the main used by testing services as you have just heard and we are only aware, and this is from our intelligence, of one of these kits being available to the general public over the counter. Most of these IVD test kits are used by testing services where the patient will send the sample to the testing house and either he will receive the results back or his general practitioner will.

Q734 Chairman: Dr Hart, when you do IgE testing, do you send that result back to the GP?
Dr Hart: We give the customer the option of having the results sent back to the GP or not and in most cases they choose not to have their results sent back to their GP. In putting the services that we provide through the IVD Directive as a self-test testing service, we have given evidence to the notified body that represents the MHRA which shows that the lay user in this case can interpret the results that we provide, or has the MHRA’s approval that the lay user can interpret the results that we provide and act upon them on their own without healthcare professional involvement.

Q735 Chairman: I wonder if I could ask Ms Young and Mr Dillon whether NHS Direct recommend the use of any self-test kits and whether any have been subject to a NICE appraisal?
Ms Young: From NHS Direct’s perspective all that we would offer in this particular area is health information advice in relation to evidence that exists that a call or a visit to the website could access to make a judgment about what type of product might be suitable and what type of questions they may wish to ask their general practitioner. We do not make specific recommendations to a particular product, we would simply advise and give information on specific questions that were asked of us.

Q736 Chairman: Are there any self-testing kits or concepts that you are advising to patients who clock on with allergy?
Ms Young: To the best of my knowledge most of the information on our website and that we would advise on is based on the referral to either a specialist, or, indeed, through the general practitioner.

Q737 Chairman: Mr Dillon?
Mr Dillon: No, is the short answer to your question.

Q738 Lord Colwyn: I am muddled about self-testing. Self-testing to me means something that the patient does themselves. Can you explain it?
Dr Hart: Absolutely. Self-testing in my definition is when a consumer receives a result, whether it be at home in doing the self-test kit that they bought in Boots or whether it be the provision of a result given to that person from a testing laboratory. My interpretation of the regulations is that they should both be regulated as self-testing services because no healthcare professional is involved. I think there is great confusion about the distinction between the allergy kit or the pregnancy kit that you buy in Boots compared with the testing service result that the consumer can also access very readily over the Internet in Holland & Barrett and various other places where people can get allergy and food intolerance tests which do not appear to be fully regulated.
Mr Gutowski: If I could add something to that, it may be of help. The concept of the self-test kit is enshrined within the medical device regulations and it is based on the concept that the test is carried out by a lay person in their home environment, so they would take the test, whether they have been given it by a general practitioner or purchased it over the counter, whether it be an allergy or a pregnancy test kit, they will do the test at home and the kit itself will give them a result at home with instructions that came with the kit as to how to make a determination on the basis of
a colour change or whatever as to what the results of that test is.

Q739 Baroness Perry of Southwark: Do those definitions include any distinction between whether you read the result of your test yourself at home as a lay person, or if you send the sample away and somebody expert gives you the result?
Dr Hart: I understand that in 2004 the MHRA and notified bodies jointly decided that not only IVD products, that is the kits, but also IVD testing services are the direct end users or consumers without the involvement of healthcare professionals are designated self-tests and it is my understanding of the regulation that the CE marking for these services was given a two year extension from 2003 to 2005, so from 7 December 2005 all testing services that provide results back to lay users should be equally regulated as the kits that can be bought in Boots. I think that is what should happen, it is something that we comply with at York Test, but it is not common practice.

Q740 Chairman: You did speak about people being able to go on the Internet and get things from Holland and so on. Are there European regulations in this area?
Dr Hart: This is the European In Vitro Diagnostic Device Regulation which is what we incorporated into the 1987 Consumer Protection Act.

Q741 Chairman: Is your implication that the European regulations are not as tight as the UK ones?
Dr Hart: There is confusion within different competent authorities within Europe, my understanding is, of how the regulations are interpreted and even within the notified bodies within the UK.

Q742 Baroness Perry of Southwark: Can you explain to me as a lay person how the IgG food allergy test works, given that people who are not allergic to specific foods can still produce an IgG antibody response when they eat those foods?
Dr Hart: I think when we consider the antibody response to an antigen challenge we need to really think that the antibody response is only the first part of the whole reaction. The presence of antibodies, and this I believe is true for IgG and IgE, does not necessarily mean disease or no disease. What does make a difference is the complex cascade of events that occurs after the antibody has been raised and what we find is that we use the IgG as a marker that a reaction has occurred, but that does not necessarily mean that the reactions could provide a cascade resulting in disease. We know that the mechanisms for this are unclear and as a company we have tried to support and collaborate with groups to find out more about these mechanisms. Indeed, we have provided tests to a leading London hospital who have now shown, and this is evidence that is going to be presented in Digestive Disease Week in Washington in May, that in inflammatory bowel disease there is significantly higher IgG titers than in normal groups and this is the first time this has been shown. In addition, the group has also shown independently, using our test, that people’s reported food sensitivities, i.e. filling in a questionnaire saying what am I sensitive to, correlates very very well with the IgG levels and this is particularly in ulcerative colitis. It is very preliminary research and it is something that we really hope the team at this London Hospital will build on. We have struggled working with others to get grants to do this sort of work, but we really want to encourage the understanding of these mechanisms which we know are not yet clear.

Q743 Baroness Perry of Southwark: How often do you find negative results?
Dr Hart: Yes, of course. We provide a food intolerance indicator test. Bear in mind that the people that come to York Test have chronic conditions. Our recent survey data, which we published, showed that over 70 per cent of the people have suffered for more than three years with their condition, so it is not a normal population that comes to York Test. What we find is that between 75 and 80 per cent of those people will have at least one positive scoring to one of our 113 foods.

Q744 Baroness Perry of Southwark: Perhaps I could ask the other members of the panel, I understand that the IgE antibody tests are an established part of NHS diagnostic routines, is there any evidence to support the use of IgG antibody food tests?
Mr Dillon: I am sorry, I have no information to answer the question. NICE has not looked at that particular area.
Dr Hart: For me, to support the use of IgG test, yes there have been independent clinical trials which have been carried out and published. This key one, is the double-blind placebo controlled trial published in Gut in 2004 by Atkinson, which was an independent study but used the York Test test. There has been a study recently published in Nutrition and Food Science, another in Headache Care and, indeed, the recent study that has been carried out using the York Test test commissioned by Allergy UK, and independently audited by the University of York, used by 5,286 of our consumers has shown that people who rigorously adhere to our diet, three out of four of those people are showing some benefit to their chronic conditions, so a considerable amount of data. We know ourselves as a company that we do
not do a lot of aggressive advertising, we cannot do that and the company has grown mainly on word of mouth because people are showing benefit and we see every day that there is, as we know, unmet need, and people are suffering and are then seeing benefit by using our service.

Q745 Lord Soulsby of Swaffham Prior: Can I be clear that with these tests you are measuring the molecules of IgG, you are not measuring specific IgG or IgE, are you?
Dr Hart: We are measuring food specific IgG in our IgG tests.

Q746 Lord Soulsby of Swaffham Prior: When you say, “food specific”, what foods are you looking at specifically?
Dr Hart: We have a range of different services but the main one is 113 different foods. The test that we use is an Elisa test methodology, so you can imagine that purified food preparation put onto one of our Elisa plates is a mixture of proteins, of course whole milk will be a mixture of different proteins. Unfortunately, in our business it is not like measuring thyroid function test where you have got a beautiful international reference preparation, all laboratories are controlled, you know exactly what they are measuring, you know the normal ranges, we have not got the luxury of our higher order standards, the international reference preparations. So that putting the foods on the plate we have got a wide range of fruits, vegetables and the key foods on the plate, that is what we use.

Q747 Lord Cobwyn: I do not particularly want to concentrate on Dr Hart all the time, and I apologise to the others, but you mentioned the report commissioned by Allergy UK, we have got a copy of it here, I wonder if you could tell us if it is published? Is it being shown in a professional journal yet?
Dr Hart: It was published at the beginning of February in the Journal of Nutrition and Food Science.

Q748 Lord Cobwyn: You talk about “chronic medical conditions”, but it is quite unspecific.
Dr Hart: That is the interesting area in terms of the type of people who come to York Test with chronic conditions. As you can see from the paper it clearly outlines the different sorts of conditions that people do come with and because I understand that in the medical community people are used to looking at specific conditions, it is very difficult to sometimes understand the concept that one or two different factors like removing food from the diet could benefit a range of conditions.
under the medicines Act granted by, in the UK, the MHRA. If it is placed on the market as an IVD, the regulations are slightly different in that the manufacturer affixes a CE mark of conformity, having gone through the various processes laid down in the regulations. If it is a highly critical test, he must have an EC certificate of conformity from what is called a notified body. That is, a third party independent certification organisation and they are designated by the competent authorities in each Member State. Unlike the medicines legislation, the medical devices legislation is based on mutual recognition so a manufacturer based in Greece can CE mark his test kit in Greece and that has access to the European Community. Each of the notified bodies is designated for competence in this area of allergy test kits. They must prove to their designated authority that they have the competence to assess those kits. I am informed that there are 80 notified bodies across Europe, but only 18 of those have the competence to deal with allergy test kits.

Q752 Baroness Platt of Writtle: Allergy tests using techniques such as hair analysis and electromagnetic field detection, we understand, are not covered by the medical devices regulations. Do you think that the scope of the regulations should be broadened to include these products too?
Mr Gutowski: I am not too sure as to why they are not included. If they meet the definition of a medical device and an IVD, they would be included under the regulations.
Dr Hart: There seems to be confusion still as to the provision of a kit that somebody uses at home to interpret results and a testing service. What we are talking about is Vega testing and others. Those are not kits that people have at home use and interpret the results on their own. They go into a shop or a clinic and have that service provided without the aid of a health care professional. That is the area that there is confusion over at the moment. My interpretation of the IVD Directive was that testing services were covered by the IVD Directive for self-test and that is how I have put through our compliance, but it is quite clear that that is not happening. This is not being policed and I think it is very important that it is regulated in future.

Q753 Lord Colwyn: Anybody who provides a self-testing system or a system that goes off to be analysed and charges money for it will eventually come under the scrutiny of the press. I remember my friend, Stephen Davis, who used to do hair testing, having terrible trouble with apparently two lots of hair from the same person producing totally different results. Has this happened to you? Is it likely to? How do you cope with it?

Dr Hart: Yes, it happens to us. Essentially, we comply with the essential requirements of the IVD Directive which is all to do with fitness for purpose. It includes looking at analytical performance data of specificity, reproducibility, cross-reactivity and sensitivity and, from my point of view, also clinical efficacy because I think not all IgG tests are the same. There is a very fine balance between the positive and the negative and whether they are measuring specific or non-specific binding. It is very important that there is regulation. We do comply with essential requirements of the IVD Directive and under that we have to look at reproducibility. Yes, we have been scrutinised and questioned about this but we have evidence to show that our test is reproducible.

Q754 Lord Colwyn: You survived?
Dr Hart: Yes, and we are here still.

Q755 Viscount Simon: How often is NHS Direct contacted about allergy related conditions and what are the most common queries sought?
Ms Young: The difficulty for NHS Direct in answering that specifically is that the service is symptomatic based. In other words, when a caller or a person activating the website makes contact with us, they are presenting us with their most common or urgent symptom. What I have tried to do in answering this question is to attack it from both directions. We estimate that we receive over 600,000 calls per month to the service and probably in excess of a million hits to the website per month. Of those calls, for instance, allergies might present as either severe breathing difficulties or difficulties with an airway. Those two particular groups will probably lead to an urgent 999 call if the caller was in difficulty. The other allergy related inquiries that will present as wheezes, rashes, nasal congestion et cetera, again dependent on seasonal differences. All of those calls are likely to be or could be allergy related. We have four specific algorithms that are launched directly as a result of a caller saying they are calling in relation to an allergy query, two for adults, one for a toddler and one for a child. We have hard data on how many times we launch those algorithms. Interestingly, those numbers are significantly lower than I expected to report to you. For instance, those four algorithms that I have mentioned—two adult, one toddler and one child—are only launched approximately 2,000 times in a year. That is not helpful to you because clearly that is masking the fact that the calls that are about wheezing, breathing difficulties, nasal congestion are likely to be allergy related. We have anecdotally looked at what nurses are doing and what types of calls they are taking. Anecdotally, I am going to report that about 50 per cent of the calls that we take that either turn out to be allergy related...
because the caller says they are, or turn out to be allergy related because we assess them as so are related to allergies in direct response to taking medication. The other 50 per cent can be broken down into allergy reactions and are likely to be due to food, non-food such as substances used in the environment or seasonal differences such as hay fever and pollen. All of these combine with problems with nasal congestion, eyes, rashes, et cetera. Above and beyond that, I can give you a breakdown of the allergy related algorithms that we launch. We see 75 per cent of the calls that we take pertaining to adults over the age of 17 years. 14 per cent of the calls that we are taking in relation to allergies are bracketed within the 5 to 16 year old related callers and about 12 per cent pertain to those calling where the child would be under the age of four. That is as comprehensive an answer as I can give you based on the type of service that we are.

Q756 Viscount Simon: I understand the 999 response you have given but how do your staff recognise a condition such as anaphylaxis and drug hypersensitivity reactions and how is the adequacy of their advice audited?

Ms Young: We absolutely recognise life threatening symptoms and those are the ones that can go to 999. Whatever the call of the life threatening symptom, it may well go to 999. Anaphylaxis is an issue that we would obviously be able to assess. In some cases we will give what I will loosely call first aid advice there and then to alleviate the condition in waiting for the ambulance to arrive or in waiting to get to an urgent GP or vice versa. In relation to how we assess our performance, our success and our clinical effectiveness, all our calls to NHS Direct are recorded and subject to peer review. A selection of the calls our nurses take will be peer reviewed by a supervisor and usually another clinician. We do pick up where the practice either needs to be improved or where we have it wrong or where a nurse had indicated that we have gone down one algorithm. We do pick up where the nurses take will be peer reviewed by a supervisor and subject to peer review. A selection of the calls our performance, our success and our clinical effectiveness, all our calls to NHS Direct are recorded and subject to peer review. A selection of the calls our nurses take will be peer reviewed by a supervisor and usually another clinician. We do pick up where the practice either needs to be improved or where we have it wrong or where a nurse had indicated that we have gone down one algorithm. We just check that it could not have been something else.

Q757 Chairman: On the NHS Direct website, am I right that there is advice on peanut avoidance for pregnant mothers and infants from families with a history of allergies?

Ms Young: Yes.

Q758 Chairman: I wonder why that is still there and what evidence there is, given that that is now disputed advice?

Ms Young: I do not specifically have evidence in front of me today to refute that or reply to that but I am willing to submit some evidence. I will review it and I will review the evidence behind it and submit that subsequently to the Committee.

Q759 Lord Colwyn: Mr Dillon, I wonder if you could update us on the submitted proposals from the Department of Health to NICE on the development of allergy guidelines? Have you any news on those and when they might be published?

Mr Dillon: NICE is already producing a clinical guideline on asthma in children. We have been consulting on that and we will publish a draft of that in the summer of this year and we will publish the guideline, subject to our consultation, in December. We have also published a number of recommendations on the use of inhalers for treating asthma and drugs for treating eczema. The Department of Health had asked us to consider the slight oddity in the way in which topics are considered and approved for NICE. There is a process which involves consideration by NHS clinicians and others of the potential topics right across the range of services that the NHS provides. A short list goes to ministers. Ministers consider which of those they wish to refer to the Institute. The DH itself though at a policy level can feed into the start of that topic selection process and they have done that for the allergy related topics. Those topics have migrated their way through the system and are now back with the Department of Health and ministers for consideration. They have not yet been referred to the Institute and I do not as of today have any indication of when they might be referred to NICE. Assuming they are referred some time during 2007, we would then slot them into the first available guideline development opportunity and if we can start them all in 2007 they would all be published at some point before the end of 2009.

Q760 Lord Colwyn: Are the Royal Colleges involved?

Mr Dillon: Yes. The way we develop clinical guidelines is to do it in conjunction with the Colleges. The guidelines are developed through a series of national collaborating centres and these centres are collectives of the medical Royal Colleges and the other main, national, professional bodies.

Q761 Lord Colwyn: Do you have any view on how these guidelines will fit into the current system of allergy service provision in view of the financial constraints of most PCTs?

Mr Dillon: They fit into the existing services in that they would represent standard good practice, so the existing services would do what the NHS does generally when NICE produces a clinical guideline. That is to base line current service provision against recommendations and develop in effect a project plan
to migrate towards broad accordance with those recommendations. They also have the effect of stimulating the creation of services where those services do not exist. There have been examples from other NICE clinical practice recommendations where that is happening. Clearly the NHS is expected to do an enormous amount for all of us and we all expect it to do all of that straight away. The reality is that local NHS organisations start from different positions for individual services. Some are well advanced in one service and less well advanced in another. The time it takes to get from where somebody might be at the point at which we publish a recommendation on a particular aspect of clinical practice to being able to say, “We are consistent with NICE recommendations” will vary. That variation is in part also a result of the ability of NHS organisations to allocate resources to implement what we have recommended.

Q762 Lord Colwyn: I suppose we might be concerned that there is such a shortage of allergy consultants throughout the country that services might vary from region to region. Mr Dillon: They do. It is not just because of the distribution and number of allergy consultants. Most allergies can be very competently managed in primary care by generalists and that is where the majority of service delivery will be. NICE guidance though would recognise both where it is appropriate for generalist practitioners, both medical and nursing, and indeed whether other health professionals can make a contribution to treating and where it is necessary to refer on to more specialist care. One of the benefits of having that guidance is that it gives the service as a whole, as well as local NHS organisations, the ability to work out what they actually need in order to deliver a good quality service.

Q763 Chairman: We have heard of GPs drowning under guidelines.
Mr Dillon: They are but the only ones they really need are ours, so they need not drown.

Q764 Lord Soulsby of Swaffham Prior: Can we turn to immunotherapy? We have heard from other witnesses that immunotherapy is not very popular, if that is the proper word, in this country compared with countries in the European Union. One wonders why this is so. Is it because the MHRA regulation for immunotherapy licences are particularly stringent compared with those in other countries? There has been a visit to Germany, for example, where the Committee found that immunotherapy was quite frequently used.

Mr Gutowski: I can answer it very briefly in the sense that the Committee on Safety of Medicines within the UK restricted the use of desensitising vaccines in, I am told, about 1986 and 1994. They advised of inadequate evidence of benefit to support the use of these vaccines. They revisited that in 1994. They recommended that these treatments should be restricted to those patients who have not responded to anti-allergy drugs. I can give the Committee a more detailed explanation of the thinking behind the CSM’s decision in this respect but I do not have any more detail of that in front of me.

Q765 Lord Soulsby of Swaffham Prior: One wonders, for example, whether NICE have carried out an appraisal of allergen injection immunotherapy. Mr Dillon, have you any information?
Mr Dillon: No.

Q766 Lord Soulsby of Swaffham Prior: In view of the more general use of it in other countries in Europe, is it not worth looking at in greater detail than hitherto? Obviously its use has been rather negated by what you say.
Mr Dillon: Anything that the NHS can and does offer, regardless of at whatever level and whatever variation, is worthy of some consideration but with limited capacity NICE has to prioritise what it looks at at any one point in time. That said, the process that we operate to generate topics allows anybody to suggest either a specific drug or another intervention or a whole disease area as being suitable for consideration. The new arrangements that we have put in place since the autumn of last year provide a much more objective approach to assessing the suitability of topics suggested and a much more objective approach to prioritising them. We could do it but in the end we have to make sure that we spread our available capacity across the whole range of diseases and conditions that people would expect.

Q767 Chairman: The Cochrane review came out with quite positive results. How much of the Cochrane review is informing your process, particularly your guideline development?
Mr Dillon: Looking at what Cochrane has produced is one of the first steps that the guideline development group take in assembling the evidence. Cochrane is a very important source of our studies and their database would be searched as a matter of routine by the guideline development group.

Q768 Lord Colwyn: Have any of you a kind word about Vega testing or kinesiological testing or homeopathic treatment?
Ms Young: I cannot offer an opinion from NHS Direct’s perspective on that. I would not feel comfortable doing so.
Mr Dillon: I do not have any unkind words but I do not have a view.

Q769 Chairman: Can I go to over the counter medication, second generation antihistamines and potent nasal corticosteroids? These are now available from pharmacies in the high street. I wonder whether you feel—I guess it would be particularly Ms Young—that the level of regulation is right or whether there is an over-availability or an under-availability?
Ms Young: in relation to whether the regulation is right, it is probably not directly my sphere but what I could perhaps offer is that it is our experience that, from a user perspective, the patients’ perspective, both the availability of these products and their usage is significantly both valued and used. Although NHS Direct do not prescribe over the telephone and we do not directly advise patients to go and take a particular drug, we do advise on groups of drugs that might be helpful in managing their symptom or their condition. It has been feedback to us and it is our nurses’ view that the availability of the products plus importantly the pharmacists’ advice on the usage of those products is very much valued by patients. Whilst I would not personally have a comment on regulation, I would say that the availability and usage of such products has certainly increased, as you would expect. It is a favourable option for many members of the public and unblocks other parts of the NHS for other care.
Mr Gutowski: The move of products from prescription only to pharmacy status was following careful consideration by the Agency as part of the general policy of making more treatments available to the general public, rather than by a general practitioner. It was based on a number of considerations: a favourable safety profiling in respect of diagnosis and misdiagnosis of these products. The lack of abuse potential is another consideration in making that determination and then there is the convenience of the availability of products from a pharmacy or general sale. When the consultation was made with regard to moving these products to pharmacy status, there was no objection raised with the Agency with regard to the new availability of these products.

Q770 Chairman: Does this mean pharmacists are now managing allergy?
Mr Gutowski: I do not know. I cannot answer that question.

Ms Young: It would be a personal view that they are a very important part of allergy management as are general practitioners but, because of the increase in the usage of products over the country and the quality of advice that needs to go with that, it is certainly worth consulting with that group because they play a particularly important role in self-care management.

Q771 Chairman: You mentioned just now that you would advise a caller to look at a particular group of drugs perhaps in terms of managing their condition. Do you advise them to seek advice from a pharmacist or do you advise them to go to their GP before purchasing drugs from that group?
Ms Young: It depends on the nature of the call. In urgent symptoms that we believe need to be seen by a GP, we would automatically screen and send to the general practitioner. Roughly speaking, about one per cent go to 999. 50 per cent of the calls that we take in relation to allergy will end up either directly going to a GP practice or some form of out of hours care. The rest of it will be self-care. We will say that a particular group of drugs might be helpful in alleviating symptoms. We will then advise them to go to the pharmacy, speak to the pharmacist and be advised on what is the best product. The difficulty for NHS Direct is that we are not always face to face so our advice to go to a pharmacy is often based on whether we have a view on what group of drugs will work but we would obviously want another clinician to have a face to face opportunity where that patient is exhibiting a rash et cetera.

Q772 Chairman: Do you think the pharmacists have clinical training appropriate to the diagnosis of these sorts of conditions?
Ms Young: I cannot specifically comment on pharmacist training. I only know about our collaboration with them in relation to sending patients or callers to them.

Q773 Viscount Simon: Novel therapies for allergic diseases are currently being developed such as anti-IgE therapies and sublingual desensitisation vaccines. Are these being appraised by NICE or MHRA and who can administer them?
Mr Dillon: We are looking at one of these therapies called omalizumab and it is for treating severe, persistent, allergic asthma. The plan at the moment, subject to appeal, would be to publish recommendations about the use of it in August this year.

Q774 Chairman: Do you have any view on the role of pharmacists in the diagnosis of allergy?
Mr Dillon: Not from the NICE perspective but there will be a general view inside the Institute that pharmacists have an important role to play in delivering services and that role over the years has increased and is likely to increase further. The judgment is all about risk set against convenience for patients or individuals accessing a pharmacy as opposed to going to a GP.

Q775 Chairman: Dr Hart, from the people who are sending in to you, do you have a feel for how many have sought advice from health care professionals, other than going through their GP, and have found that advice helpful or unhelpful?
Dr Hart: I do not have exact numbers or details. People who come to us have suffered for a long time and they tend to come to us as for other therapies as more of a last resort because they do not feel their needs have been met.

Supplementary memorandum by YORKTEST Laboratories Ltd

Nomenclature
Medical opinion recognises that food intolerance/sensitivity exists. However, because there is no agreed nomenclature there is confusion about what various parties are claiming or even discussing. An agreed nomenclature used to clearly define food allergy, sensitivity, intolerance etc would be beneficial.

Unmet Medical Need
There is a huge unmet medical need for people who suffer from food “sensitivity”. The provision of validated testing services would reduce NHS costs, and allow people to make informed choices to enable them to lead more productive and satisfying lives.

Policing Testing Services
All medical tests and testing services should go through an agreed validation process before being offered to the general public. Specified bodies should be responsible for ensuring that all tests available to the public have gone through an agreed scientific validation process. Organisations providing testing services to the public should be regularly audited.

Existing Regulatory Requirements
YORKTEST has fully met the regulatory requirements in providing a self-test testing service by ensuring the whole testing service is compliant with the IVD directive 98/79/EC annex III section 6 (self-test). We know that this is not common practice, but we have understood these regulations to be compulsory.

YORKTEST’s Position
YORKTEST, a small laboratory, has made every effort to ensure that food-specific IgG testing carried out at its laboratories complies with necessary regulations and good clinical practice. YORKTEST has encouraged academic bodies to undertake research into IgG testing and its role in identifying food intolerances. A double-blind placebo-controlled study was published in the international journal GUT, an audit of migraine sufferers was published in Headache Care, and just recently (last week) a major audit of over 5,000 people who had taken a YORKTEST food intolerance test was published in the journal “Nutrition and Food Science”.
While we recognise that many people in the medical profession are not yet convinced of the role of IgG as an indicator of food intolerances, and we do not fully understand the mechanisms involved, we have proven that three out of four people who follow the advice given by the YORKTEST test report, get significant relief from their symptoms.

**LARGE NUMBER OF UNQUALIFIED TESTS AVAILABLE**

A large number of tests are available to the public that have no scientific basis or have never been validated. For example, the use of electrodermal testing (Vega test) for determining whether an individual is intolerant to a particular food has absolutely no basis in science, yet it is widely available, not only through complimentary or alternative healthcare practitioners, but also in walk-in clinics and health food shops on the high street.

**CONFUSION**

The public are frequently confused by the vast range of tests available. The regulatory control over testing services outside of the NHS is woefully inadequate, especially if the test is not validated and is not accompanied with any interaction with a health care professional.

**THE LACK OF REGULATION**

The lack of regulation (or lack of policing of the existing regulations) could actively be preventing people from finding relief from their ill health symptoms.

**CHOICE AND TAKING RESPONSIBILITY**

Giving patients more choice about how, when and where they receive treatment is one cornerstone of the Government's health strategy. Patients should be able to take more responsibility, and have access to tests that can empower them, not potentially damage them. The consumer needs to be suitably protected.

**YORKTEST SUPPORTS REGULATION**

YORKTEST support the view that a system of regulation is needed to assess the efficacy and to assure the quality of such testing services, particularly if they are being accessed directly by the public.

**MHRA POLICING OF TESTING SERVICES DIRECT TO THE GENERAL PUBLIC**

There is clearly considerable confusion about the regulation of testing services, within the MHRA. YORKTEST calls for:

1. A Competent Authority to be set up to regulate diagnostic testing services.
2. That all testing services should go through an agreed validation process before being offered to the general public.
3. Organisations providing testing services to the public should be regularly audited.

Reference should also be made to the report that is about to be issued by the Science Council’s Science in Health Group *Integrated Diagnostics* project.

**CLINICAL TRIALS (FOOD-SPECIFIC IgG TESTING)**

While YORKTEST as a small company has encouraged academic bodies to undertake independent research into food-specific IgG testing and its role in identifying food intolerances, there is a clear need for a great deal more research to better understand the mechanisms involved in non-IgE mediated food allergy.

The independent studies which have been carried out include a double-blind placebo-controlled trial in IBS published in GUT which, for clarity in response to other statements made during this inquiry, showed that the number needed to treat for compliant patients was 2.5.
Two more independent randomised controlled trials (RCT) in IBS are scheduled for completion this year and funding is being sought from the Clinical Trials Unit at the University of York for an RCT in Migraine.

Studies into IgG testing in Inflammatory Bowel Disease are being presented at Digestive Disease Week in May 2007.

In February a major audit of over 5,000 people who had taken a YORKTEST food intolerance test was published in “Nutrition and Food Science”. The feedback YORKTEST has received demonstrates that many people in the medical profession are not convinced of the role of IgG as an indicator of food intolerances. YORKTEST does not claim to fully understand the mechanisms involved, but the trials, surveys and anecdotal reports consistently show that three out of four people, who follow the advice given by the YORKTEST test report, get significant relief from their symptoms.

Scientific Advisory Board

In order to provide scientific support for their services, YORKTEST established a Scientific Advisory Board of independent scientists, leading medical consultants and dieticians to advise the company on clinical trials, exploring the science behind the various tests as well as reviewing and advising on the supporting materials and advisory services offered by YORKTEST to its customers.

Unmet Medical Need

There is a huge unmet medical need for people who suffer from food “sensitivity”. The wider provision of properly validated testing services would reduce NHS costs, and allow people to make informed choices to enable them to lead more productive and satisfying lives.

Supplementary letter from the Medicines and Healthcare products Regulatory Agency (MHRA)

The Committee for Human Medicines (CHM) has reviewed license applications for three allergy immunotherapy products in the last two years. Each application is assessed based on the scientific evidence provided and taking into account the current prevailing medical/scientific opinion. One received a positive opinion (Grazax) and the two others were unable to show a positive benefit:risk ratio, either due to inadequate clinical data (due to testing over only a single pollen season and no confirmation of efficacy) or unacceptable side-effects.

The answers to your further questions are as follows:

1. What subcutaneous and sublingual immunotherapy products currently have a UK product licence?

Grazax (Timothy grass) is a sublingual immunotherapy product and Pollinex (grasses and rye, or tree pollen) and Pharmalgen (bee/wasp venom extract) are subcutaneous immunotherapy products which currently have UK product licences.

2. For which type of patient can these approved immunotherapy products be used, and who can administer the treatments?

Grazax is for patients with hay fever with positive skin test to Timothy grass. Pollinex is for patients suffering from seasonal hay fever who have failed to respond to standard anti-allergy medication and Pharmalgen is for patients with hypersensitivity to bee/wasp venom.

Grazax is an oral tablet for sub-lingual (under the tongue) administration. Treatment with Grazax is initiated by physicians with experience in treatment of allergic diseases and the first tablet is taken under medical supervision (20–30 minutes). After this, the patient will be able to self-administer the medicine, according to the instructions.

The Pollinex preparations are given by sub-cutaneous injection and are therefore administered by a physician. Treatment of patients should only be carried out where full facilities for cardio-respiratory resuscitation are available. These preparations are contra-indicated in patients with asthma.

Pharmalgen is administered to patients with confirmed hypersensitivity to bee/wasp venom by sub-cutaneous injection. Treatment of patients should only be carried out where full facilities for cardio-respiratory resuscitation are available and special care should be taken in patients with asthma.
3. Are there no plans in the near future to review the 1994 decision to limit the use of immunotherapy treatments?

CHM advises MHRA on license applications on the basis of assessment of the scientific evidence provided by the company and taking into account the current prevailing medical/scientific opinion. The license for Grazax illustrates the fact that there is no fixed view on any product class and scientific evidence is the most important determinant of the regulatory decision(s).

4. In particular, is it true that the MHRAS still advises that patients have to remain under medical supervision for at least one hour after each injection whereas in most other countries this is usually 20–30 minutes?

No. MHRA approved the recommendation in Grazax product literature that observation for 20–30 minutes is sufficient. Product literature for the older products, Pollinex and Pharmalgen, recommend observation for 60 minutes after treatment, but the Marketing Authorisation Holder is entitled to apply for a variation to the license to change this recommendation, if required.

5. What criteria do immunotherapy products have to meet to be granted MHRA approval, and how do these criteria compare to those used by regulatory authorities in other countries?

The products will need to establish quality, safety, efficacy and a favourable benefit: risk profile, as for any medicinal product. This does not fundamentally differ from other regulatory agencies.

6. Does the MHRA use the mutual recognition process to assess immunotherapy products in the same manner as other treatments, and if not, why not?

UK uses mutual recognition procedure for these products in the same manner as other treatments.

7. What is the present MHRA policy regarding the prescribing of unlicensed immunotherapy products (manufactured both within the UK and abroad) on a “named patient basis”?

In the UK an unlicensed relevant medicinal product may only be supplied in accordance with the provisions of Schedule 1 of The Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 [SI 1994/3144], (the MA Regs) Schedule 1 exempts from the need for a marketing authorisation a relevant medicinal product which is supplied to fill a “special [clinical] need” and in response to a bona fide unsolicited order, formulated in accordance with the specification of a doctor, dentist or supplementary prescriber and for use by his individual patients on his direct responsibility. In the interest of public health the exemption is narrowly drawn, because these products, unlike licensed products, may not have been assessed by the Licensing Authority against the criteria of safety, quality and efficacy.

In practice, subject to the normal legal requirements, prescribers are free, on their own direct personal responsibility, to prescribe whatever unlicensed products they believe appropriate to meet the special clinical needs of their individual patients in the absence of a suitable equivalent licensed product being available. However, the MHRA recommends that wherever possible a product licensed for the UK market should be preferred.

Memorandum by the Royal National Throat Nose and Ear Hospital (RNTNE)

The RNTNE hospital is the national centre for ENT, treating annually some 60,000 patients, referred locally and from all over the UK. It is recognised internationally as a centre of excellence.

Allergy is a form of dysregulated immunity such that antibodies of the IgE class are formed against harmless molecules (allergens) eg house dust mite faecal proteins, grass pollen and cat dander. Subsequent allergen contact causes a reaction involving mast cell degranulation and release of powerful mediators resulting in eosinophilic inflammation.

Several thousand allergic individuals are seen at RNTNE, predominantly with rhinitis, ie inflammation of the nasal lining. The prevalence of allergic rhinitis has quadrupled since the mid 20th century and now affects one in four persons in the UK. The prevalence is continuing to increase in many parts of the world. The reasons for this are uncertain—the hygiene hypothesis may explain early onset rhinitis, but is unlikely to account for its later development. Other possible factors include pollution, diet and persistent infection and need investigation.
Rhinitis, which can be allergic or non-allergic, ranges in severity from mild intermittent symptoms of rhinorrhoea, itch, sneeze and nasal blocking to severe, persistent problems with marked effects on quality of life, greater than those attributable to mild or moderate asthma. Secondary effects of rhinitis include development or exacerbation of asthma, sinusitis, otitis media with effusion, pharyngitis, sleep problems, and vocal dysfunction. At RNTNE these severe forms of rhinitis form the major part of those seen by the Allergy service led by Dr Glenis Scadding.

Using medical treatment, including allergen avoidance, the need for surgery in conditions such as rhinosinusitis, nasal polyposis and otitis media with effusion has been considerably decreased and quality of life has been improved for sufferers. A beneficial effect of upper respiratory tract therapy upon concomitant asthma has been noted.

*If it were possible to improve diagnosis and treatment of rhinitis in its early stages the need for these patients to be seen in secondary care could probably be reduced.*

**Government Advice**

The setting up of asthma clinics with standardised management in primary care is an undoubted success but does not include allergen recognition nor rhinitis management. Unfortunately rhinitis is often trivialised or overlooked, misdiagnosed and mistreated. Rhinitis is present in about 80 per cent of asthmatics and contributes to airways hyper-reactivity, with retrospective studies demonstrating significant benefit such as reduced A&E visits and hospitalisation from rhinitis therapy. A recent survey of General Practitioners with an interest in airways diseases (General Practitioners in Airways Group, GPIAG members) showed that few knew the symptoms of rhinitis, very few were aware of tests to substantiate a diagnosis of allergic rhinitis or were capable of treating it adequately. GPs should have the recognition and therapy of rhinitis added to their supervision of asthma patients.

Another reason to improve allergic rhinitis care is the possibility of its progression to asthma. This is preventable in children by appropriate specific subcutaneous immunotherapy (SCIT). Recently sublingual immunotherapy (SLIT) has been shown to be of proven benefit for rhinitis in a Cochrane meta-analysis. Preliminary results suggest that this form of treatment may also prevent disease progression as well as reducing symptoms and the need for other medication. There is an urgent need for large well-controlled studies to validate this, to examine the doses of allergen needed and to look at pharmaco-economic implications since this form of immunotherapy is safer and more convenient—it can be carried out by the patient at home after initial dosing in a setting with resuscitatory facilities.

A further area of interest and promise is the interaction of infection, particularly with rhinoviruses, and allergy. The combination of allergic sensitisation, allergen exposure plus a rhinoviral cold result in a twenty fold risk of a child being hospitalised for asthma. Similar disease exacerbation of nasal polyposis occurs with viral colds suggesting synergy between two different inflammatory processes which requires further study.

**References** [not printed].

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**Memorandum by the Institute of Food Research (IFR)**

The Institute of Food Research (IFR) is an independent research organisation, with charitable status, sponsored by the Biotechnology and Biological Sciences Research Council (BBSRC). IFR’s mission is to undertake international-quality scientific research relevant to food and human health, and to work in partnership with others to provide underpinning science for consumers, policy makers, the food industry and academia. IFR has two research programmes relating to the subject of this inquiry, and this response was written by Dr Clare Mills who is the Programme Leader on one of these. IFR welcomes the opportunity to respond to this Inquiry.

Reference is made in the text to EuroPrevall. This is a European-funded Framework 6 Intellectual Property project which is aiming to define the prevalence and cost and basis of food allergy across Europe.
DEFINING THE PROBLEM

1. Allergies are a disease state which results from malfunctioning of the immune system. They can involve either cellular or humoral (antibody) based reactions. With regards to food allergies, the European Academy of Allergy and Clinical Immunology classifies them in the context of many adverse reactions to foods, including IgE-mediated allergies (sometimes also referred to as type-I hypersensitivity reactions) and non-IgE-mediated allergies. Coeliac disease is the best characterised on the non-IgE-mediated allergies; there may be others which have not been clearly defined involving the humoral and/or cellular immune system. In the EAACI classification immune-mediated allergies are distinguished from non-immune-mediated food intolerances which include lactose intolerance and other undefined but reproducible reactions to foods. The evidence given below is focussed on food allergies rather than respiratory or other types of allergies, although the diseases are often connected.

2. IgE-mediated food allergies, like other allergies, involve a sensitisation phase, where an IgE response is generated towards an environmental agent (pollen, dust, food) in a susceptible individual. Predisposition towards developing IgE is associated with a polarisation of T-cell responses towards a Th-2 phenotype. However, the mechanism whereby one individual, and not another, begins to develop IgE towards an agent is not clearly understood. It may be that during early life the immune system is plastic and that interaction with microbes and infections may play a role in avoiding the development of an atopic phenotype. Much of the ideas surrounding this are presented in the “Hygiene Hypothesis”. There is also an emerging issue with regards to nutritional status and development of allergy. The development of the allergic phenotype has a clear genetic element and efforts are underway to identify genetic markers related to development of allergy although this is very much in its infancy with regards food allergy.

3. Following sensitisation of an individual an allergic reaction may be elicited on subsequent exposure to an allergenic agent. The mechanisms whereby this occurs are generally well understood. However, the mechanisms underlying interactions with other factors, such as those in exercise-induced anaphylaxis (a symptom which can be associated with food allergies) are less clear. In addition the food allergies of some individuals (especially young infants) resolve whilst for others there can be a rapid progression from mild to severe reactions. The mechanisms underlying the evolution of allergies responses in this way is not understood and is hard to predict, presenting a problem regarding management of food allergies for the individuals concerned.

Why is the incidence of allergy and allergic diseases rising? Why does the UK in particular have such high prevalence of allergy?

4. Estimates of the prevalence of food allergy are generally imprecise. Many studies have not used unselected populations and none have employed the “gold standard” for diagnosis of food allergy, double blind placebo controlled food challenge (DBPCFC) as there are many shortcomings with current serological approaches to diagnosing food allergies. Such a diagnosis is necessary since serological analysis for food-specific IgE is not an effective predictor of actual food allergy—many have food specific IgE in their blood without suffering any allergic reactions associated with consumption of a particular food. Best estimates of reactions are 5–7 per cent of infants and 1–2 per cent of adults. There has been no study to determine effectively the overall rate of food allergy outside the UK. In the UK the most effective study has been undertaken for peanut in the Isle of Wight, which was undertaken at two time points several years apart for one food (peanut) in young children. It showed an increase in the sensitisation to peanuts, although there was insufficient statistical power to determine changes in the prevalence of DBPCFC symptoms. It has been generally assumed that food allergies are following other types of allergic disease (the “atopic march”) but studies (EuroPrevall) have only just begun to define the incidence of food allergy in several countries, including the UK. It may be that exposure to environmental factors (eg indoor environments


affecting exposure to dust mite allergens, tree and crop pollens, and pollution) together with infections in early life all play a role in the apparent increases in allergic disease in general. However, a cohesive explanation is currently lacking due to our not having an adequate mechanistic explanation as to why some individuals, and not others, develop allergies.

What gaps exist in establishing the overall disease burden for all types of allergy and what are the barriers to filling these gaps?

5. Lack of funding for epidemiology studies of sufficient size to define the incidence of food allergies and linking them with other types of allergic disease means we are missing vital objective information on the size of the food allergy problem. Research to provide this information needs to be undertaken in young children, school-age children and adults and backed up with effective objective diagnosis of allergy with DBPCFC for food allergies.

6. There are no data on the socioeconomic impact of food allergies as the instruments are only just being developed to do this (see above). All that is available is anecdotal information. There have been no instruments for assessing the economic impact of food allergies. These are being developed in EuroPrevall but will not be applied in the UK. In order to ascertain the burden of allergic disease the population studies need to be linked to the socioeconomic instruments developed for measuring the disease burden which are available for allergic asthma and other allergies, and now becoming available for food allergies.

Treatment and Management

7. Treatments for inhalant allergies include immunotherapy which is much more widely used in mainland Europe than the UK. This involves administering increasing doses of an allergen and requires considerable commitment from the patient to receive the treatment on a weekly to monthly basis with repeat visits to the clinic. In some instances immunotherapy for inhalant allergies associated with food allergies may affect the latter.

8. There are currently no effective treatments for food allergies. Patients with severe symptoms are given emergency medication (adrenaline) and told to avoid problem foods. There may not be adequate resources in hospitals to allow re-testing of individuals to assess if the allergy has resolved, which is especially relevant in children. Without this becoming more routine it is likely that individuals are living with mitigation strategies which are no longer necessary, with all the socioeconomic burden that carries to practice food avoidance.

9. There are potential avenues of research ongoing which may lead to development of effective preventive measures. Since funding is limited their development is slow. The application of recombinant immunotherapy using proteins resembling allergenic molecules, but with the major IgE-epitopes to desensitise individuals, is showing promise for food allergy, including putting in novel delivery vehicles including bacteria. These may, for those individuals with severe reactions, need to be coupled with anti-IgE therapy to avoid adverse reactions to the immunotherapy. There are also potential therapies emerging using parasites, since individuals with parasitic infections do not appear to manifest allergic reactions. Probiotic and prebiotic approaches may act as a preventive by helping to establish a gut microflora that promotes a non-allergic phenotype. These require more effective intervention studies which also take account of the timing of the intervention. For example, is it only effective if given in the first months of life when the gut microflora becomes established?

Is the level of UK research into allergy and allergic disease adequate?

10. With regards to food allergy research, the majority of the UK research portfolio is funded by the UK FSA in support of food allergen management. However, FSA does not fund the fundamental mechanistic studies that will be required to develop more effective diagnostics, therapies and preventive strategies. There is no clear avenue to allow funding of multidisciplinary research regarding the socioeconomic burden of food allergy and to join it up to population studies with individuals with clearly defined food allergies.

11. The information and advice given by governments in general can be confusing and conflicting. This reflects the fact that scientific opinion is not clear and the fact that the research and knowledge that is required to form opinion is currently lacking in two areas: defining the size of the allergy problem (from the number of people with allergies to the cost and burden to society of this disease) and the mechanisms underlying what makes some people become allergic and what makes some substances more allergenic than others.

How effectively are food policy and food labelling regulations responding to the rise in food allergies?

12. The lack of knowledge about food allergies is resulting in policies being implemented which aim to protect the consumer which have not been thought through and are not founded in fact but on assumption. For example, soya has to be labelled as a food allergen and yet studies on soya allergy are difficult to undertake because of a lack of patients that can be recruited with a defined soya allergy. There is a need also to address how information about food allergies is conveyed to consumers—this has yet to be done. There is a real danger that consumers are being deluged with information but that this is not provided in a targeted and useful way. Providing information is not communication. There is a clear need to target information to particular at-risk groups such as young men, who are at greater risk of not managing their food allergies adequately resulting in severe or even fatal reactions. This reflects the risky behaviours this age group may adopt with regard to other health problems. Food allergic teenagers may not carry their adrenaline and read labels in the same way that teenage diabetics do not manage their blood sugar levels. With regard to the industry, allergic consumers are at greatest risk from suffering an allergic reaction whilst eating in a restaurant. These risks would be reduced if there was more support for the development of the tools and materials necessary to promote adequate training on food allergen management in the catering sector.

13. We are not in a position to comment on the two questions posed below.

Are current regulatory arrangements, for example, those governing private clinics offering diagnostic and therapeutic services and the sale of over the counter allergy tests, satisfactory?

Do housing policy and regulations governing the indoor environment pay enough attention to allergy?

6 October 2006

Memorandum by Asthma UK

1. ABOUT ASTHMA UK

1.1 Asthma UK is the charity dedicated to improving the health and well-being of the 5.2 million people in the UK whose lives are affected by asthma. We work together with people with asthma, health professionals and researchers to develop and share expertise to help people increase their understanding and reduce the effect of asthma on their lives. As the voice of people with asthma, Asthma UK is a proactive organisation that offers solutions and puts people with asthma first.

1.2 Asthma UK is pleased that the House of Lords Science and Technology Select Committee has decided to investigate issues surrounding allergy in the UK. This is a significant issue for the millions of people affected by allergies, and presents an evolving challenge for health professionals and government. We welcome the opportunity to share our expertise with the Committee, and would be very pleased to nominate a representative to give oral evidence should this be required.


2. Defining the Problem

2.1 Asthma and allergy are global problems, and prevalence of both in the UK is among the highest in the world, which has been highlighted by several recent studies.57

2.2 Asthma and allergy are very closely interlinked. For the majority of people with asthma, symptoms are brought on through allergic mechanisms. Many common allergens are also common asthma triggers: 90 per cent of people with asthma tell us that their symptoms are triggered by dust and 79 per cent say their symptoms are triggered by pollen.58 Additional allergic conditions including allergic rhinitis, conjunctivitis, eczema and food allergies are also common in people with asthma. Even non-allergic asthma triggers such as cigarette smoke and air pollution can worsen the impact of allergic asthma, and there is much still to be learned about the interplay of different factors in the development of the condition.

2.3 There are significant flaws in our ability to accurately establish the total disease burden of allergy, and particularly allergic asthma. This is in part because of a lack of funding for research in this area. The UK Clinical Research Collaboration reported that research into asthma and other respiratory conditions received a disproportionately low level of funding in relation to the impact of these conditions, which represents a huge barrier to the effective development of our knowledge base.59

2.4 However, perhaps an even more fundamental reason for our inability to conclusively establish the total burden of allergic disease is that current diagnostic procedures mean that it can remain unidentified. Only 30 per cent of people with asthma tell us that they have been offered allergy testing to help them to identify what triggers their asthma.60 Skin-prick tests, which can be used to identify allergies, are not widely applied to people with asthma, meaning that the precise allergens that trigger symptoms in allergic asthma are not formally identified or recorded: this can inhibit the quality of treatment as well as preventing us from forming a complete record of the extent of allergy in the UK.

2.5 We estimate that over 12.7 million working days are lost each year as a result of asthma, and that the total annual cost of asthma to the economy is £2.3 billion.61 The high prevalence of allergic asthma means that a significant proportion of this cost is likely to be directly related to allergy, but unfortunately, the lack of allergy testing for people with asthma and the resulting absence of data on the people affected by it means that precise figures are unavailable. Nevertheless, the total economic impact of asthma and other allergic conditions is likely to be very substantial.

3. Treatment and Management

3.1 As yet it is not clear how to prevent asthma and allergy, but Asthma UK sponsors approximately £3 million of research into asthma every year. Asthma UK has developed a comprehensive research strategy to identify priorities by bringing together the expert knowledge and opinions of people with asthma, researchers, clinicians, the major UK funding agencies, the pharmaceutical industry and the Department of Health. The results of these national consultations provide a framework for the development of Asthma UK’s research programme, which covers basic and clinical research. We are currently supporting 18 research projects specifically relating to allergy, which together represent a financial commitment of £2,470,758.

3.2 In addition, Asthma UK works in partnership with the Medical Research Council to fund the MRC-Asthma UK Centre in Allergic Mechanisms of Asthma, which is a world-class centre of research into allergies and asthma based at Imperial College London and King’s College London. Established in 2005, the centre aims to understand asthma better and to develop new ways of preventing and treating the condition, as well as acting as a training ground for new researchers and as a public voice for new achievements in asthma research. The creation of a centre of this kind provides a unique opportunity to translate basic science findings from the laboratory to healthcare professionals treating people with allergic asthma and will encourage scientists to fast-track the development and testing of new treatments.


59 The impact of conditions was measured in Disability Adjusted Life Years. UKCRC, UK Health Research Analysis, May 2006: 27.


3.3 It is not certain why the rate of allergy is so high in the developed world, but there are several promising areas of research. For example, there is increasing evidence that infection with gut parasites may protect against asthma and allergy. Asthma UK and the Wellcome Trust are independently funding clinical trials to study the effects of hookworm in allergy and asthma respectively.

3.4 Also, some studies have suggested that diet may increase a person’s risk of developing asthma and allergies. For example, a recent study funded by Asthma UK showed that children born to mothers who had a low intake of vitamin E during pregnancy were five times more likely to have asthma than children whose mothers had eaten a diet high in vitamin E.62

3.5 There is also clear evidence that infants who contract respiratory syncytial virus (RSV) bronchiolitis are more likely to develop asthma later in life and in severe cases they may also be at greater risk of developing allergies. A number of antiviral therapies are in development for RSV and rhino virus infections that may potentially prevent asthma development.63

3.6 Treatments for allergic asthma are also developing. Recently a novel therapy called Xolair has been developed and licensed for use in people with severe allergic asthma. It is an antibody that binds to and removes the “allergic antibody” Immunoglobulin E (IgE) from the circulation. It is currently being appraised by NICE.

3.7 Also, specific immunotherapy aims to make an allergic person tolerant to the substance causing their allergy by injecting them with increasing doses of the substance they are allergic to until their symptoms are abolished or reduced. However it carries a risk of adverse reaction and trials are underway to administering the treatment in a quick dissolving tablet under the tongue (sub-lingual immunotherapy). This approach looks promising and might provide a new, cost effective way for people to manage their asthma.

3.8 Nevertheless, the level of spending on research into allergic conditions is far from adequate. This is a substantial barrier to the advancement of our understanding about both the causes and treatment of allergic conditions. The Department of Health’s recent review of allergy services identified a number of significant gaps in research into treatment, particularly in our understanding of effective models of service delivery and the effects of patient knowledge on treatment outcomes.64

4. GOVERNMENT POLICIES

4.1 As well as identifying weaknesses in our understanding of effective services, the Department of Health’s report illustrated the poor outcomes of current service provision, which can only be remedied by improving policy. There has been a lack of strategic direction, with the result that services are not well integrated and have failed to address the problems associated with allergy. More explicit attention should be paid to allergy and allergic asthma, with better services provided in both primary and secondary care. It is important for the Government to ensure that NICE guidelines on allergy are commissioned as soon as possible in order to help structure future treatment.

4.2 However, improving health is not solely the domain of the Department of Health, and without public health measures across government, the problems associated with allergic asthma will not be resolved. There is work to be done across government and the public sector: in training professionals working with the public to be aware of what to do in an asthma attack, in securing asthma- and allergy-friendly workplaces and in improving indoor and outdoor air quality.

4.3 Poor housing in particular can severely exacerbate asthma symptoms. Damp conditions in particular allow common triggers for allergic asthma such as mould and house-dust mites to thrive. Public health policy and housing policy should be well co-ordinated at all levels of government, and more attention could be paid to the improvement of housing conditions with specific regard to allergy and asthma, particularly in rented accommodation. The consultation on the Code for Sustainable Homes made reference to the use of allergy minimising materials, but it remains unclear whether this will be implemented, or whether it will have any success.65


64 Department of Health. A review of services for allergy—the epidemiology, demand for and provision of treatment and effectiveness of clinical interventions. 2006.

5. Patient and Consumer Issues

5.1 The impact of allergies and allergic conditions on quality of life can be enormous. Some allergens are difficult to avoid, meaning that many people with allergic asthma are forced to adjust their lifestyles to compensate for this, or live in fear of a severe asthma attack triggered by an allergen.

“My quality of life is non-existent. I know this may sound extreme to a lot of people but I would be prepared to lose an arm and a leg if it meant my asthma would go away. I face daily restrictions in every aspect of my life. I can’t go into pubs or clubs because of the smoke, I can’t visit friends because of their pets and people’s cigarette smoke. I also have problems visiting friends for barbecues because the smoke sets off my asthma. I find it really difficult to do day-to-day activities on my own—I don’t have enough breath to push a trolley around the supermarket. It’s impossible for me to go to the gym and I’m banned from the local swimming pool as the chlorine and humidity sets off my asthma. I’m too much of a liability to them. I’m not allowed on an aeroplane and it’s impossible for me to get travel insurance. Winter is also a problem for me—I can’t go outside because the cold air can set off my asthma.” Suzanne Edwards

5.2 A number of steps can be taken to help ensure that patients and the public are better informed about allergy and allergic asthma. Improvements in our ability to diagnose allergy would be very beneficial, as would more specialised training for healthcare professionals, and the provision of better-structured allergy services. For example, poor knowledge about allergic conditions often stems from the lack of an integrated and holistic approach to their treatment. People with multiple allergies are forced to see multiple specialists for separate treatments rather than a single allergy specialist, with the result that they are not well informed about their allergies as a whole.

5.3 It is also noteworthy that many people are badly informed about what it means to have an allergy, and about the difference between allergy and intolerance. In addition to the development of more robust clinical practices and better-informed health professionals, the production of accessible health promotion materials available in a variety of locations and formats may help to resolve this problem.

6. Conclusions

6.1 Allergy and allergic asthma do not currently receive the priority they should, in either research or services. The problems allergic conditions cause are severe for the individuals affected and for the national economy. There is a clear need for more research into the basic causes of asthma and allergy, as well as into the clinical effectiveness of different forms of treatment service to fully develop our understanding of allergic conditions. Yet, even with our current level of knowledge, it is apparent that not enough is being done to treat allergy and allergic asthma. More diagnostic testing is needed, and services across both primary and secondary care stand to be improved. Only then will people with allergic conditions get the treatment they need.

October 2006

Memorandum by Allergy UK

Introduction

1. Allergy UK is the operational name of The British Allergy Foundation a charity formed in 1991 to provide information, advice and support to people with all types of allergy/intolerances and their carers.

2. An extensive database of in excess of 80,000 people who have sought help from our charity are registered on our database. In addition to this we also hold a large database of healthcare professionals who have used our services to provide information to their patients and have come to us for educational materials for their own use.

3. We have a dedicated helpline and a growing on-line advisory service and the number of people using the helpline services have increased in the year since March 2005 to April 2006 by 5.37 per cent with 19,554 being received.

4. Helpline callers are supported by our network of “Friends”—volunteers who provide a befriending service which offers practical non medical advice and a listening ear to sufferers and families under strain due to the impact of allergy on their lives.
5. Allergy UK recognising the lack of knowledge also provides education and training to healthcare professionals via Masterclasses and an increasingly popular on-line e-learning European Diploma in Allergy accredited by the University of Greenwich.

6. Allergy UK works in all areas that impact on the lives of allergy sufferers, schools, employment, voluntary groups. We work particularly with manufacturers of products that aim to improve allergen removal/reduction and we are gradually moving into environmental areas such as house building and air quality in the indoor environment of both the home and office.

**THE PROBLEM**

7. For the patient the major problem is the lack of knowledge at primary care level. GPs do not recognise allergic symptoms when presented with them due to a lack of training in allergy. This lack of knowledge at best causes distress, at worse can be life threatening, particularly when the GP refuses to refer to an allergy specialist even when the symptoms are clearly beyond being dealt with at primary care level.

8. I list below a few examples of the numerous anecdotal reports we hold of the difficulties experienced by patients:

- Mother with young son skin bleeding with eczema—told to just continue with steroid creams, no point in allergy testing as it is a waste of time and money.
- 73 year old ate something at son’s house had an anaphylactic shock. Emergency admission to hospital where she suffered three heart attacks.
- Hospital A&E wonderful and did everything possible advised referral to allergy specialist. GP refused referral but admitted that another attack would be possible as it was unclear what was the original trigger.
- GP told Mother her five year old son was too young for allergy testing but he would like to see the reaction when he was suffering his next anaphylactic shock.
- Lady 50s taken to hospital after having difficulty in breathing while out walking—given adrenaline by hospital. GP won’t refer as thinks that it isn’t possible to get allergies in later life.
- Child age seven skin sore, eyes covered in eczema and very puffy. Referral refused by GP who says that nothing can be done for the child.
- Child aged four diagnosed as being allergic to cows milk. GP advised that the child could drink goats milk instead—result child died.

9. If there is recognition that the symptoms presented could be due to an allergic reaction the GP is frequently unsure of where to refer the patient and frequently will advise the patient to contact Allergy UK for advice on an appropriate clinic.

10. There is a lack of recognition, due to minimal training, within primary care that allergy is a multi-organ disease and GPs will refer a suspected allergic person often to two organ based specialists rather than one referral to an allergy specialist. Very typically this will be a dermatologist and respiratory or Ear Nose and Throat specialist. The result of this double referral often results in additional costs to the NHS and very importantly patients being treated inappropriately with the potential of using more pharmaceutical interventions than might otherwise be needed.

11. The lack of training in allergy and therefore the lack of recognition of patients presenting with allergic disease to the GP means that the reason for a patients visit is usually incorrectly recorded. The lack of correct data means that the problem and level of allergic disease is not properly recognised and this together with the lack of training is the greatest barrier to filling the gaps in establishing the overall burden of the disease.

12. The lack of recognition of allergy also impacts seriously on research into allergic disease. Without properly diagnosed NHS patients there can be no basic research, clinical trials or, importantly, research on NHS service delivery for allergy.

**TREATMENT AND MANAGEMENT**

13. For people suffering from allergy the recently reported advances in research into allergic disease have offered a great hope for the future. However the reality of the situation is very quickly realised by sufferers as of little benefit unless:
we have trained GPs able to diagnose allergy—if the problem is not recognised how will patients access any new treatments; and
we have allergy specialists able to deliver the new treatments and train Primary Care colleagues in supporting the allergic patients undergoing treatment.

**Government Policies**

14. Government policy has consistently pushed back the possibility of any progress in dealing with the rise in allergy.

15. The refusal to accept the findings of the House of Commons Health Select Committee and, following the Department of Health review released in July this year, to place the delivery of services for allergy into local responsibility will result in an escalating problem for people with allergy.

16. Allergy UK carried out a survey of PCTs in 2005 regarding their plans for allergy, this clearly showed that PCTs are largely unaware of allergy and generally have no finances available for the service and no plans to improve the situation. We have recently carried out a similar survey which will be released in November 2006 and there is nothing within the new figures which provides any hope for the future in this area.

17. We do not believe that sufficient attention is paid to the quality of the indoor environment in terms of housing policy and regulations. The rise in allergies, particularly those associated with indoor allergens call for greater consideration to be given to the area of building both of homes and offices.

18. The difficulties for those suffering from food allergies are considerable. It is appreciated that there are severe difficulties for the food industry but unfortunately the “may contain” labelling is now so widely used that it has resulted in increased difficulty in achieving a balanced diet for some people with severe allergies and in some instances sufferers becoming somewhat blasé about the warning. The Anaphylaxis Campaign have recently launched an initiative, funded by the Food Standards Agency, which hopefully will assist in this very difficult area.

**Patient and Consumer Issues**

19. Allergies impact heavily on the quality of life of patients and their families. In a survey of 6,000 sufferers conducted by Allergy UK for its “Stolen Lives” series over 62 per cent of those questioned stated that allergy significantly affected all aspects of their lives. The difficulties in maintaining the ability to work is very much highlighted by all sufferers which in turn has a financial impact on the family. Allergy causing poor sleeping patterns results in lack of concentration and energy. This in turn leads to poor levels in the school room with examination results reflecting this. In the work place sufferers are aware of not operating to the best of their ability. Simple things with the family such as outdoor activities, picnics, sports, taking part in social activities are all highlighted as extremely difficult if not impossible for sufferers.

20. People with allergy rely heavily on the patients organisations for information, services and support. The charities are trusted by the public and we in turn fiercely guard our independence and integrity in delivering our services.

21. The UK is fortunate to have excellent organisations who are dedicated to serving allergy sufferers but all of the services provided by the patients organisations are delivered from charitable funds which are hard won. The expertise within the patients organisations is considerable and with reliable and consistent funding this expertise could be maximised to extend the range and quality of information, advice and support to sufferers and those undiagnosed.

22. As has been highlighted the lack of knowledge in primary care, the inability to obtain proper diagnosis is driving an increasing number of people into undertaking alternative testing. One highly respected paediatrician from a London Hospital stated this week that in the region of 70 per cent of the patients he saw had been told by their GP to go for alternative testing.

23. All of this makes it increasingly urgent that the lack of regulations governing private clinics, diagnostic testing and therapeutic services should be addressed. It is at the present time totally unsatisfactory. Currently there is nothing to guide the consumer on whether the test, clinic or service has been clinically proven in any way. There is nothing to show that the laboratory that is carrying out the testing holds any form of validation.

24. The impact of these alternative companies is considerable on the health and finances of those using them and I give below three examples from our database to demonstrate this:
15 March 2007

— Mrs S age 32 suffering IBS, Migraine and skin rashes. Visited local health shop for allergy testing. Told allergic to 116 foods and to remove them from her diet.
Cost £40

— Mr J age 28 suffering from sneezing, runny nose, cough. Visited iridologist. Told suffering from wheat and dairy allergy And to remove them from diet.
Cost £70

— Miss W 58 suffering from headaches, migraine, joint pains, IBS, runny nose and wheezing. Visited private clinic for consultation was admitted and given treatment of what were described as “allergy shots and vitamins” Stay in clinic three weeks, three follow up consultations.
Cost £28,000

25. Miss W lost her life savings in seeking a diagnosis and treatment for her problems. This lady and many others have been severely let down by the lack of service for people like her and the lack of guidance on alternative testing and treatment.

26. The anecdotal evidence that we have gathered highlights the seriousness of the situation which will only get worse unless something is done about the lack of allergy services within the NHS.

GENERAL

27. Allergy UK are extremely concerned for the future given that a sizeable number of the few allergy specialists there are in this country are due to retire within the next five years.

28. Unless funding is directed into allergy services allowing education and training to be addressed particularly at Primary Care, the excellent research which is currently taking place will never translate into actual treatment for the majority of allergy sufferers in the UK.

7 October 2006

Examination of Witnesses

Witnesses: Dr Glenis Scadding, Consultant Allergist, Royal National Throat, Nose and Ear Hospital, Dr Clare Mills, Head, Structuring Food for Health programme, Institute of Food Research, Ms Donna Covey, Chief Executive, Asthma UK, and Ms Lindsey McManus, Deputy Information Manager, Allergy UK, examined.

Q777 Chairman: Thank you for coming today to give evidence. I have met some of you before. I am Baroness Finlay and I chair this Committee. We have a list of our declared interests which is published so we will not be running through all of those today. Could I ask you to introduce yourselves?
Dr Scadding: I am Dr Glenis Scadding. I am an NHS consultant allergist working at the Royal National Throat, Nose and Ear Hospital in London.
Dr Mills: I am Dr Clare Mills. I am a biochemist and I work at the Institute of Food Research in Norwich which is a not for profit research institute funded by the BBSRC.
Ms Covey: I am Donna Covey. I am the chief executive of Asthma UK.
Ms McManus: I am Lindsey McManus. I am the deputy information manager at the charity, Allergy UK.

Q778 Chairman: Can I ask what are the most common questions from members of the public who phone Asthma UK and Allergy UK helplines?
Ms McManus: Right across the board from: Where is my nearest allergy clinic? Where do I get allergy testing carried out? What type of test might I expect when I go to the hospital? Could I have an allergy? They might phone up with symptoms and we can only point them in the right direction. We are not medically qualified, but we can give practical advice on allergy management. They may have been diagnosed already and want help on how to avoid certain allergens and we offer very practical advice such as bedding and cleaning. We can also give advice on different types of tests and alternative testing, should they ask us.

Q779 Chairman: Do you provide advice on those types of tests?
Ms McManus: We cannot provide advice on tests that we do not believe have undergone any clinical trials. We would not be happy to do that. We do tend to direct them straight to their GP if they have not been there.

66 If callers are enquiring after an NHS clinic we would give details of the British Society of Allergy and Clinical Immunology BSACI.
Ms Covey: At Asthma UK we have a nurse run advice line which takes telephone calls and also answers e-mails and letters. They take anything between 7,000 and 10,000 queries a year and we monitor those. About 30 per cent of calls to our advice line are from people experiencing symptoms, either a new symptom of their asthma or a worsening symptom. Just over 20 per cent are about medication. People find it difficult to get good advice about asthma medication and a lot of those queries are about side effects. About 5 per cent of our callers are newly diagnosed and it is the, “Hello, I have asthma; what does that mean?” call. About 3 per cent are on the indoor environment. About 3 per cent are about complementary therapies and about 3 per cent are product queries. The rest are a mish-mash of various things. That is basically how our calls to the Adviseline pan out.

Q780 Chairman: Do your organisations work with others such as the National Eczema Society and the Anaphylaxis Campaign to support allergy patients? Ms McManus: Yes.
Ms Covey: Yes, we do. We run holidays called Kick Asthma holidays. We used to run something called PEAK holidays which we ran jointly with the National Eczema Society because so many children with asthma also have eczema. We make the Kick Asthma holidays available to children with eczema and a lot of the work we do on those holidays with the children is about them getting used to their asthma and their allergies. We try to make things like food allergies easier. Instead of it being awful when they had to go in front of the whole class and say, “I cannot eat this and I cannot eat that”, at the start of the weekend everyone does it. “Who does not eat shellfish? Who does not eat peanuts?” It normalises it and an understanding of allergy is a really important part of that work because with conditions like asthma people do not always understand. It is not just about the medical symptoms. It is about how asthma impacts on your daily life and things like eating. If people go into a restaurant and order they take it for granted. For people with asthma and other allergic problems that is such a loaded thing all the time.

Q781 Chairman: What would you identify as the largest gaps in the management of allergic diseases at home, at school, at work and out in society? Ms McManus: Initial diagnosis is the first stumbling block. A lot of people self-diagnose and that is quite a worry. We need advice there for these people when they need it right from the very first step. We would like to see more education at the primary care level, particularly for GPs and practice nurses, right the way through to pharmacists.

Ms Covey: Firstly, it is diagnosis. In terms of the baseline diagnosis, it still takes the average person seven trips to a doctor before they get to a diagnosis of asthma. On top of that, we are still very poor in the UK at diagnosing when the asthma is allergic and when it is not. Our data shows that only 30 per cent of people with asthma are referred for any sort of allergy test by their GP. Most people do not even know whether their asthma is allergic or non-allergic, which then means that even starting a conversation about how you self-manage, how you avoid the triggers, becomes almost impossible. There is secondly the next level about what sets the condition off, what is likely to be causing it. There is also an issue about people needing much more information themselves, knowing what their asthma is triggered by, how to understand when their asthma is being triggered and self-management. We know that self-management plans, for example, in asthma make a huge difference in terms of hospital admissions, days off work and quality of life; yet fewer than one in five people in the UK with asthma have a personal asthma action plan even though the British Thoracic Society guidelines make it very clear that this can really make a difference and recognise the Asthma UK plan as a gold standard. It is about information and understanding and also about people around you understanding, things like perfume, for example. That can be a huge trigger to people’s asthma. One of the things that we do a lot of work on in Asthma UK is just getting the real world to understand small things like not having heavy perfume in buildings and thinking twice before animals are wandering around all over the place. Those can make a huge difference to people in terms of the management of their asthma. The other issue with asthma is second hand smoke which is one of the biggest triggers to people’s asthma and we welcome the role the Lords are playing in ensuring that we are going to have a smoke free UK.
Chairman: Thank you so much for that last comment in which I will bask.

Q782 Baroness Perry of Southwark: The Charity Commission published a report last month. I think it was called Stand and Deliver: the future for charities providing public services. They highlighted that many charities were not really being paid the full cost for the services they deliver to patients. To what extent do allergy charities provide patient care activities? What does that mean for patients and how does it impact on the funding they receive? Ms McManus: As a patient information charity, we do not have an awful lot of outside activities for patients but we provide a nationwide network of support contacts so that people with allergies are not out there on their own. They can be in contact other
sufferers. Obviously it is not medical advice but they can give support. We do become very much a listening ear. Often our calls are quite lengthy in supporting these people. If they have just been diagnosed, they are very frightened. If a child has just been diagnosed with a peanut allergy, the mum is absolutely terrified. She does not know what to do or where to go so it is listening and giving them the time that is so important. We do provide a lot of education. We are about to start an expert patient course later this year which is going to be totally online and it will be for the likes of parents, sufferers, playgroup leaders and Scout leaders so that they can get a better understanding of what allergy is. Most people do not understand the basics of an allergic reaction. It takes away the fear and helps them manage better. We also offer a bereavement counselling service for those who have lost members of their families to allergy.

Q783 Baroness Perry of Southwark: My question was about the funding.

Ms Covey: This is a huge issue for Asthma UK because we provide a number of what are really NHS plus services. They complement what the health service does in terms of individuals but also working directly with the NHS. That includes our Adviseline which is staffed entirely by nurses, all of whom have an asthma qualification on top of their normal nursing qualifications. There are our Kick Asthma holidays for children. There is our provision of health promotion material, including things like self-management plans which are something used jointly by the health care professional and the person with asthma to manage their asthma. We also work with local primary care trusts, particularly in areas with high asthma morbidity in terms of funding pilot projects in different areas to try and work out how we can move asthma care forward. At the moment we do all of that from voluntary income, not government funds. We do get caught in this Catch 22 situation. When we apply for government funding for our Adviseline, we get turned down on the grounds that it overlaps with NHS Direct. It does not. NHS Direct nurses quite rightly often refer people with asthma to our nurses who can have a detailed chat about their asthma. Similarly, we have been turned down before with regard to our health promotion materials on the grounds that asthma self-management promotion is the job of the NHS and yet we know large parts of the health service do that really badly and when they do it well it is because they are using our materials. That is an outstanding issue for organisations like us who have been doing stuff for a long time so we do not qualify for new money that you get for doing new and shiny stuff. We feel what we do complements what the NHS does. For example, our nurses will spend up to an hour on a call. A GP has seven minutes to talk to somebody and listen to them when they have asthma. He has to diagnose and prescribe at the same time whilst doing that. Whilst we are not in the trap of people who provide services and do not get paid their full costs, we are in a different trap where what we are doing is promoting best practice and we are not being paid for it at all. We know what we do transforms people’s lives and in some cases can save lives. We produce something called an asthma attack card which people can carry with them. It tells somebody else what to do when someone is having an asthma attack. About 80 per cent of people with severe asthma cannot ask for help when they have an asthma attack because they cannot speak. Every time we advertise that using voluntary funds we get inundated with calls. Two years ago when we first launched it we had to get a new phone system at our national office. At Asthma UK we feel quite passionate about the service we provide and the failure of government to take up these issues.

Dr Mills: In terms of food allergies, the Anaphylaxis Campaign worked very hard to train anaphylactics in the use of adrenalin pens and that is crucial. A lot of their work is funded from donations and corporate donations and I am not sure that they have any other funding for that work.

Q784 Baroness Perry of Southwark: Staying with the Department of Health system of contracting and funding, will that put allergy charities in competition with each other, do you think, or will it foster mergers? What will the effect be on patients of all that?

Ms McManus: It could possibly foster mergers. We all work hand in hand with each other anyway. We tend to keep in touch so that we know what is going on, but at Allergy UK we do not get any funding from outside apart from donations.

Ms Covey: In the allergy sector we do not have that multiplicity of charities that you see in some other sectors. For example, Asthma UK is the only national organisation that solely does asthma, although others do a bit of asthma as part of what they do. We do work closely together. We do not by and large duplicate each other’s work. If there were to be more government money available for providing more advice, information and services to people with the full range of allergic conditions, I am sure that there is such a huge gap that we would all manage to work together to work with the Department of Health and health care providers to fill that gap. The real problem is at the moment that nobody is trying to fill the gap except us and we are doing it from voluntary income.
Baroness Perry of Southwark: Do you think it would have an effect on patients if there were better collaboration and more mergers perhaps?

Ms McManus: They are already getting a pretty good service anyway. We give the best advice we possibly can. We all spend an awful lot of time on the phone and we almost provide a counselling service for these people.

Ms Covey: Unlike some areas of health care, asthma, respiratory and allergy are areas where the charities work really closely with health care professionals. I know that is not always the case in some areas with the health care bodies. Our area is a model of how we can work together in terms of how the charities work together and have their own areas of expertise. Also, we work very closely, for example, with people like the British Thoracic Society, the GP in Airways Group. I know you took evidence from Professor Tak Lee earlier on in these sessions about the work he does, running the centre that we run jointly with the Medical Research Council. I would hope that patients do benefit but they would benefit by having more money to spend. I think we get the best of both worlds at the moment because we have a good level of specialisation. For us as an asthma charity, not everyone’s asthma is allergic so by being asthma specialists we are able to handle the asthma specific issues and refer people on. If we were to lose that we would lose a lot. For us, the “Tescoisation” of the service anyway. We give the best advice we possibly can. We all spend an awful lot of time on the phone and we almost provide a counselling service for these people.

Viscount Simon: I was wondering what advice Allergy UK offers to patients or callers who claim to suffer from multiple chemical sensitivity or environmental disease.

Ms McManus: One of the biggest problems is that we find, by the time people call us, they are quite desperate. There is very little knowledge of the condition and people become quite depressed and very isolated with the condition and the way it has developed, because they are reacting to things in the environment. A lot of professional health advisors do not believe that is possible, so they become labelled. Obviously, because we are not medically qualified, we have to check whether there is an underlying condition there, so we do always check that they have been to their GP for other tests to make sure there is not something else wrong there. If there is not, we can give advice on how to avoid chemicals within the home environment, how to avoid a chemical load on their body if that is the kind of information that they are looking for. We can give support because often they become very isolated from their family and in their workplace. We have advisers on our health advisory panel who are very knowledgeable on chemical sensitivity. If there is nowhere else we do pass them on to the British Society for Ecological Medicine where they can get expert advice.

Chairman: Dr Mills, do you want to comment?
Ms McManus: Yes, a lot and we are getting more unfortunately.

Q791 Lord Colwyn: Could all of you say what you feel about the use of neutralisation/provocation tests? Are they supported by Allergy UK and all of you?

Ms McManus: It is one of these tests that have not undergone trials so we cannot support them. There are other tests that we would not pooh-pooh because a lot of people do seem to find benefit from them, but you have to be very careful when you are deciding what clinics you go to. Many of these treatments are done privately which is a big worry.

Dr Scadding: I did a paper 20 years ago trying to disprove this. I was very cross about this kind of technique. In a very small study it looked as though there might be something in very low dose, sublingual desensitisation. I got so much flack from the allergy community at that time that I largely stopped doing it but now sublingual immunotherapy is accepted and there is a Cochrane meta-analysis of high dose immunotherapy. If you look at the ALK data on GRAZAX there is the beginning of a curve and it may well be that there is an effect of low doses. I think this needs proper scientific investigation in good hands on a double blind basis. This will be somewhere to spend some experimental money.

Dr Mills: I would endorse that. It is quite important to understand this. In a study that was done in the Netherlands looking at desensitisation to pollen, the individuals lost their pollen allergy but they did begin to develop an allergy to apple, which is related. This is why immunotherapy is a very complicated therapy and it does not get rid of people’s allergies. It stops them perhaps expressing some of their symptoms and there may be quite complex interactions with some allergies disappearing and others reappearing.

Q792 Chairman: What was your response to the answer we had from Mr Dillon from NICE?

Dr Scadding: I was a little shocked that NICE is not prepared to look at sublingual immunotherapy or at immunotherapy in general because it can cure allergic disease and it is the only hope of curbing it at the moment. Corticosteroids are pretty effective but they do not cure the disease and it is a long term treatment. I think the government and NICE should take the long view about funding. It may be that immunotherapy is expensive in the short term but if it can give long term results then it is a long term cost-effective measure.

67 There is nowhere on the NHS that sufferers can get help, and it is not recognised by the medical profession as a whole.

Q793 Lord Colwyn: We had a discussion about pharmacists in the previous session. I wonder whether any of you want to add to what Helen Young said when we discussed whether the department were getting the correct advice from pharmacists about which allergy treatments to use and when they should use them?

Ms Covey: I would quite like to put in a plug for pharmacists certainly with regard to asthma. We have just done some work at Asthma UK with the Pharmaceutical Services Negotiating Committee as a result of which we have produced a joint pack around medicine use reviews on asthma because we feel that for some people, particularly with follow-on advice, the pharmacist is a good place to go if it is done properly for people who live with a condition all their life and do not want to go back to a GP every five minutes. The pharmacist is a real resource and we have had 10,000 of those packs ordered already by local pharmacists. Obviously at the moment pharmacy advice is still patchy but we see a real willingness amongst certainly the trade bodies in pharmacy to work much more closely with organisations like ourselves on some of these issues. We are hopeful that in future there will be much more scope for pharmacists providing advice so that people can get advice in a much wider range of places when it suits them. One of the problems is that, because people do not always like to go to their doctor, they let things drag on and they get slowly worse. They do not want to go to their GP unless it is really bad and it is half a day off work. Quite often, the pharmacist can be a fantastic stop-off point for people in that situation. The PSNC have done this work with Asthma UK around these issues in asthma and we are having a huge take-up already from local pharmacists so I think that is really part of the way forward.

Q794 Chairman: You said 10,000 packs. How many individual pharmacies are there in the UK? Does that represent 10 per cent, 20 per cent or 50 per cent?

Dr Scadding: I think there are around 40,000.
Q796 Lord Soulsby of Swaffham Prior: I am detecting a much more positive attitude to immunotherapy from you ladies than we have heard previously from other witnesses. Maybe you heard earlier that we found when we went to Germany, for example, that immunotherapy was quite popular. Could I bluntly ask you, should it be more widely used in this country?
Dr Scadding: Yes. I think probably it should be used very much earlier in this country. At the moment it is reserved for patients failing on pharmacotherapy. However, if you look at what happens in Europe there is a study looking at children with rhinitis treated by immunotherapy and now after 10 years they are 2.5 times less likely to have asthma than a cohort of children of a similar age treated with drugs. That progression from rhinitis to asthma, which we see to have a threefold relative risk, can be almost completely ablated by immunotherapy.
Dr Mills: I think it is also worth saying that sublingual therapy offers a much better route for administration than having the kind of conventional injections at frequent intervals, it makes it much more realistic to use.
Ms McManus: I do not think people realise the impact of something like allergic rhinitis or hayfever on people’s lives. They think that hayfever is quite a minor condition, but it can impact dreadfully, particularly on children who are just about to sit their exams right at the height of the hayfever season. There has been research carried out that they do not do as well in their exams as they did in their mocks earlier in the year, so it is very important.

Q797 Lord Soulsby of Swaffham Prior: We could take from you that we should include in our report a positive statement that immunotherapy is something this country should embrace a bit more?
Ms Covey: I think aligned with the point that it is very important, as people have said, that we have more information so that people are able to work out what is the best thing to do, what is the lowest risk thing to do. Also, like Glenis, I was sorry to hear what Andrew Dillon said earlier because really until the Department of Health and NICE start moving issues like this up the agenda then we are never really going to see a move forward, so it is not just about it being more widely available in theory, it is about it being more widely available in practice, having proper guidelines and also a strong message that it is a priority. The reality is that in busy general practices, in terms of referrals and how people understand things, GPs are focusing on the things they are being told are a priority, essentially either because it has financial incentives for the practice attached to it or they are expected in order to get the right number of stars to do it. It would have to be wider availability aligned with all those things, more information both for doctors and patients so that it is available in practice and the right people get it in the right way in the right place and at the right time.

Q798 Lord Soulsby of Swaffham Prior: Where would one put the pressure to get NICE to look into it in a more positive way?
Dr Scadding: I suspect directly on NICE, if possible. Could I say that I think it is an absolute nonsense that NICE is looking at omalizumab, which is a very expensive treatment. It does not cure, it needs to be taken long term, it is not particularly effective in severe asthma and they are considering that and failing to consider immunotherapy which is a more effective treatment and can be curative.

Q799 Chairman: Going back to the diagnostic end of this, do you think that there is adequate regulation for private clinics and the procedures which they offer for allergy diagnosis and treatment, and how can the patients choose who they should go to if they are going to a private service rather than going through their GP?
Ms McManus: I think this is a very difficult question. A lot of these private clinics are not regulated and you only have to look on the Internet to see the amount of different forms of allergy treatments that are popping up, some of them are very, very strange that you have never heard of. Some things should cause great concern like NLP, neurolinguistic programming, where, theoretically, psychologically you can cure an allergy. How you decide which one is good I do not know. We tend to give NHS clinics because we know that they are going to be looked after there, but there is just not enough of them, unfortunately.

Q800 Chairman: Dr Mills?
Dr Mills: The British Society of Allergy and Clinical Immunology has a list of people that is where I point people to because I feel that is a trusted list of accredited people who know what they are doing.
Dr Scadding: I agree. Anyone can set up as an allergist and it should simply not be allowed, we should have some kind of proper accreditation with a recognised qualification.

Q801 Chairman: Are there false claims being made over allergy treatments?
Dr Scadding: Yes.

Q802 Lord Colwyn: I think we covered this subject in the earlier questioning and it is about the University of York study that was commissioned by Allergy UK. Is there anything you want to add to that? You probably heard our discussion.
Ms McManus: I think Dr Hart covered it very adequately. The study that we commissioned was on over 5,000 people and of those who stuck to it rigidly, which was something like 67 per cent, I believe, 75 per cent found a huge improvement in their condition.

Dr Scadding: It is well known that irritable bowel syndrome can respond to dietary exclusion, I have no dispute with that. What I do dispute is that it is worth making any attempt to identify IgG antibodies, we all make IgG antibodies to food. Dr Pamela Ewan will tell you that 100 per cent of the population she studies had IgG antibodies to egg and I see no way in which this can be used to guide diet. In the Gut paper, which is the best paper produced, the sham group did not avoid dairy or wheat, which are the two major problems with IBS patients, and, therefore, it is not surprising that at the end of the study there was a 10 per cent difference. In that paper the number needed to treat was nine, whereas if you do an exclusion diet the number needed to treat is somewhere between two and 2.5, so I do not think there is any point in spending money on IgG antibody tests, you are better off going to see a dietician and using an exclusion diet followed by re-introduction. The IgG antibody tests are liable to leave patients on diets that are inadequate and patients often like to think they are improving and they carry on in the teeth of very little improvement and may end up malnourished.

Q803 Lord Colwyn: Are these self-testing kits you are referring to?

Dr Scadding: No, this the York Laboratories blood testing.

Q804 Lord Colwyn: Tell us what you think about self-testing kits and are they sufficiently regulated?

Dr Scadding: They should be banned. I am very sorry, but I saw a child this morning before coming here. We did skin tests, which are well recognised, and she had skin tests to house dust mite and also to tree pollens. She has absolutely no symptoms referable to the tree pollen whatsoever, she does not have spring hayfever, she has good symptoms related to the house dust mite, so I treated her with house dust mite avoidance and immunotherapy. If she had got a kit then she would have felt that she was tree pollen allergic as well and something had to happen about that. She has sensitisation but not clinical disease, and if you do a test only about half the people with that positive test will have clinical disease, so you cannot have self-testing kits, they are going to lead to misdiagnosis, wrong-allergy avoidance. You need both the test and a detailed history taken by somebody who has some experience of allergies to be making an interpretation of tests.

Q805 Lord Colwyn: Of course the number of experts are so few and far between, inevitably you are going to be using tests.

Dr Scadding: Absolutely, people and training. A lot of primary care nurses are being trained in doing skin prick tests and interpreting them in places like the Respiratory Training Centre at the Athenaeum in Warwick and I think that may be a way forward.

Dr Mills: I would just like to endorse what Glenis has said and for food allergy it is even worse. There are a lot of people who will have apparently been sensitised to foods like wheat but do not have any symptoms, and that can be really problematic when people eliminate important food groups from their diet.

Q806 Chairman: What about the issue of inflammatory bowel disease that we heard about in the last evidence session?

Dr Mills: In terms of the IgG?

Q807 Chairman: Yes.

Dr Mills: It is not particularly my area of expertise, but I think that it is a symptom in that people do benefit from dietary interventions, but the link at a molecular basis between IgG and irritable bowel syndrome is not apparent and we make these antibodies to our food protein as part of our normal functioning.

Q808 Chairman: Ms McManus, this was a study that, if I am right, your organisation commissioned. I wonder if you have anything that you want to add to what has been said?

Ms McManus: The main thing that I have to say is it is because of a lack of NHS services, we have nowhere else to send these people to. We would give the York test purely because it is the only one that has undergone clinical trials, particularly for IBS, and that is why we are happy to endorse it for those kinds of symptoms, but we would not recommend any other test.

Q809 Baroness Perry of Southwark: A question for Dr Mills really. What role does the Institute of Food Research play in the primary prevention of allergic disease?

Dr Mills: I have been thinking about how to answer this one. If you see preventing allergic disease in two parts, the first part is preventing somebody becoming allergic, how do we stop people even producing IgE. At a fundamental level we still really do not understand the mechanism whereby one person becomes allergic and another one does not, we really do not at a very fundamental level, and that is where the IFR has a role because we have a lot of the BBSRC-funded research on a fundamental level of what are the molecular mechanisms underlying that
and, particularly, there is the dialogue between the gut bacteria and the human host in early years understanding that at a molecular level. I think that is fundamental in designing preventative strategies that really work in an incontrovertible way. That is one level. The other level is somebody who gets allergic and how do you prevent them from getting an allergic disease. We have heard about immunotherapy and one of the things that we are developing is possible oral vaccination strategies using engineered lactic acid bacteria, but there is another level related to my own personal research which is understanding the allergens in foods and how they trigger allergic reactions to food. That is very important when you start looking at doing allergenic risk assessments of novel foods, you do not want to introduce a novel food that is going to cause problems, like peanut, and how do you do that. That is part of the role, for example, I have in putting into the advisory committee on novel foods and processes which do that. The IFR provides lots of fundamental research which underpins that. The other thing we have is a big database that we set up with EU funding which has a lot of information about foods that people are allergic to and I think providing them with that information is where we see us working hand in hand with the allergic consumers.

Q810 Baroness Perry of Southwark: Following on from that, do you think it is appropriate that the current government advice still recommends the avoidance of peanuts for babies who have a family history of allergies?

Dr Mills: That was founded on research that was done some years ago and I think an awful lot has happened since then.

Q811 Baroness Perry of Southwark: Exactly.

Dr Mills: I suspect the Food Standards Agency, which is particularly involved in some of that, is probably wanting to go back and re-examine it, particularly in the light of the recent studies where in the USA they have been introducing peanut in an effort to desensitise; clearly, that has to be done under clinical supervision because you do not want a child to have an adverse reaction. I am involved in this big European study and we also work with people from around the world and in Ghana, where they eat a lot of peanuts, they introduce peanuts as a weaning food in subsistence farming and eat peanuts as a very large amount of the diet. I think understanding how the exposure aspects affect allergy there are lots of lessons we can learn from other communities around the world I think to help prevent that in the future.

Q812 Lord Colwyn: We heard from Gideon Lack from the hospital over the road about the work he is doing. I imagine it will not be long before you identify the cause of the allergy in the peanut and then genetically modify it?

Dr Mills: Some people have already started doing that. One of the difficulties is that there are quite a lot of proteins in the peanut that cause allergy and if you remove them by genetic engineering you will not have a peanut any more, it will be something else.

Dr Scadding: I was going to mention Gideon Lack’s work of feeding peanuts early to babies but you already know about it.

Q813 Baroness Perry of Southwark: Yes, indeed, thank you. Apart from food avoidance, are there any other effective treatments which can be recommended for people with food allergies?

Dr Mills: Not at the moment.

Q814 Baroness Perry of Southwark: Really?

Dr Mills: If you have got food allergy you spend your life reading labels. My other plea is really if we are going to address these issues and get to the bottom of them, we need some joined-up thinking with the fundamental science, the biological science and the clinic, but we also need the social science. In the work we have done in EUROPREVAL, my EU project with economists, we have shown in preliminary evidence that in the families which have to live with food allergies it is women who bear a disproportionate burden of the cost because they are the carers and have significantly lower socio-economic status. They miss a lot of work because of hospital appointments and so on, so there is a big economic burden. I think that is a given for allergy as a whole and is part of the equation in saying, “Well, okay, immunotherapy may not be perfect but it is going to give a benefit to quite a lot of people”. It might cost more, but if you have somebody who is 14 and they are going to have to take that for the rest of their life, that is a long time for somebody to have to suffer that burden of disease and we need to do some sums which incorporate that.

Q815 Baroness Perry of Southwark: Of course it is expensive to the economy anyway because they have time off work.

Dr Mills: But we do not have the numbers which back that up.

Q816 Baroness Perry of Southwark: What do you think the Government should do to educate patients about their food allergies or intolerance for those with true allergy about emergency medication?
Dr Mills: We did some work quite a few years ago looking at this, and trust is a very important part of giving people information. There are two groups that are pivotal in all of this. The first is the clinic, the clinician and the doctor, and the second is the allergic patient groups. Those are two providers of information that are very, very important and I think they should be supported in doing that. I see us as a fundamental science institute providing that information in a form which allergic consumers can use to pass on to their membership.

Q817 Baroness Perry of Southwark: We heard evidence from Dr Jean Monro who said she could treat food allergy with sublingual therapy, even for peanut allergy. What do you say to that, particularly Dr Scadding?

Dr Scadding: I think we need proper trials of sublingual immunotherapy. There are reports from the American Academy of Allergy and Immunology on the sheer sublingual desensitisation to hazelnut, so it may be a possibility, but it needs to be properly done in a very carefully-controlled setting.

Dr Mills: I think the options for that may also be more viable for those people who suffer nut allergies which are associated with pollen allergies and that is a much more realistic therapy for food allergy as opposed to the people who are just allergic to nuts.

Q818 Chairman: Leaving aside the need to improve allergy services, I wonder if you would agree that is number one to improving allergy services but, if we put that on the side, what are the most important areas that now need to be addressed to improve the services for patients generally in terms of prevention, treatment, research and so on?

Ms McManus: I think for Allergy UK it is education.

Q819 Chairman: Of?

Ms McManus: Primary care, local GPs and practice nurses. They are the first port of call.

Ms Covey: For us there is a real issue about research. Asthma UK funds a fair amount of research into asthma generally and also the allergic mechanism of asthma but really it should not just be left to a charity through voluntary donations to be trying to move this debate forward. Our Basic Asthma Research Strategy identified a number of priorities and that is how we bring together a whole tranche of different scientists, clinicians and other experts to try and say, “Well, if we have to focus on asthma research what should we do?” That identified a number of areas that were allergy-explicit, in particular the whole issues around how allergy and allergic asthma develop. There are things like the hygiene hypothesis that people still cannot agree on, but if we could get to the bottom of it it might be a really useful way forward from where I sit as a lay person. We are keen to see more work into the role of infection in producing allergic inflammation, the relationship between infection and allergy. Also we need to see more research into immunology, which we have already talked about, and new treatments for allergy, including the potential vaccines we have for allergy. I think in the long term what we really want to see is allergy taken much more seriously and much more research on these issues so we can start to understand what the real answers are going forward, not just to enable them to live with allergic conditions but also to reduce the amount of allergic conditions in the UK going forward because it is an epidemic and it is a growing epidemic.

Dr Mills: I have already said I think we need to have better joined-up and a greater proportion of fundamental research into the biology because the clinicians are not going to get the answers that we need, they have a different role to play.

Dr Scadding: I think we need to look at primary prevention: whether we can mimic bringing up children on a Bavarian farm with something like endotoxin; whether something else like vitamin D is playing a role is an interesting idea from America, that lack of vitamin D may be relevant since this helps to regulate T-cells; whether secondary prevention is possible: whether we can switch off with immunotherapy early on in the course of disease, switching off rhinitis and preventing the downward slide into more complex allergies; and I think the link with infection is very important. If we could cure the common cold we could prevent an awful lot of exacerbations of asthma, sinusitis and otitis media with effusion. Then, finally, there is a possibility that bacterial infection may be a complicating factor of many allergies, we see it with polyps, atopic dermatitis and asthma and whether by then it is too late to do anything about the allergy because there is the secondary problem of a chronic bacterial presence and a different kind of T-cell infiltrate.

Q820 Chairman: I wonder if I could ask you, Dr Scadding, how often do you see patients whose treatment has been inappropriate? I am not talking about the ones where the allergic element has been missed but where they have been treated inappropriately for their allergy and, therefore, have come to clinical harm before they are referred?

Dr Scadding: At least once a week and often more than that.

Q821 Chairman: What are the main causes?

Dr Scadding: The main causes are that they have been unrecognised and under-treated or treated for something other than allergy.

Chairman: Thank you.
Q822 Lord Colwyn: Not being a great fan of antibiotics, would you suggest, in fact, treating people with colds with antibiotics to prevent further infection?

Dr Scadding: No.

Chairman: Could I thank you very much for having come today and giving us evidence so clearly. If there is anything else you would like to submit we will look at it as part of the evidence from today. Thank you all.

Supplementary memorandum by Allergy UK

This evidence addresses issues raised in the oral evidence session of 15 March 2007 which it was not possible to fully explore within the session.

Thank you for sending through the transcript of the minutes of evidence taken before the House of Lords Science and Technology Sub-Committee.

Q796 Allergy UK would like to pick up a statement made by Dr Glenis Scadding that Pharmacists should not diagnose allergy. It is the belief of Allergy UK that the majority of allergy could be successfully diagnosed and managed in primary care and this includes, as an essential part, Community Pharmacists. We believe that given the correct training there is absolutely no reason why Pharmacists could not play a major part in meeting the desperate need of people with allergy to know and understand what is causing their allergic symptoms. We appreciate that in an ideal world everyone presenting with allergic symptoms would be seen by an allergy specialist, we are however realistic that this is not going to ever be possible given the lack of specialist training posts in allergy and the present thinking of health services being delivered at primary care level rather than secondary care settings. We have therefore carefully considered the needs of primary care and as stated in evidence the greatest need is for education of OP’s and Practice Nurses and we also believe in education to maximise the tremendous skills and knowledge available in local pharmacies.

Q809 Allergy UK would also like some clarification placed before the Sub-Committee regarding the York Test. As the Lords were made aware by Lindsey McManus this is the one test that we endorse. The test, as was made plain, has undergone clinical trials at Manchester Hospital and this coupled with our own anecdotal survey led us to look in more depth at the service and advice given by York Test. In her evidence Dr Scadding states that it is better for patients to see a Dietitian and nobody would dispute this, however our extensive experience has shown that being able to obtain a referral to a Dietitian who understands food intolerance is extremely difficult on the NHS.

I think it is important for members of the Sub-Committee to be aware that in addition to the clinical trial and the anecdotal studies, we also assured ourselves of the service level to their clients by York Test. In her evidence Dr Scadding states that it is better for patients to see a Dietitian and nobody would dispute this, however our extensive experience has shown that being able to obtain a referral to a Dietitian who understands food intolerance is extremely difficult on the NHS.

We have yet to receive a complaint from anyone who has undertaken the York Test and in fact have many calls from people stating that it has revolutionised their life and given them back their quality of life.

Q785 Allergy UK would like to echo Donna Covey’s comments that the advice services of both our Helpline and Information often falls between two stalls. We are in fact doing the work of the NHS, in providing advice, support, information for the general public and we are educating healthcare professionals, all from our funding which is generated outside of statutory funding.

It is extremely difficult for charities such as Allergy UK to generate funds from a totally unbiased source of income. We regard it as vital to do so to guarantee “best advice” is given. As Donna Covey stated we are often rejected for funding on the basis that we are providing what should be a statutory service and in other areas we are often rejected for funding because the service is well established and is not “a new project”. Our materials are used extensively by healthcare professionals as is our advisory service, yet we do not receive funding to guarantee the production of these materials and their ongoing reviews.

21 March 2007
Q823 Chairman: Good morning. Thank you for coming. Could I welcome you, Under Secretary of State, and also Mr Bell and Mr Bromley for coming today. I am Lady Finlay; I am chairing this Sub-Committee on Allergy. This is being web cast and we will be going round asking questions. There is a Members’ note of declared interests so we will not run through those prior to any questions because it is all there and will be published. Could I ask you if you would formally like to introduce yourselves for the record, and then we will go into our questions?

Mr Lewis: Thank you very much Lady Finlay. I am delighted to have the opportunity of appearing before the Select Committee. I am Minister for Care Services in the Department of Health. Essentially I have two sets of responsibilities: one is for children’s health and the other is adult social care. I think we would all agree that allergies are a massively important issue for the many, many families that are affected by them and it is an issue which perhaps has not had sufficient priority or profile, historically, but the impact that allergies can have on the entire family is quite serious indeed. So I personally think we have quite a long way to go in terms of, first of all, giving this issue the priority status that perhaps it deserves, but also in the way that we diagnose allergies and also obviously both health and social care response to families experiencing this particular condition. I will leave it at that in terms of opening remarks.

Mr Bromley: My name is John Bromley. I am the Head of National Service Reviews, so I look at all at the clinical reviews in the Department of Health. Recommended that the health agenda should be considered across all government departments when developing policies. Can you explain to us how you work with other departments, particularly in relation to the needs of allergy patients and how these needs are taken into account?

Mr Lewis: I think essentially, if the NHS is to move from what it has been, effectively a sickness service, to a health service, the reality check for all of us is that there are a whole variety of factors which impact on people’s health and well-being, many of which are not within the controls solely of the Department of Health, so it is absolutely essential that we make a reality of the rhetoric around joined-up government. Anybody who has been anywhere near government knows that it is one of the more challenging tasks that we face because joined-up working is not the same as sitting around the same table at Cabinet Committees, frankly: it requires a far more integrated and profound way of looking at different policy areas than that. I can give a specific range of examples of how, relevant to this issue, we are trying to work in a more corporate way. First of all, at ministerial level, there is a Domestic Affairs Cabinet sub-committee on public health. That is underpinned by a supportive structure at official level of programme boards, including the Health Improvement Board. So essentially you have a ministerial oversight of a number of groups of officials working on specific programmes and policies. In terms of our work with other government departments on a bilateral basis, if you like, which is relevant to the focus of our discussion today, we are working very closely with Defra on air quality issues. Defra chairs an Air Quality Interdepartmental Group, which meets every couple of months, and there is an Air Quality Forum which brings together other stakeholders from outside of government as well as the relevant government departments. In 2005 we issued joint guidance with the DfES on Managing Medicines in Schools and Early Years Settings, and that includes specific guidance on anaphylaxis, which obviously is a welcome and important step forward. We obviously have to work very closely with the Health Improvement Board.
and Safety Executive to exchange information on occupational allergies, and in terms of looking at our policies on indoor air quality we did work closely with the Department for Communities and Local Government and they also worked with us in terms of their proposals for ventilation rates as part of the Building Regulations. In terms of children and young people, obviously there is a Minister for Children, which is a very, very important step forward. There is the Every Child Matters strategy, which seeks, more than anything, to demonstrate the case for the earliest conceivable intervention with children and young people, whether it be through the NHS or whether it be through the education system in formal childcare. Certainly the Every Child Matters agenda seeks to bring all government departments together to look holistically at the needs of children and families, starting from the beginning of a woman’s pregnancy and all the way through to the beginning of primary school and then beyond. So I think there have been advances in terms of interdepartmental and cross-government working, but I personally think—not just on this issue but on a whole range of issues—that if the big picture challenge is to secure the health and well-being of local populations it is no longer enough simply to regard that as the responsibility of the Department of Health or Primary Care Trusts at a local level; there really has to be a joined-up approach. My own view is there needs to be a much closer relationship between PCTs, local government and the voluntary sector in every community and we need to move away from a woolly notion of partnership to a more hard-edged notion of a genuinely integrated joined-up approach.

Q826 Chairman: Could you just explain why allergy comes under your remit as care services? Is it just because it has been lumped on you or is there a specific area of activity?

Mr Lewis: I think I would be in serious trouble if I described it as having had it lumped on me. As I said at the beginning, my responsibilities are clear—they are children’s health and social care. If you looked at the other Ministers’ responsibilities it would not necessarily be simple to decide where responsibility for allergies would belong in terms of any one Minister’s responsibility. I think it is a difficult call to make, if I am frank, because it covers acute NHS care, primary care, social care, and with kids it has relevance, so there is a whole range of policy areas. I think it could sit with several members of the ministerial teams—public health—so why it is with me—and, as I say, I will not use the word “lumped” on me—I am not totally certain.

Q827 Earl of Selborne: The Cooksey Review has recommended that the Medical Research Council funding and the National Health Service research funding be coordinated through an Office for Strategic Coordination of Health Research. Can you tell us how you would expect this to impact upon the level and allocation of funding for allergy research?

Mr Lewis: Obviously we first of all have to consider properly Cooksey’s recommendations. The interim oversight group for the Office for the Strategic Coordination of Health Research was only established in January, and it is at the moment discussing the detail of how the recommendations made by the Cooksey Review will be taken forward. That Office for the Strategic Coordination of Health Research will be working with UK health departments and the Office of Science and Innovation to define our health research strategy going forward, and that will include the strategic direction for research into particular disease areas. To be very frank with you, at this stage I cannot tell you the level of financial commitment that will trigger over the next few years—as much as anything else, as Members of the Committee will be aware, the Comprehensive Spending Review deliberations are not concluded—so in terms of being absolutely clear about the level of government resource that will be available in this area at this stage it is not possible for me to say that. Would I hope that, by having the Cooksey recommendations and the new structure that will be created as a consequence of Cooksey’s recommendations, it will lead to a higher priority being given to allergies and a clearer focus? Clearly I believe that that will be the case but I cannot give you a tangible commitment on how much additional resource this may trigger.

Mr Bromley: One thing I would like to say is that we in the Department spent quite a lot of time to try and get the organisation up to speed as quickly as possible, so that it could make a bid as part of the CSR 2007. So it has made a bid and I think that bodes well for the future. Effectively it is a question of timescale but we wanted to get the organisation up and running so that it could do that.

Q828 Earl of Selborne: The case that Sir David Cooksey made very persuasively, I felt, for bringing together this Office for Strategic Coordination was the mismatch between some of the basic work done very effectively by the Medical Research Council and the inability to get this translated into clinical research. Given that the MRC has funded such work as molecular mechanisms of allergy, and at the other end of the spectrum there is this great need to get this translated into clinical research, where would you expect the emphasis to change if the Office for Strategic Coordination gets into its stride?

Mr Lewis: I think we would want obviously better coordination; we would want a clearer strategy going forward because I think if you look at the history it has not been particularly impressive and I think that
is why Cooksey’s report was so important. So more focus, greater priority, clearer focus on the outcomes we are seeking to achieve. I think the Committee will be aware that £4.75 million has been allocated over five years to the National Institute for Health Research, specifically to look at allergy. I would hope that essentially it would lead to more resource but a clearer focus on allergy as an issue in terms of research in this country.

Mr Bell: If I may briefly add to that as well. The Committee will be aware that one of the recommendations of the Cooksey Review was to establish a Translational Medicine Board to work jointly between the new National Institute for Health Research and the Medical Research Council, to give a strategic direction for translational research within the context of the overall health research strategy. That is something that we certainly propose to take forward once we have OSCHR itself up and running properly.

Q829 Lord May of Oxford: My question sort of relates to this but a particular aspect of it, in that clinical allergy research often involves long-term prospective studies that require funding over many years and a lot of it is not in the elegantly precise, sexy imagery of molecular biology where you can do nice, clean precise things. So there are two kinds of tensions: one the long-term and one the fact that it does not fit some people’s image of what is the best kind of basic research. When you couple that together with the disconnection that the Cooksey report seeks to address between our excellence in clinical research and perhaps in a global league table positioning near the top in delivery of healthcare, I wanted to ask how do you see the new arrangements affecting for the better funding for these kinds of long-term prospective studies?

Mr Lewis: I think we would say that Best Research for Best Health, which is obviously the new strategy, is all about ensuring stability in terms of research funding. We think it also opens up the possibility of sustained funding specifically for high quality research proposals, epidemiological studies and clinical trials. We think that that strategy offers a significant new opportunity. I suppose an example of that is the resource that has been allocated that I referred to earlier over the five-year period. There is the NIHR, which also provides a key mechanism through which the Department of Health will deliver the new research and development strategy. So I think there is a framework now which gives us an opportunity to create a longer-term, more stable approach, but in the end we will be judged by the difference that that makes and at this stage that new framework, that new strategy is at a very early stage in its conception. I think we would say that what has happened to date has not been satisfactory, has not always been as good as it needs to be and that the health research strategy that we have published will make a real difference in that respect.

Q830 Lord May of Oxford: More specifically, the clinical research by its nature is linked to allergy services, so precisely how will the OSCHR coordinate this kind of research when the allergy services themselves are being commissioned locally by individual Primary Health Care Trusts?

Mr Lewis: The link between practice and research is obviously one you will be far more aware of than myself, but it is absolutely clear. What we have is nine organisations now, essentially Strategic Health Authorities, and the PCTs in every locality are responsible to those Strategic Health Authorities, and it would seem to me that there is an opportunity there in terms of perhaps one of the Strategic Health Authorities taking lead responsibility and being a conduit in terms of making sure that in what is happening there is a link, there is a direct correlation between research and practice at a local level. It would be a nonsense to suggest—I am not sure how many Primary Care Trusts there are these days—that there could be a realistic or credible relationship at Primary Care Trust level and research, but I think certainly Strategic Health Authorities, which are organised on a regional basis, would also of course—and maybe we ought to make more of this—have coterminousity with Regional Development Agencies, which also obviously have a role to play in terms of research. So I think that may be a model that we need to explore as a Department and maybe one option, as I say, would be to get one of the Strategic Health Authorities to take lead responsibility.

Q831 Lord May of Oxford: One other follow-up question, of a more technical kind too, is that it has been suggested to us by some of the people we have talked with that it would be extremely useful if there was a coordinated central disease registry that held details, in so far as they are available, of allergy patients’ genotypes, phenotypes and responses to various types of treatments as a unified and coordinated whole. What is the Department’s view on this?

Mr Lewis: My initial response to you is that I do not have a view.

Q832 Lord May of Oxford: I would have thought your initial response might be it would be a bloody good idea!

Mr Lewis: I am not sure. You always have to look at whether the infrastructure that we need to create to ensure that we have that database—I do not think my official agrees with you that it would be a bloody good idea, by the way, judging by the note just passed to me! I am sorry, you are not supposed to say words
like that in such august surroundings! The reality is that I will go away and reflect on that and consider whether the benefits really do bring the added value that would be necessary in terms of the cost in investing in the infrastructure. If the cost brings real added value and real benefits then it is something that we ought to look at, absolutely. But I think the case is not proven.

Q833 Chairman: Does Mr Bell want to comment in the light of this note?
Mr Bell: I think I had better now! I was simply going to suggest, as I think the Minister has really, that this is an issue that does come up quite frequently across a range of diseases and it is always going to be a case of weighing the benefits against the costs, which can be quite considerable.

Q834 Lord May of Oxford: There is a huge comparative advantage we potentially have with the NHS, which is not exploited nearly as effectively as many of us think it could be.
Mr Lewis: Can I suggest, to help the Committee, that we write specifically on that issue because that will mean we will go away and give it some very serious thought?
Chairman: Thank you, because there are, I think, 150 PCTs across the country, which is why this link between research and translation in clinical practice becomes important. Lord Haskel.

Q835 Lord Haskel: Could we turn to the effect of allergy on the economy, and can you tell us what steps you are taking with the Health and Safety Executive to know the true number of people suffering from occupational allergic disorders, and as well tell us about the types of jobs most commonly affected? And can you deduce from that the cost to the nation’s economy?
Mr Lewis: A bit of a tall order, but we can certainly talk through the work that we do with the Health and Safety Executive. We exchange information on occupational allergies, and we have joint membership of Committees and direct involvement of NHS physicians in some of the Health and Safety Executive’s activities. The HSE uses a number of sources to obtain information about the number of people suffering from occupational allergic disorders and their jobs. I think those are outlined in the Memorandum that we submitted to the Committee. There is a particular database, which is The Health and Occupation Reporting network, which records new cases of occupational allergic disease referred to consultant level, and the details in that respect include the case’s occupation, the industry they work in and the suspected causative agent. I believe that recently the Health and Safety Executive has also commissioned an occupational health trained GP reporting theme and the expectation is that that will provide additional data and in particular—and I think this will help with evidence—certificated sickness absence. The HSE, as Lord Haskel is probably aware, has recently published a report on the costs, in their view, of asthma. The Memorandum for the Committee included some specific examples of how the Department and HSE work together—I am not going to at this stage report those. What is the true cost? There is no doubt that the cost burden of new cases falls most heavily on the individual worker and society. The report that was published estimates that total lifetime cost to society of new cases of occupational asthma diagnosed in 2003 was ranging from around £71.7 to £100.1 million, and if comparable numbers of new cases were diagnosed in future years this would give rise to additional streams of lifetime costs of similar magnitude. So that is an attempt to respond.

Q836 Lord Haskel: Thank you. You did refer to the database, and when we saw Professor Agius, who runs The Health and Occupation Reporting network at Manchester, he told us that he thought that this database was under threat. Has the Department of Health discussed the importance of data capture with the Health and Safety Executive and will funding be guaranteed for this project, for this database in the future? He was obviously concerned that funding was going to be cut off.
Mr Lewis: Lord Haskel will be well aware of this kind of advice—it says it would be unhelpful for me to comment. But of course my responsibilities to a Committee of the House allow me to say that. As I understand it, there are ongoing contractual negotiations, so the question is, is there a question mark over this and the answer is yes—that is the logical conclusion of there being contractual discussions and contractual negotiations. So to be very frank with you, until those are resolved we are not clear about what is going to happen going forward, but that is the truth of the position.

Q837 Chairman: Could I just ask, it would be helpful for us to have an update as well after this session because it was on 10 January that we had evidence and Professor Agius in that evidence commented that the funding had finished at the end of the month and they are carrying out schemes partly through reserves of funds and partly through charitable support, and that was back in January. So if we could have that in writing afterwards?
Mr Bromley: I will make sure you get an update as quickly as possible.
Mr Lewis: This is the THOR scheme?

Chairman: Yes.

Mr Lewis: As I understand it, the funding is 2004 to 2008 and the option in terms of the contract that was agreed was whether beyond 2008 we would go to 2012, so I would be surprised if there was an immediate funding problem.

Chairman: It would be really helpful then to have it clarified for the Committee.

Mr Bromley: We will write to you.

Chairman: We know that the prevalence of hair dye allergy as an occupational problem, and indeed for consumers, is increasing and the Scientific Committee on Consumer Products in March produced a memorandum, following which the European Commission announced that it will extend its assessment of hair dye products. We also know that there are cross-problems with black, semi-permanent tattoos. Can you tell us who is responsible for ensuring that allergenic chemicals in these products are properly labelled in the UK and what the government is doing to make sure that the public are aware of the potential risks when using these products?

Mr Lewis: I certainly never expected my ministerial brief to take in hair dye! But it a serious issue actually, an increasingly serious issue.

Chairman: We know that the prevalence of hair dye allergy as an occupational problem, and indeed for consumers, is increasing and the Scientific Committee on Consumer Products in March produced a memorandum, following which the European Commission announced that it will extend its assessment of hair dye products. We also know that there are cross-problems with black, semi-permanent tattoos. Can you tell us who is responsible for ensuring that allergenic chemicals in these products are properly labelled in the UK and what the government is doing to make sure that the public are aware of the potential risks when using these products?

Mr Lewis: You also mentioned the question of tattoos and that, again, raises all sorts of very, very significant health issues that maybe we would not have been responding to only a few years ago. I think there are different levels of responsibility here, so it would be helpful to go through those. First of all, the manufacturers of cosmetic products, including hair dyes, sold in our country are responsible for ensuring that their products comply with something called the Cosmetic Product (Safety) Regulations 2004, as amended. Those Regulations were designed to implement the EU Directive on the safety of cosmetics, for which the Department of Trade and Industry is the enforcing authority, and on their behalf it is Local Authority Trading Standards Departments that are responsible for implementation on the ground. Amongst the obligations under these Regulations are strict labelling requirements in terms of making consumers aware—all cosmetic products must be marked with a full listing of the product’s ingredients, including colouring agents. In actual practice, the testing for allergy to hair dyes is commonly carried out by using a small sample of the dye on the skin; tests sold separately to test hair for adverse reactions prior to dyeing can be considered to be a licensable medicine, if they act immunologically and the primary intended purpose is to test for an allergic reaction. However, to date—and this may change—the MHRA has received no applications at this stage for market approval.

Chairman: Does the government have any input into the raising awareness days, such as the Bad Hand Day, which the Hairdressers’ Association is running, or is that organised completely independently by their own association on their own initiative?

Mr Lewis: I am not aware at this stage that the government has any involvement in it.

Mr Bromley: I think it is through the DTI and I think there is some kind of sponsorship. Once again, I can find out, but I am sure that there is government sponsorship in the relevant department for that.

Chairman: And it would be helpful to know the amount of sponsorship when you are investigating that.

Mr Bell: I would add that the other government body with an interest as far as hairdressers go is of course the Health and Safety Executive and that body has produced written guidance specifically for hairdressers.

Chairman: But a lot of these products are not sold and used by hairdressers, they are used at home. And tattoos certainly are not done by hairdressers; but that is another area. Lord Soulsby.

Chairman: But a lot of these products are not sold and used by hairdressers, they are used at home. And tattoos certainly are not done by hairdressers; but that is another area. Lord Soulsby.

Lord Soulsby of Swaffham Prior: The next question is somewhat related to the previous one. From previous evidence we have heard that the terms “hypoallergenic” and “dermatologically tested” are meaningless. The question is how will the government ensure that consumers are protected from misleading claims placed on cosmetics, bed linen and other products?

Mr Lewis: There is first of all the general. Any description of a product by a manufacturer or a vendor must not be false or misleading, and this also applies to labelling, whether provided voluntarily or required by regulation. So, in general, there must not be false or misleading information or labelling. There is action that can be taken, if that were to happen, under the Trade Descriptions Act of 1968: it is a criminal offence for a person in the course of a business to apply a false or misleading trade description to goods. Enforcement of the Act again is the responsibility of Local Authority Trading Standards services. There is also a new Directive—the Unfair Commercial Practices Directive, adopted on 11 May 2005, which will, as a consequence of Regulations, take effect in April 2008, where the Department of Trade and Industry is the lead department. What that will do is to introduce a
Standards are not often made at point of sale; so the Trading Standards Officers are at a disadvantage. Perhaps the Advertising Standards Authority also would have a say in this. Are they affected in this way by the Unfair Commercial Practices Directive as well?

Mr Lewis: They certainly have a code of practice, they certainly have parameters, yes, and there are rules—there are codes of practice. I cannot say today whether they have even looked at this issue—I suspect that they have not—but there is absolutely no reason why we could not refer this matter to them and seek information from them—the Committee could do it but we could do it as well—and get them to focus their attention on whether this is a serious problem in terms of advertising and whether there are potential breaches of their code of conduct. It seems to me that the question triggers an action from both us and the Committee, which could only be helpful.

Q847 Lord May of Oxford: I may have misunderstood something here—and I do not think we should spend too much more time on it—I thought you just said from the pending legislation that it said “hypoallergenic” is a medical term, whereas the spirit of the question that is being asked is we have heard people say it is gobbledygook, that is to say it is not so much misleading as meaningless, but misleading by trying to sound like it means something.

Mr Lewis: Yes, and that is the problem legally because if a member of the public were to view it as incomprehensible that is not the same as it being misleading or inaccurate.

Lord May of Oxford: You read a form of words a moment ago which suggests that the pending legislation defined, gave it meaning, which is going to be complicated for us if we get to say anything about this. We should look at it in detail later.

Q848 Chairman: We do not want to spend too much time on it but, actually, talking about something hypoallergenic should mean that it has a low potential to trigger allergy and cause an allergic response, but it does not mean that it is non—it is hypoallergenic—and I am not sure that we have really seen claims for particularly non allergenic attached to substances for which there is no known allergy anyway, such as water.

Mr Lewis: I have to say I think this reinforces the point. I suspect that there are two issues here. One is whether the manufacturers believe that the new legal framework requires them to change the language they are using because their lawyers will clearly have to make judgments about that; secondly, whether ultimately in this area there would be a test case, in my view.

Chairman: I think I would like to move away from cosmetics, if we can. Lady Platt.

Q849 Baroness Platt of Writtle: This does change the subject. The House of Commons Environment Committee’s report on “Indoor Pollution” recommended at that time that the government...
clarify and simplify the departmental responsibilities for indoor air quality. Who is now responsible for ensuring a healthy atmosphere inside buildings and who should be educating the public about the management of dampness, house dust mites and mould? I might add, is the Interdepartmental Liaison Group on indoor air quality still operating and what work does it carry out?

Mr Lewis: I think we accept that responsibility in this area remains across a series of government departments, and we have to do something about that. There was a meeting only on 22 March of the Defra Air Quality Forum, which met then specifically to look at the scope for clarifying and simplifying these responsibilities. So the government acknowledges that there is a need to clarify but that has not yet been done and I think the work of this Committee will, frankly, help the government—and I am sure you will want to do that—to clear up responsibility in this area. The primary responsibility for ensuring a healthy atmosphere inside buildings is shared between ourselves and the Department for Communities and Local Government. That department is responsible for the Building Regulations system for England and Wales; that includes setting standards for ventilation in new buildings and those that are undergoing material change of use. The purpose of ventilation is to draw fresh air from outside into the building to dilute pollutants and so to maintain good air quality inside. There are many hundreds of airborne chemical compounds inside buildings and the effects on health of only a few are well understood. The Department of Health’s Committee on the Medical Effects of Air Pollutants provided guidance on the effects on health of indoor pollutants in 2004 and that report suggested maximum levels for selective pollutants. The Department for Communities and Local Government used that information to set ventilation standards in the Building Regulations, to control, as far as possible, those pollutants. The Regulations are not tailored to the needs of individual occupants, but individuals are not precluded from improving their indoor air quality by using all sorts of means—filters, dehumidifiers, et cetera. Also, the Department of Health and the Health Protection Agency provide advice on the impact on health of indoor air pollution. So it is true to say that there are lead departments that would have a greater focus on this than others, but there is still a need to clarify roles and responsibilities across government and that work is ongoing at the moment.

Mr Lewis: I cannot answer that at this stage; I can write to the Committee if that would be helpful. We know that the Air Quality Forum, which may or may not be the same body that you are referring to, does still meet because it met on 22 March and it seems to be the body that took responsibility for considering the best way of clarifying roles and responsibilities, but I do not know if you are referring to that body or a different body?

Baroness Platt of Writtle: Perhaps you could clarify it afterwards.

Chairman: We understood that there was another body as well. Lady Perry.

Q851 Baroness Perry of Southwark: Minister, we were very interested in a recent development in Scotland where Fairfield Housing Cooperative has built 14 affordable low allergy homes. These used non-toxic materials, they avoided the use of gas heating and they incorporated various heat recovery and ventilation strategies. Have you discussed with other departments whether the construction industry should use more of these strategies when building new houses? How could you encourage that?

Mr Lewis: As I understand it, the Department for Communities and Local Government offered some funding specifically for the design and monitoring of the Fairfield development. As a consequence of that, guidance has now been produced on the subject to guide others who would want to go down this path, but that would be on a voluntary basis. I think the question here really is how active government is going to be in saying that the Fairfield development produced evidence which is highly persuasive and desirable in terms of other types of development, and I suspect at the moment it is simply by having guidance that is available; that is quite a passive position to adopt. Whether we ought to be more proactive is something we ought to reflect on. Again, what I can offer to do following this evidence is to write to the appropriate colleague in that department, flagging up this issue, raising the question of Fairfield and the persuasive evidence that Fairfield offers, and ask them to consider what more they can do, rather than simply issuing guidance, to get future developments to look at the Fairfield model.

Q852 Lord Haskel: What is more, it would be putting it into the Building Regulations.

Mr Lewis: Absolutely. The Building Regulations are uniform at the moment, they are not focused on distinct needs. But absolutely, that ultimately would change behaviour.

Q853 Baroness Perry of Southwark: As I understand it, Minister, this particular project produced houses which were not only low cost but which were healthy
Chairman: And they were energy efficient as well.
Mr Lewis: I was just going to say that, in terms of what is happening next, the DTI is consulting at the moment on a new strategy for sustainable construction, and it seems to me that there would be another opportunity to influence what will come out of that because if they are going to publish a new strategy in the near future it would be logical, if Fairfield is as persuasive as it appears, to have that as part of the new Strategy. So I will write to colleagues in both those departments if that would be helpful.

Chairman: Yes, it would.
Mr Lewis: And flag this up and when we get the response we will forward that to the Committee.
Mr Bromley: I would say that as a department we are having discussions with the trade bodies, the Construction Confederation and the National Federation of Builders as well on this issue, so we are being proactive on that and looking at these forms of construction and how they affect people’s health. I think there are other trade bodies as well that we need to contact, but we have started the process.

Chairman: I am afraid we are coming at you from all angles and this is a total change of subject, about pregnant mums and young children and advice that is given to them. We have been in Denmark recently where the National Board of Health specifically does not issue dietary avoidance guidance for mums and infants because they say there is not adequate evidence to support the claim that this prevents allergy development. On the other hand, we are also aware of studies that show that levels of vitamin D in mothers-to-be have a pronounced effect on the chances of their children developing a condition, and lack of vitamin D, found in oily fishes, et cetera, can hinder the development of a child’s lungs and immune system. We know about the importance of selenium and zinc. Can you tell us who is responsible for updating the Department of Health’s dietary advice and then perhaps after that I could be a little more specific and ask you what specific advice you are giving on peanut consumption and maybe avoidance for pregnant mums.
Mr Lewis: Hairdressers and peanuts, there is an interesting combination! The current advice that we make available, which is described as precautionary, is based on a report that was issued by an independent expert committee, the Committee on Toxicity, in 1998. There have been two research projects which have been undertaken to actually consider the impact of that advice, and that has been done by the Food Standards Agency—those were only published recently and I do not know if the Committee has sight of them? It would be worth the Committee having sight of them. The outcome of those two research projects was published in March and April of this year so they are very, very contemporary. We are going to need to seek the view of the independent expert committee, which is still established, on the findings in terms of the Food Standards Agency’s research. Having done that we will then consider whether the existing advice needs updating, refreshing or completely changing, but we need to consider what that advice tells us. Would it help the Committee if I were to be a little more specific about essentially some of the key elements of the advice that we currently give to people?

Chairman: But, Minister, we are becoming aware that that advice is not correct.
Mr Lewis: Pregnant women who are atopic (which some members of the Committee will be aware, is an inherited tendency to develop allergies) or for whom the father or any sibling of the unborn child has an atopic disease, may wish to avoid eating peanuts and peanut products during pregnancy and breast feeding. Those same mothers are also recommended to avoid introducing peanuts into the diet of their children until their children are three years of age. For mothers from non-atopic backgrounds, the Government advice is not to introduce peanuts into an infant’s diet before six months of age, and then only crushed or flaked to avoid choking hazards. Whole peanuts should not be introduced until five years of age. We can laugh at this because for some parents this is commonsense but for other parents they would simply be unaware of some of these issues.
Lord Colwyn: But, Minister, we are becoming aware that that advice is not correct.

Chairman: We visited the research unit at St. Thomas’ where there is a big study going on, and they were suggesting that it may actually be making the situation worse to avoid peanuts during pregnancy and to delay exposure to any peanut products. The position with whole nuts is completely different, that is about choking and not about allergy, and we have to be very clear that we separate whole nuts that can block off the windpipe of a baby from the allergy potential. But there was concern expressed to us during that visit—and they have a large research
Chairman: That was particularly from Israel and from African countries where they are often weaned on to groundnut soup.

Mr Lewis: Looking at the research that has just been published, which has considered the impact of the advice that is out there, what that has indicated is that the advice is misunderstood—that is their take on this—in that many non-atopic mothers also avoid peanuts during pregnancy and breastfeeding. There was no clear effect seen in either study on the prevalence of peanut allergy in the United Kingdom. They have looked at the impact of the advice that is out there, and that is their conclusion in this information that has been published only within the last few weeks.

Mr Bromley: I would say that the FSA is close to agreeing a contract to conduct mechanistic research based on the clinical study that you have talked about, so we are involved in looking at that.

Mr Lewis: This is quite serious.

Chairman: Yes, it is serious.

Mr Lewis: It seems to me that if people are misunderstanding the advice that is one issue but if the advice is entirely wrong and counterproductive and actually damaging people then we really need to move rather quickly, rather than having ongoing incessant reviews. So what I will commit to do is to get the research that has been published, have a very intensive look at that in the next few weeks and then come back to the Committee, having drawn some conclusions about what we need to do next. But if we continually set up reviews it seems to me that we have information and we now need to act and make a judgment, and this will always be a judgment based on available evidence; but we have a responsibility, if the advice is wrong or damaging or counterproductive, we ought to change it as quickly as possible.

Lord Colwyn: And I think this advice should come from the Department rather than from the Food Standards Agency.

Chairman: Yes, I think the questions are quite different—the question the Food Standards Agency is asking. Could I also ask you on that to look at the advice in relation to breastfeeding because we also heard about the very high allergenic potential of using top-up formula when women are breastfeeding, and there is a concern over the lack of support to mothers, particularly with their first baby, during establishing breastfeeding and that there is a tendency still in this country, more than in others, to default to formula simply when the women have not had enough support to establish breastfeeding, and it becomes particularly important for those who have atopy.

Mr Lewis: I think what we have to do is look at all of the content of the current advice with the independent body that initiated it the first place, which still exists. I think we have to take account of the FSA’s research on the impact. But we should also utilise international evidence; and if it is evidence rather than simply judgment or perspective then we ought to take account of that, and if it is persuasive we have to ensure that it influences our advice.

Lord Broers: This brings us back again to labelling, having been around the houses, as it were. Evidence has shown that the ubiquitous use of defensive allergy warnings on food labels unnecessarily limits the range of products allergy suffers can buy. How will you work with the Food Standards Agency to ensure that information regarding allergens is made more accurate, or should I say sufficiently numeric, when the EU reviews its food labelling legislation this year?

Mr Lewis: The FSA acts on behalf of the government in this area and we will expect them to ensure that our views on this are taken very, very seriously as part of the European Union review. Having spent a lot of time in the EU when I was a Treasury Minister I certainly cannot guarantee the outcome, but I can assure the Committee that we will be seeking to influence this review so we end up with the outcome that we desire. Would it be helpful to give you some update on what they have recently done on this issue because the European Commission has actually made some changes in this area recently?

Lord Broers: Yes, please.

Mr Lewis: They have recently decided to extend the list of allergenic foods to include molluscs and lupin, and that is based on advice from the EFSA that these also present a public health concern. The consequence of the Commission’s decision is that national legislation to add those two additional foods to the list of allergenic foods will be implemented by 23 December 2007. I am not sure that the Committee is aware of that particular change? I certainly was not aware of it before I looked at the information for this Committee.

Lord Broers: I would like to extend that a little. It is the actual quantity of allergen that may be the problem. If you take sulphites in wine, all wines contain sulphite and people will only be allergic, perhaps, if the quantity exceeds a given amount. So
that is what I see this question getting at to a certain extent, because if you put on every single bottle of wine that it contains sulphites then you are either stopping people drinking—which may be a very good thing indeed, but that is not the purpose of the label, which is meant to tell people who are going to be allergic to something. So my suggestion is that it should actually be quantitative and say so many milligrams or such and such a percentage.

Mr Lewis: I think I can confirm that stopping people drinking wine will not form part of our manifesto at the next general election! Yes, I think that is a very specific point that we ought to feed into the FSA. What I can say to my Lord is that I can write to the Committee with a bit more information about how the FSA are approaching their attempts, on our behalf, to influence the EU decisions on these matters, and we can ask very specifically, as part of the way that we are seeking to influence the EU, taking account of the point that you have just made.

Mr Bell: Might I just stress that our understanding is that this current review that the EU is undertaking of all food labelling, which, as we have been saying, we will feed into through the Food Standards Agency in this country, is really going back to basics and looking at all aspects of food labelling and the requirements for and the scope of allergen labelling as part of it.

Chairman: I think that becomes very important because lupin cross reactivity with house dust mite is not something that people would initially think of in relation to food, and yet we know that asthma is triggered by house dust mite in those who are allergic to house dust mites. Lord Broers.

Q865 Lord Broers: We have also heard that teenagers and young adults who suffer from food allergies tend to be less vigilant when buying food and take risks when eating out. Who is responsible for educating these patients about how to manage their condition responsibly?

Mr Lewis: I think most of the work in this area is training caterers and enforcement officers. I am not sure, to be clear, that there is a great amount of work going on, focused or targeted, if I am frank with you, about young people in terms of the choices they make when they are eating out. There is genuinely quite a bit of investment in training caterers and enforcement officers in terms of allergen-related issues but I am not aware of any great awareness-raising programme in terms of the choices that young people make.

Mr Bromley: What I would say is that the Committee is probably aware that catering establishments do not have to list allergens on menus, but what the FSA is doing at the moment is they have quite a large engagement programme. They are operating training courses where they have environmental health and trading standards officers in local areas to educate caterers on how to provide information on allergens and also be more educational in terms of their menus. So I would say that, although there is not a huge amount going on, there is work that the FSA is doing. Also, in terms of educating young people, there is a lot of work now going on in schools as well and that is part of the NSF, but also in part of the programme that we have, the public health programme that is now getting school nurses into every school. So I would say in defence of the Department of Health that we are working with the FSA on that.

Q866 Chairman: When we were in Denmark we heard about programmes for young people in particular to have their threshold of allergy to different substances properly diagnosed so that they knew themselves the level that would trigger a response, or would be likely to, and they also set up allergy schools which as schools for one day, two days, or sometimes later, to teach the young people with the allergy about the dos and don’ts and the things that they could do to free them up, rather than telling them all the things that they could not do, and to help them understand the things that they could do safely and how to live a very active life safely. It did seem there that they were empowering the patients much more through these programmes that were organised through the allergy centres.

Mr Lewis: I think there is an opportunity here. The Healthy Schools programme has been a tremendous success, essentially a voluntary programme and, as far as I know, probably the majority of schools have signed up to this, which means that they spend a lot of time as part of the school’s educational programme on health-related issues with their students. It seems to me that on this specific issue there has to be a question mark, under the banner of Healthy Schools, whether schools will, unless they are encouraged, be focusing on some of these issues specifically, to be very frank.

Q867 Chairman: These were not done through the schools; these were done through the allergy clinics. They called them schools because they went along to learn about them rather than being treated.

Mr Lewis: I am sure, but what I am saying is that this programme would give us an opportunity to maybe do some testing, some piloting and it may well be that we want to have at an official level on this one a dialogue with our DfES colleagues to see whether we could integrate into that programme some level of discussion about allergies and the consequences for young people; so, rather than create a separate programme, whether something could come out of the Healthy Schools initiative which would help in this area.
Q868 Chairman: Yes, but patient programmes.
Mr Lewis: Yes.
Mr Bromley: We know of the scheme in Denmark, it is just that there are issues around young people that you cannot predict people’s sensitivity day to day because it does change. So there is a risk about telling somebody, “You have this level of allergy” and then that changing, and I think we need to take account of that as well.
Chairman: I think they were aiming to help them assess risks for themselves, though. Lady Platt, I think your question has probably been answered in that last answer.
Baroness Platt of Writtle: I think so too.

Q869 Baroness Perry of Southwark: Minister, turning yet again to another topic, do you know how many adrenaline auto-injectors, often called EpiPens, are prescribed through the NHS each year and what the cost is of issuing those?
Mr Lewis: I do. I can give you very precise information. In the year to 30 September 2006, almost 165,000 prescriptions were dispensed in the community in England for Epipens, at a cost of about £8.2 million.

Q870 Baroness Perry of Southwark: Thank you for that. We understand that there is disagreement amongst experts as to when these EpiPens should be issued and yet the decision about issuing them is left to GPs, most of whom have virtually no allergy training at all. We wondered if there are any plans to develop national guidance over who needs to carry an EpiPen at all times and who does not?
Mr Lewis: No, there are not any plans to do that, as I understand it, at this stage.

Q871 Baroness Perry of Southwark: There is a sub issue about this, which we regard as extremely important, Minister. The Anaphylaxis Campaign has suggested that a stock of generic auto-injectors should be kept in schools for allergic children, because many of them need a second dose in addition to the emergency adrenaline they carry. Do you think this would be useful and cost effective because, as we understand at the moment, there is a very restrictive policy over school nurses, that they are unable to issue an EpiPen to a child unless it is their own prescription—they cannot pass on a prescription, so they said that a recent RCN survey showed that virtually 16% of school nurses are unable to carry an EpiPen at all times and who does not?
Mr Lewis: I agree. I think it is a major issue. I think what we need to do, because I do not think we have made a decision on this in terms of schools, is to review it, and within a relatively short period of time make some decisions about what is appropriate. I think you are right to raise the issue, but we have not at this stage made a decision.

Q872 Lord Haskel: If we move on to schools, the DfES told us that any school nurse who administers an immunisation in a school setting would receive anaphylaxis update training on an annual basis. However, we have also heard that the standard and amount of training received varies widely between nurses in different areas. Can you tell us who is responsible for ensuring that all school nurses receive comparable training? Are any standards set? Who pays? Is this the same for both private and state schools?
Mr Lewis: First of all, I would say that any nurse responsible for immunisations should be properly trained as a matter of course. Most school nurses are employed by Primary Care Trusts and therefore they have responsibility for their training. Clearly there will be some who are employed directly by schools—increasingly budgets are devolved to individual schools, certainly in the individual sector—and the school will then be the employer. It seems to me in those circumstances that there are two issues; one, that the school, in the state system or the private sector, has a responsibility to secure adequate training for anybody providing those kinds of services within their school environment; equally, nurses are bound by certain professional expectations and best practice and therefore, if they do not feel adequately trained in that area, they also partially have some responsibility to access the training. It seems to me that the employer has a duty to make sure that anybody carrying out this role on their behalf is appropriately trained and there is funding to enable that to happen; but also the professional has to make sure in terms of standards of best practice that they are up to date and are accessing training that is appropriate.

Q873 Lord Haskel: The problem that was put to us is that the Royal College of Nursing said that virtually across the nation at the moment school nurses are not being allowed to go on training, even the training for their specific degree course or for their professional training places; that they have been cut. And in further evidence from the Royal College of Nursing they said that a recent RCN survey showed that almost a quarter of school nurses were unable to take time off to undergo further training, and we wondered how you reacted to that?
Mr Lewis: The RCN is issuing very helpful press releases at the moment. I think we have to be very, very clear about this. By next year the amount of
money going into the health service in this country will have tripled. Has there been a difficult year during the course of the past 12 months and has that had an impact in certain health economies? Absolutely, because the Government, for the first time in the history of the health service, has looked people in the eye and said overspending and out of control budgets are no longer culturally acceptable in the health service, just in the same way that it is not acceptable in any other part of the public sector or any other sector. So it has been a difficult year for the NHS and that difficult year has impacted in different areas in different ways, and there is no doubt that just like every other part of the system school nurses will have been affected by that. But we should not make sweeping generalised statements based on one challenging and difficult year. To be absolutely clear about where the Government’s position is in terms of funding and commitment to school nurses, the relevant White Paper, the Choosing Health White Paper, made a commitment to provide new funding for school nurses so that by 2010 we will have at least one full time qualified school nurse working with each cluster of primary schools and its related secondary school. That remains the position of the Government. What we also have to be clear about, in the same way as I talked about maximum devolution now of power responsibility and budgets to schools, is that we have a similar scenario in the National Health Service, in that we do not run a command and control health service from offices at Richmond House. It would be nice sometimes to be able to do so but we no longer do, we devolve significant amounts of power and resource and budget to individual PCTs and the key decisions that are being made in those organisations these days are to do with commissioning. But in terms of commissioning, it is absolutely clear the expectation is that commissioners in every PCT will secure the outcome that I have just referred to, and the outcome is making sure that those clusters of schools in their communities have access to the nurse. Now, the training related issue is of course that if you are going to employ a school nurse who is going to be fulfilling certain tasks in schools then it is the employer’s responsibility to make sure those people are appropriately trained.

Q874 Lord May of Oxford: Changing direction a little and coming back in a sense to Denmark and Germany, the MHRA recommends that immunotherapy be restricted to patients who fail to respond to other allergy treatments, but that is a decision that has not been reviewed since 1994 and NICE has never even carried out an appraisal of allergen injection immunotherapy. The Committee heard evidence both in Germany and Denmark on the efficacy of immunotherapy, so is it not time that more thought should be given to this and the policy be re-reviewed or, perhaps, one might less generously say, reviewed?

Mr Lewis: An option that is available to us would be to ask NICE to appraise immunotherapy, but obviously what happens really on an annual basis is that there are all sorts of competing suggestions about what we ought to ask NICE to appraise. But we can certainly consider putting this as part of that process. Essentially the question, I assume, was rhetorical in the sense that my Lord believes that it is time for a fresh appraisal.

Lord May of Oxford: That is certainly what we heard; in fact we heard it in some rather strong terms. One of the people who spoke to us—not even in Germany or Denmark—is a paediatrician from Cork University Hospital and he said that the NHS is the laughing stock of Europe for its absence of immunotherapy for allergic diseases. I am inclined maybe to discount that as rhetorical overstatement—my own background being partly Irish—and Irish blarney, but nonetheless it gives a sense of the sort of things we heard. We also heard that immunotherapy treatments that do not have a UK product licence can be used to treat patients on a named patient basis within the NHS and that struck us as a peculiar anomaly within the more general question. So I wonder if you are, in a sense, not as up on this—which would be fair enough—but if you could give us some sort of lengthy reply.

Q875 Lord Colwyn: And of course if the patient can afford to pay for it it does work.

Mr Lewis: I think we ought to go away and reflect on whether this ought to be a matter we send to NICE for appraisal; but equally we will have to come back to the Committee with the process because we cannot guarantee that this will end up as one of the priorities this year. I think it would be about saying that, over a specified period, we will seek to get NICE to look at this as one of its priorities. I would be happy to write to the Committee to that effect.

Q876 Chairman: I think one of our concerns that arose, Minister, and it may be helpful for you to know, from the NICE evidence that we had, was that we had the sense that immunotherapy was not really on their list at all and they did not seem to be aware of the sublingual immunotherapy route, which is extremely acceptable to patients and has a very good safety profile, and they did not seem to know about product licensing of sublingual immunotherapy. So that was our concern. And it also linked to the shortage of specialist centres who obviously will be key in driving forward any such therapy, but particularly for young people: if it frees them up from being shackled by severe allergic response it can be very dramatic, and we are concerned about young
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people with hay fever under performing in exams and so on, and that it can blight their careers. So that is some of the background to our concern. I hope that is helpful to you.

Mr Lewis: It is; it reinforces the point.

Q877 Lord May of Oxford: That was Lord Soulsby’s question and my question was carrying us back to the review of services for allergy that we discussed at the beginning, which, amongst other things, recommended that Primary Care Trusts and local health authorities should develop local allergy services based on need. When might we look to see that being commissioned?

Mr Lewis: As Lord May will appreciate, as we no longer do command and control we basically issue guidance to PCTs, to commissioners; we have drawn their attention to this and the possibilities of, in their localities, creating specialist services, but we cannot force or impose that at a local level. I could go through a long description of the way we are seeking for the NHS to work now, but the more useful and constructive response to the question would be that, again, this evidence session highlights the potential benefits of having a lead Strategic Health Authority for this issue and then seeking to get that lead Strategic Health Authority to engage with perhaps one or more than one PCT within their region, to say that it would be really good if you could take responsibility as a national lead, if you like, for creating some specialist allergy services and then consider what we can learn from those services. I would certainly be willing to explore, as a result of this session, and of course to give the Committee due credit for this, to have a dialogue with the NHS about a Strategic Health Authority taking lead responsibility with allergy as part of that, to see whether they can engage with PCTs in their region to stimulate some new specialist services.

Q878 Lord May of Oxford: I take your point about command and control but how does the Department know what local commissioning of allergy services are taking place? That is being informed.

Mr Lewis: Again, it is the balance, is it not, between being accused of seeking more and more data and information, which is called bureaucracy, and wanting evidence to inform policy—it is a constant tension. I think part of a lead Strategic Health Authority’s responsibility, Lord May, would be to consider how we do on a national basis, to ensure that we are collecting appropriate information and evidence to inform policy. So I would see that as part of a lead Strategic Health Authority’s role in this area.

Q879 Lord May of Oxford: Just continuing this one more moment, we heard from officials from the Department of Health—and I am quoting now—that “gaps in current knowledge around issues like service configuration, the best skill mix, the best balance of generalist against specialist services and, also, in data on cost-effectiveness”, that there are gaps in all of those things. More specifically, what analysis is being undertaken to assess whether allergy is best treated by primary care workers or specialist services? We heard quite a lot on that theme from people in general practice who felt that they did not know what to do within their local remit.

Mr Lewis: I am not sure that we have a very robust system which is actually providing us with reliable data to inform policy development. I think that is probably the frank answer that we ought to give. The question then is, what mechanisms are available to us to develop that kind of infrastructure and I think, to be honest, it is not just the responsibility of the Department of Health or government it is also the responsibility of the Royal Colleges and also some of these specialist professionals who work in these areas.

Mr Bromley: I think we recognise this. When Martin Marshall, the DCMO, came and gave evidence you questioned him on how we are going to engage with the service on this particular area, and the first step is that the DCMO is organising a high level meeting with a number of the Royal Colleges to look at and address the issues that you have put forward. We also have in the Department a small team that works on this particular topic, and that team will look at the future of how we develop a service around allergy, and that will form part of the work in the Government Response to this inquiry that will take place over the summer. I think the Minister is right, no, we do not have a framework set up at the moment but we hope to have a framework set up when this Committee has reported and when we take a view of how we develop the services, as the Minister has said, through a Strategic Health Authority format or through another format.

Chairman: One issue that Lady Platt wanted to ask specifically about is GP education and I think it would be appropriate to switch to that now in the light of your comments, Mr Bromley.

Q880 Baroness Platt of Writtle: We have heard in evidence that GPs receive very little undergraduate training in managing allergy and cannot appropriately diagnose or treat allergic diseases. What is the Department doing to improve allergy training for GPs, either in initial training or during continued professional development?

Mr Lewis: The straight answer is that we do not define the curriculum content for training; what we can do is bring this issue to the attention of the bodies
that do have that responsibility—the Postgraduate Medical Education and Training Board, and the General Medical Council, to name but two. So we do not decide the content of the curriculum for training GPs. But we share your view that early intervention is really important and for early intervention to happen it is going to be the GP in most circumstances who is going to be absolutely crucial. I think there is significant evidence to suggest that many, many GPs have inadequate knowledge in this area. Of course the other issue would be about continuing professional development beyond initial entry-level training, and again I think we need to have a dialogue with the relevant professional bodies that are responsible for that to make sure that allergies are taken more seriously than they have been hitherto.

Q881 Baroness Platt of Writtle: This does seem to us to be very important indeed. How many postgraduate training places are there per annum and are there any incentives to encourage GPs to undergo further allergy training? Would you consider including all allergic diseases in the Quality and Outcomes Framework for GPs?

Mr Lewis: I can give some statistics. There was a survey done in 2002, and of 500 UK GPs only 50 per cent had undergone training in managing allergic problems and most of them—78 per cent of that 50 per cent—as undergraduates. There was a study done in 2006 of people who used these services and very interestingly 76 per cent of them felt that their GP did not understand their health needs at all well. I think we have in a sense two issues: one is that we need every GP to have a basic minimum level of knowledge; we then need to find a way of encouraging some to develop far more specialist knowledge.

Q882 Baroness Platt of Writtle: Yes, because there is a shortage of specialists too.

Mr Lewis: And on a network basis you need people who are seen as leaders, specialists, who can then support and influence professional colleagues, peers.

Q883 Baroness Platt of Writtle: Perhaps on a regional basis.

Mr Lewis: Absolutely. Again, it is for us, I think, to engage seriously with the bodies that are responsible for training, to make sure that this issue is taken more seriously.

Baroness Platt of Writtle: We think this is vital.

Q884 Earl of Selborne: Minister, you said just now that many GPs have an inadequate knowledge on how to diagnose, treat and refer patients for allergies and I think the Committee would agree with that. GPs, of course, get guidelines thrown at them from all directions but this does seem to be an area where accessible guidelines for GPs are very much in need. What is the Department doing to provide guidelines for GPs on this matter?

Mr Lewis: There is quite a lot of guidance available—good practice guidance, for example, drawn up by a number of Royal Colleges and other professional bodies for specific conditions. The National Prescribing Centre has published a number of documents to inform GPs and other health professionals on specific allergic conditions. NICE is currently developing guidelines for atopic eczema in children. We are, as you know, as part of the review that we have undertaken, committed to look at the options for referring to NICE a request to specifically develop clinical guidance for the diagnosis and management of allergic conditions, so that is something that is active and under consideration at the moment. We have asked the Royal College of Paediatrics and Child Health to scope work to develop care pathways for children with allergic symptoms, and we have also commissioned Skills for Health to develop National Occupational Standards for the UK for allergy, and those competences stemming from those standards would be relevant to all clinical staff including GPs. So there is quite a lot of guidance and guidelines out there in the system.

Q885 Earl of Selborne: You referred to the NICE guidelines and you say they are under consideration. We heard in March from the Chief Executive of NICE that these proposals were now back with the Department of Health Ministers, so what happens now?

Mr Bell: If I may, the position on that is that Ministers, including Mr Lewis, are at the moment awaiting a large submission from officials in the Department making recommendations for the next wave of clinical guidelines products to be referred to NICE. I cannot anticipate what those recommendations will be or what Ministers will decide on the basis of them, but that is due, I am told by colleagues in the Department, in the next few weeks.

Mr Lewis: There are obviously competing priorities and the question for me is, if this does not make it into this series of referrals, whether we can commit to saying that it may not happen this time but we can give a specific timeframe, otherwise I think people will be quite sceptical.

Q886 Chairman: Mr Bell, could you just clarify because I think you said Ministers—is this going to several Ministers or is it going to be specifically—

Mr Lewis: The NICE issue obviously cuts across—what we refer to NICE will cut across several Ministers.
Mr Bell: The process as I understand it, Lord Chairman, is that the team within the Department that coordinates the various recommendations that have come from different directions, including us, put together this magnum opus, which goes to Lord Hunt as the lead Minister for NICE but is copied to all the other Ministers including our Minister, and it gives them the opportunity to comment. The Secretary of State will then make the final decisions.

Q887 Earl of Selborne: And the Department of Health officials told us that the Department was working with the Royal College of Paediatrics and Child Health to fulfil its pledge to develop care pathways for children with allergic symptoms. Can you tell us what progress has been made towards this and how you will disseminate these guidelines through the medical community?

Mr Bell: I can tell you where we are at on that. We have had constructive discussions with the Royal College of Paediatrics and Child Health and, at our request, they have gone away and are working up a scoping document at the moment for taking forward this work, which they are very keen to do. I am hoping that we will be able to commission them to take this forward very quickly, with the expectation that the work would be completed by the College, bringing together all the other professional groups and other stakeholders with an interest to do this development work, in the current financial year.

Q888 Baroness Perry of Southwark: One of our witnesses, Professor Davies, told us that 11 new training posts had been agreed to train clinical academics in allergy. However, other expert witnesses were quite unaware of this. Could you clarify for us whether these posts have been allocated, whether they are specific to allergy and how they will impact upon clinical practice?

Mr Lewis: I can tell you what has happened in terms of training. Basically, the National Institute for Health Research Integrated Academic Training Pathway has established academic training programmes in strong host environments to provide training support for either Academic Clinical Fellowships or Clinical Lectureships. Once identified, successful programmes may appoint trainees into the posts through local competition and via the Postgraduate Deanship. A total of 17 programmes relevant to allergy have been funded, each for five years. During the course of these programmes, a total of 33 Academic Clinical Fellowships and 16 Clinical Lectureships will be supported. A range of universities are carrying out these programmes—Birmingham, Brighton and Sussex, Imperial College, King’s College, Manchester, Newcastle-upon-Tyne, Oxford, Sheffield and Southampton. What I am unclear about is the specific reference to these 11 posts and perhaps officials will be able to help me with this.

Mr Bromley: Yes. We refer to the 16 Clinical Lectureships—that is what Sally was referring to, so in fact we actually have more than the 11.

Q889 Chairman: Those are the Walport posts for the Walport money?

Mr Bromley: Yes.

Q890 Chairman: Can you just clarify what “relevant to allergy” means because are you including in those numbers dermatology, respiratory medicine and so on?

Mr Bromley: Yes.

Mr Lewis: Immunology, dermatology, respiratory medicine and paediatric allergy and infection.

Q891 Chairman: And you are including the specific allergy training posts as well, of which there are eight currently SpRs in the country, or not?

Mr Bromley: Can we get back to you on that because if it is possible we would like to check? I would like to check because it is not in the written evidence. I think what we would like to say is that we have researched what Sally has said and we are quite pleased to say that, yes, the 11 are there, plus.

Q892 Chairman: Can I just finish with asking you about a completely different area, which is complementary medicine? We heard that a lot of patients are going to complementary therapists of different sorts, often because they feel that they cannot get the services from their GP or within their area. We know that there is legislation being developed to regulate acupuncture and practitioners of herbal medicine. We wondered whether there are any plans to extend such regulation to other people who provide services for patients, either diagnostic or reportedly therapeutic?

Mr Lewis: You are right, we have asked Professor Pitillo to look at acupuncture, herbal medicine and traditional Chinese medicine, and we are waiting for recommendations in those areas. We have also funded the Prince of Wales’ Foundation for Integrated Health to set up a voluntary register of unregulated professions, and we are also setting up a UK working party to consider the criteria to be used to decide whether a profession should or should not be statutorily regulated. The very direct answer to the question, do we have any immediate plans, is no.

Q893 Chairman: We have heard of the lack of evidence to support the efficacy of some of these treatments and yet a very high uptake and high level of belief on the part of the public, and we wondered who you felt should be pushing for and funding
evaluative research of some of these different diagnostic and treatment modalities?

Mr Lewis: You mean who should be assessing the health benefits of these alternative interventions?

Chairman: Yes, in terms of cost-efficacy, rather than people just having pressure groups suggesting that some of these things should be available or making claims on their behalf.

Mr Lewis: I suppose evidence-based policy would be an exciting development! The answer to that is I do not know. As far as I know, at the moment the Department of Health is not formally undertaking evaluation of the impact of those interventions which will then be made public. Are there other bodies? Do officials know other bodies that are actively doing that in terms of trying to gather hard evidence in these areas?

Mr Bell: Lord Chairman, I am aware that there is research that is being done by academic bodies into different complementary and alternative medicines, so it is not a completely un-researched area, but clearly there is a lot we do not know.

Mr Lewis: I think we can perhaps write to you.

Mr Bromley: I think the answer is we do not know. The problem is, as you know, some of these products are food; some of them are not medicines, that is the problem at the moment. We need to look at this area about well being, which is a healthy debate, and how do we separate the responsibility in terms of whether it is a food product or maybe a cosmetic product? I think that is the problem at the moment.

Chairman: Our other concern was on the diagnostic side, that there are patients who are absolutely desperate who will be spending several hundreds of pounds on processes believing that that is diagnosing an allergy, and yet the evidence is not there that that is actually diagnosing an allergy, and that there is not any particular group that have a vested interest into researching into this because, unlike the pharmaceutical industry, where they will be producing a product which is prescribable, it does not fall into that group and these people are often not trained in scientific approaches to research; and so, even if they do want to do some evaluation and apply for a grant, with the competition for research grants they are going to fall out before they even start. So there are difficulties in kick-starting good evaluative projects and that is the background to this question you are going to be looking into.

Mr Bromley: I think when the DCMO, Martin Marshall gave evidence, this is one of the things he took away, as well as with the GPs’ issue—it was one of the issues he took away, and wanted us to work on more of this issue.

Chairman: Lord May.

Lord May of Oxford: Very quickly, and not all my colleagues will agree with what I am about to say, but my own view is that one of the most under researched areas is the interplay between health and mental state, because if you look at the studies of most of these complementary medicines what turns out is real benefits accrue, but if you do double-blind it does not matter whether you give them the medicine or not—it is the actual act of treatment. That is a comment—many of the practitioners believe that they are doing something, when in fact they are not, but the interplay between mental states and health is real and it is something that we seem to distance ourselves from, that it belongs in the more difficult areas of the social sciences and yet it is a really important thing. I do not see the answer to it because no one wants to pick it up.

Chairman: A concern that I would echo is that sometimes the wrong question is being asked in the research.

Mr Lewis: I think there is a debate beginning in this area about well being, which is a healthy debate, which then over time may lead to a very, very different approach to some of these issues. There is also the Layard work around CVT. We can agree or disagree that CVT is an incredibly effective psychological intervention, but the point is that for a lot of people at the root of their health problems and conditions is unhappiness, depression, anxiety and sadness about their lives genuinely, and I think we would all as civilians—if we take away our respective titles—understand that that is real. The difficult bit is how you set about proving that and how you create a situation from a very, very low base where you have sufficient evidence to suggest—which I think Layard tries to present—the economic case and the societal benefits of investing far more significantly in those kind of psychological interventions, which in the end not only end up leading to a much better society and happier individuals and more well individuals but actually mean we of course spend less resources at the acute end of the National Health Service. I think this debate is rolling and I think it is a very important debate we need to have in society.

Lord May of Oxford: If I may just say, it is a splendid book but it is on economics and how you measure how well off we are. I encouraged people at the Royal Society to have one of our dozen a year discussion meetings on this subject. I thought it was a good idea to do it—there is a lot of criticism for doing it and some of the papers really were a bit off putting, but nonetheless important. The difficulty is that the practitioners of alternative medicines would not welcome what I have just said—or many would
Mr Ivan Lewis, Mr Alan Bell and Mr John Bromley

not—so they are not keen on it. On the other hand, many of the people in the heart of science would disagree with my statements about the need for better understanding of the interplay. I just do not really see how we get there from here.

Mr Lewis: I do not think we should limit this to alternative medicine. Every day in this country there are many health practitioners and professionals who are issuing prescription drugs when actually there would be far better solutions. That is the way that primary care frequently deals with mental health, and we have revolving or rotating patients who sit and fill up GPs practices in many parts of the country, where the answer is the prescription in terms of the antidepressants or whatever. That is not getting to the root of the problem, it is not being innovative and imaginative and it is not trying to support the person to change their life, if you like. I think this debate, in a sense, needs to be removed from the confines of the practice of alternative medicine and look far more broadly at “is the health service a sickness service or is it a health service” and what do we mean by well being, which is the new, trendy, fashionable word? But we need to do a lot more work in defining what we mean by well being and how we go about securing it for as many people as possible.

Q898 Lord Colwyn: I think I prefer you to call it complementary medicine. I had a letter yesterday from George Lewith and I have left the figures behind, but despite the millions of people who have treatment I think the total research budget is 0.008 per cent of the entire budget, which is minute.

Mr Lewis: I was not really seeking to make any statement by using the term alternative—I am equally happy using the term complementary, so I do not want to provoke a debate that is not necessary.

Chairman: Minister, can I thank you very much? I feel as if we should continue this debate, even in another forum and informally because it is absolutely fascinating, and some of it relates to the role of the practitioners themselves on the individual patient and whether they augment or decrease anxiety and how the whole situation is managed in helping the patients change their behaviour as well. Thank you very much for coming today, for having spent so long giving this detailed evidence and also for offering to take away so many issues and look at them. We look forward to working with the Department. We will be producing our report, obviously, but we hope it will be a very constructive dialogue. Can I thank you also, Mr Bromley and Mr Bell, for having come with the Minister today.

Supplementary memorandum by the Department of Health

You asked me to comment on a number of questions which were not explored fully during the meeting. I shall deal with each of these in turn, and add comments on a few other matters on which officials and I undertook to submit additional material to the Sub-Committee.

What is the Department’s view of establishing a central disease registry? (Q.832)

Our view is that, in general, investment in disease research registries is not a good use of central research and development provision. Such registries are expensive to develop, and funding their long-term maintenance can create difficulties in a system that has to be responsive to changing demands and priorities. The setting up of disease registries for the purpose of clinical audit is a matter for local decision and funding.

Has the Government agreed to fund the specialist THOR schemes in the future and for how long will this funding be agreed? (Q.838)

The Health and Safety Executive (HSE) is seeking to secure the long term funding of both the THOR GP and THOR Specialist schemes of work. Representatives met with Professor Agius on 4 April and made an offer which, if accepted, will guarantee funding of data collection within the THOR GP scheme until 31 December 2010 and the THOR Specialist scheme until 31 December 2011. Professor Agius is yet to respond formally to the offer but is due to do so by mid-May. (Please see p 111, Supplementary Memorandum by Professor Raymond Agius).

A significant reason for the delay in responding is that Professor Agius has been preparing a request seeking EU funding for his THOR related work. This process was due to be completed by 26 April. It is not clear whether any EU funding would be used to subsidise the work that Professor Agius is undertaking on behalf of HSE, or whether he intends to use it to broaden the scope or scale of his work.
The Sub-Committee also asked (Q.843) about sponsorship of the “Bad Hand Day?” campaign. HSE developed this campaign by working in partnership with Local Authorities and industry Habia (Hair and Beauty Industry Association) and NHF (National Hairdressers’ Federation). It aims to raise awareness of dermatitis among hairdressers, and to offer help and advice on the simple steps that can be taken to prevent it. As part of the campaign, Local Authority inspectors visited salons around the country, and ran awareness raising events for local businesses and colleges.

Information on the “Bad Hand Day?” campaign, and the resources developed to support it, are available from the HSE website at http://www.hse.gov.uk/hairdressing/index.htm.

HSE has formally evaluated the impact of the campaign and this has shown that it was very well received by hairdressers. HSE is now working with Local Authorities and industry to develop a second phase for the campaign, to build on this initial success and further to promote the uptake of preventative measures within salons and during hairdressing training.

Could you clarify the details of the DTI strategy for sustainable construction, the work that has been carried out so far, and how your Department might be able to work with the DTI to take the needs of allergy sufferers into account when building new homes? (Q.855)

Following a review in 2006, the Department Of Trade and Industry (DTI) is co-ordinating the current development of a combined industry/cross-Departmental strategy for sustainable construction. The proposed new strategy will provide a framework to guide future progress within the construction industry. It will go to public consultation in the near future. During that consultation, contributions on this and other matters relevant to sustainable construction would be welcomed.

Responsibility for the Building Regulation, however, rests with the Department for Communities and Local Government (DCLG). Through the Building Regulations for ventilation (Part F), Government can have some control over indoor air quality in new homes, including the provision of sufficient ventilation to dilute reasonable levels of the main pollutants—which include volatile organic compounds (VOCs) and moisture—thereby stemming the development of mould growth.

There is, however, still a lack of evidence on the direct impact of some types of building materials on health or the balance between the effects of building materials, furnishings and cleaning solvents. It is not clear if the Building Regulations have powers to control use of VOC-emitting materials, even if a health case could be made. They cannot control emissions from furnishings and products that people bring into their homes. Currently, building material manufacturers are not required to declare emission levels.

The Sub-Committee also asked (Q.850) about Departmental responsibilities for indoor air quality. I have looked into this complex area and an overview follows.

First, I should clarify that although I made reference to the Department for Environment, Food and Rural Affairs (Defra) Air Quality Forum, that body’s remit does not include indoor air pollution. The Forum was established in 1998 as part of the requirements under the Environment Act 1995 for the Secretary of State to consult stakeholders when developing and reviewing the Government’s Air Quality Strategy. The Strategy is concerned with ambient air quality and does not cover indoor pollution.

Despite this, at its quarterly meeting held on 22 March, the Air Quality Forum did specifically look at the matter of the responsibilities across a series of Government Departments. I should emphasise, however, that this was done as a single exercise simply to inform the Forum of the current position.

I also undertook to write to the Sub-Committee about the Interdepartmental Liaison Group on Indoor Air Quality. The Group was originally set up by the then Department of the Environment (DOE) and was responsible for considering a programme of commissioned work around the quality of indoor air. This programme continued as the DOE later merged with the Department for Transport (DfT) to become part of the new Department for the Environment, Transport and the Regions (DETR). Towards the end of the 1990s, the programme ended and, consequently, the work of the Interdepartmental Liaison Group on Indoor Air Quality ceased.

Responsibility for indoor air quality has fallen to different Departments, largely as Departments have merged or new Departments have been formed. It originally sat with DOE but in 1997, when DOE and DfT merged to form the DETR, the health aspects of indoor air were assigned to the Department of Health (DH) whilst DETR retained responsibility for indoor air quality with respect to the Building Regulations.
In 2001, the picture changed again when DETR was ended and its work was split into a number of separate Departments. As a result, responsibility for the Building Regulations went to the newly formed Office of the Deputy Prime Minister (ODPM), now DCLG, and the health aspects of indoor air remained with DH. This is how it currently stands.

May I add that, in recent years, DH has funded the World Health Organization (WHO) to help it develop guidelines on indoor air quality. Health Protection Agency (HPA) colleagues attend its meetings.

In addition, at the fourth WHO Europe Ministerial Conference on Environment and Health in Budapest in June 2004, DH and Defra Ministers, on behalf of the UK Government, made a commitment to develop and implement a Children’s Environment and Health Strategy for the UK. This would address national priorities as well as set goals to address the four key objectives, one of which is to ensure clean outdoor and indoor air.

To date, much work has been done towards the UK Strategy and this is being co-ordinated by an Interdepartmental Steering Group chaired by DH, with a membership comprising representatives of relevant other Government Departments, Devolved Administrations, the Environment Agency, the Scottish Environment Protection Agency, the HPA, the Food Standards Agency and others.

My officials will continue to work with their DCLG colleagues, and those other Government Departments as necessary, on indoor air issues.

In Q.861 you committed to review the evidence regarding peanut avoidance during pregnancy and weaning. What plans does the Department have to review its dietary guidance as soon as possible?

In my oral evidence, I referred to two (recently published studies that investigated the impact of the current Government advice on avoidance of peanuts during pregnancy and lactation. I am enclosing copies of these papers with this letter [not printed]. I also undertook to ensure that the basis for this advice would be re-evaluated as quickly as possible. This review will proceed as follows.

As you are aware, the current advice, which was issued in 1998, was based on a review of all the scientific literature available at that time by one of the Government’s scientific advisory committees, the Committee on Toxicity (COT). In order to review its advice, the COT will need not only to review the two papers that I am now providing for you, but also to evaluate carefully any other relevant evidence that has become available since 1998. This is in accordance with the Office of Science and Technology Guidelines on Scientific Analysis in Policy Making, which set out the basic principles which Government Departments should follow in assembling and using scientific advice, and the Code of Practice for Scientific Advisory Committees, which was issued in 2001.

I can report that the Food Standards Agency has already begun the process of identifying and systematically reviewing the evidence, and a paper will be taken to the COT as soon as this review is complete. The COT will then consider this evidence at an open committee meeting and will issue a statement. After that, the Government will reconsider its advice in the light of the views of the COT. Given the need to evaluate fully and carefully all the relevant scientific evidence, this process is likely to take six to 12 months.

How is the Food Standards Agency attempting, on your behalf, to influence the EU review on food labelling to specify the levels of allergens in food products? (Q.865)

The current EU review is a fundamental review of all food labelling. Following initial discussions, the European Commission is expected to produce a proposal by the end of 2007. The Food Standards Agency will negotiate this proposal on behalf of the UK and will liaise with other Government Departments to agree a UK line. The experience gained in developing the guidance that the Agency published last year, on allergen management and advisory labelling, will help the UK in ensuring that future EU labelling is as helpful and informative as possible for food allergic and food intolerant consumers.

I should like to add some further detail to my reply to Q.865, regarding limits for sulphites. The current legislation requiring the declaration of allergenic ingredients does contain a threshold limit for sulphites and requires only added sulphites above 10mg/l or 10mg/kg to be declared.
The arrangements for selecting topics for the National Institute for Health and Clinical Excellence (NICE) work programme were changed in September 2006. Under the new system, there is a more transparent approach to assessing the suitability of topics suggested and an objective approach to prioritising them, which is supported by a larger role for NICE in the selection process. I hope the Sub-Committee will find it helpful if I outline the process of selecting topics for referral to NICE.

NICE administers the initial stages of the topic selection process and is the principal point of contact for individuals and organisations wishing to submit proposals. NICE has established consideration panels dedicated to specific conditions and diseases, whose specialist composition allows topics to be assessed on their relative priority within a given specialty. Topic proposals are assessed against published DH selection criteria. Ministers make the final decisions on the referral of the NICE work programme on the basis of the advice they receive from a variety of sources including NICE, the NHS and strategic policy advice from within DH.

The process for determining the next NICE work programme, its fifteenth, has not yet completed. Whilst I can confirm that there are a number of topics in relation to allergy under consideration as part of this work programme, it is not possible for me to provide any further information until the Secretary of State has taken a decision on the referral of the programme.

With regard to allergen injection immunotherapy, we have passed the Sub-Committee’s views to the NICE topic selection team, who will feed the suggestion in to the topic selection process. This will allow the topic to be considered alongside all other topics in order to establish its relative importance and priority for referral. At this stage, I could not offer a guarantee of its inclusion in the NICE work programme.

You stated that 33 advanced clinical fellowships and 16 clinical lectureships will be supported by new training programmes (Q.889). Does this figure include the eight Allergy Specialist Registrar training posts available in the UK? Could you outline which discipline each of these posts cover—for example are they specifically for allergology, immunology, dermatology or respiratory medicine?

I referred to the academic training programmes that the National Institute for Health Research (NIHR) Integrated Academic Training Pathway has established, through two rounds of national competition, in strong host environments (through partnerships between universities, local NHS Trusts, including PCTs, and Postgraduate Deaneries), to provide training support for either Academic Clinical Fellowships (ACFs) Or Clinical Lectureships (CLs).

In all, 17 programmes relevant to allergy (including immunology, dermatology, respiratory medicine and paediatric allergy and infection) have been funded, each for five years. During the course of these programmes, a total of 33 ACFs and 16 CLs will be supported. Details are given in the appended table. [not printed]

There are six ACFs and two CLs awarded solely in allergy. However, it is not possible to say whether these are the same as the eight allergy Specialist Registrars. The reason is that, although the scheme provides funding for posts, it is up to the local institution how it uses the funding to create posts and who is appointed to them. For ACFs, 25 per cent salary (for up to three years) and for CLs, 50 per cent salary (for up to four years) is new funding to protect time for academic activity. It is up to the hosting partnership to integrate this new funding with existing posts. In some cases, whole new posts are being created locally where additional funding can be found. Not all of these posts have yet been filled, as far as we understand.

In Q.893 you commented on funding for the Prince of Wales Foundation for integrated health and the UK working party to consider statutory regulation. Could you provide some further information about these groups, the work they are carrying out, and the level of funding and support they receive from the Department of Health?

In previous evidence we have referred to the joint working group (JWG), chaired by Professor Michael Pittilo, which we have set up actively to prepare for statutory regulation of acupuncture, herbal medicine and traditional Chinese medicine. JWG members receive funding from DH for travel expenses, including loss of earnings where, appropriate. Our budget for the JWG is £25,000 for 2007–08.

The Government currently has no plans to extend statutory regulation to any other professions. However, DH has commissioned the Prince of Wales’ Foundation for Integrated Health (FIH) to develop voluntary self-regulation amongst a range of currently unregulated professions. The professions working towards self-regulation are Alexander Technique, Aromatherapy, Bowen Technique, Cranial Sacral Therapy, Homeopathy, Massage Therapy, Naturopathy, Nutritional Therapy, Reflexology and Yoga Therapy.
The FIH has undertaken a public consultation exercise, which closed at the end of July 2006. The results show a clear mandate to move forward with a federal approach to regulation. The FIH has set up a joint working group to move towards the agreed federal model for self-regulation. We have awarded a Section 64 grant to the FIH for the above work, totalling £900,000 over the three years 2005–06 to 2007–08.

In oral evidence (Q.893), I also mentioned the proposed UK working party to consider statutory regulation. Paragraph 7.9 of the White Paper Trust, Assurance and Safety—the regulation of health professionals in the 21st century (published on 21 February 2007) says, “For emerging professions, the Department will establish a United Kingdom working party to develop criteria to determine which roles should be statutory regulated.” DH will be announcing its proposals for taking forward the policies set out in the White Paper at a direction-setting event at the beginning of June. We shall announce the working groups and their terms of reference at this event.

The Sub-Committee asked as well (Q.894) about funding for evaluative research on CAM diagnosis and treatments. In recent years, the Government has made a substantial investment in CAM-related research. Following the recommendations of the House of Lords Sixth Report on Science and Technology (2000), over £3.5 million of new funding is being invested in research and development under the National Complementary and Alternative Medicine Personal Award Scheme. The Scheme is designed to develop research capacity in the area of CAM, and to promote the development of a robust research evidence base in the future.

DH has funded a programme of research at the University of Sheffield on complementary medicine in primary care, and research studies on the use of CAM in the care of cancer patients. The National Coordinating Centre for Research Capacity, as well as being responsible for the personal award scheme, has contributed funding to CAMEOL (Complementary and Alternative Medicine Evidence Online). This programme, funded at the level of around £300,000, involves a detailed review and critical appraisal of the published research on specific complementary therapies, focusing on key areas of NHS priority—including chronic conditions.

The Government’s health research strategy; Best Research for Best Health, will allow researchers to bid for research in the area of CAM. The strategy includes a responsive funding scheme—the Research for Patient Benefit programme—that is open to research proposals on CAM therapies, among other topics.

Finally, the Committee has also been made aware of the Skills for Health team which are establishing a Project Reference Group to develop National Occupational Standards for Allergy Services. I would be very grateful if you could clarify how the Skills for Health team relates to the Allergy Services Review team in your Department and what work you plan to carry out together on this project?

I mentioned on 18 April (Q.885) that DH had commissioned Skills for Health to develop National Occupational Standards (NOS) for the UK for allergy. This was one of the next steps identified in our review of services for allergy. NOS will help employers determine the skills needs of staff involved in allergy. Employers and education and training providers will be able to integrate the NOS into training programmes. The DH allergy services review team is represented on both the project executive group and the strategy group for this project, and also attends meetings of the national reference group, which brings together a wide range of stakeholders. We expect the NOS for allergy to be produced by December 2007.

Following your letter of 24 April, you also asked a further question on behalf of the Sub-Committee—

In the evidence, you have said that the cost to the NHS of allergies is over £1 billion. To put this in perspective, what is the overall cost of the NHS? And can you provide a source for this figure?


Total NHS expenditure in England has increased from £33.0 billion in 1996–97 to £75.8 billion in 2005–06. Investment is expected to rise further, to £90.7 billion in the current financial year. This extra money, most of which is held locally, has improved access to healthcare for millions of people.
Finally, I should like to clear up some apparent confusion that arose from my response to Q.845, in which one of the points I made was that “hypoallergenic” is a medicinal claim and, if made for a medicine, would have to be supported by clinical data before it was given a marketing authorisation by the MHRA. I was not suggesting that the term “hypoallergenic would be thus defined in the Regulations to implement the Unfair Commercial Practices Directive, to which I had just referred and to which I subsequently returned.

14 May 2006

Letter from the Advertising Standards Authority

INTRODUCTION

1.1 The Advertising Standards Authority (ASA) welcomes the opportunity to submit written evidence to this inquiry. The ASA is responsible for supervising the self-regulatory system for advertising standards in both broadcast and non-broadcast media, ensuring that all advertisements, wherever they appear, are legal, decent, honest and truthful.

1.2 This submission will address the following points:

1.2.1 The role of the ASA. This submission aims to provide a brief overview of the advertising self-regulatory system in the UK and the ASA’s relationship with relevant statutory regulators.

1.2.2 Respond to your questions about the ASA’s approach to regulating advertising claims and, in particular, how we would go about investigating claims that state a product’s suitability for those suffering allergies.

2. ABOUT THE ASA

2.1 The ASA is the UK self-regulatory body for ensuring that all ads, wherever they appear, are legal, decent, honest and truthful. The ASA has been responsible for policing non-broadcast advertising standards for more than 40 years. The success of the self-regulatory system was recognised in November 2004 when Ofcom contracted-out the regulation of broadcast (TV and radio) advertising to the ASA system. This move was approved by Parliament and created a “one stop shop” for advertising complaints.

2.2 The ASA administers three main advertising standards codes. Two industry bodies, the Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP) are responsible for maintaining the Advertising Standards Codes. CAP is responsible for the non-broadcast Code and BCAP is responsible for the TV and Radio Codes.

2.3 The full names of the Codes are:

— The British Code of Advertising, Sales Promotion and Direct Marketing (“the CAP Code” (non-broadcast)).
— The BCAP TV Advertising Standards Code.
— The BCAP Radio Advertising Standards Code.

2.4 Further information about CAP, BCAP and the Codes can be found at www.cap.org.uk.

2.5 The ASA receives complaints from both the public and the industry about advertisements that are alleged to have breached the Advertising Codes.

2.6 The ASA system operates within a legal framework. For non-broadcast advertising the ASA is the “established means” for enforcing the Control of Misleading Advertisement Regulations 1988 (as amended) (CMARs). The Office of Fair Trading acts as a legal backstop to the system for misleading advertisements. The ASA’s role in regulating misleading advertising is unlikely to alter under the Unfair Commercial Practices (UCP) Directive.

2.7 As already mentioned, for TV and radio advertising, the ASA operates in a co-regulatory partnership with Ofcom. Therefore, Ofcom acts as a legal backstop to the broadcast side of the ASA system.

2.8 The rationale behind creating a “one stop shop” for all advertising complaints was to simplify advertising regulation. Dealing with a single regulator makes it easier for consumers to complain and is simpler for advertisers to work with. The ASAS “one-stop shop” is in line with better regulation principles.

2.9 All the costs for running the ASA are met by a levy of 0.1 per cent on advertising space paid by advertisers and collected by at arms-length from the ASA by the Advertising Standards Board of Finance and its broadcast equivalent (Asbof and Basbof, www.asbof.co.uk).
2.10 Further information about the ASA and the work that we do can be found on our website at www.asa.org.uk. The website also contains a searchable database of all our adjudications from the past five years.

3. Responses to the Committee’s Questions

3.1 “Is the use of the phrases ‘hypoallergenic’ or ‘dermatologically tested’ regulated in any way by the Committee of Advertising Practice (CAP) code?”

As already mentioned, there are three Advertising Standards codes regulating advertising in the broadcast and non-broadcast media. These Codes do not provide specific rules on allergy claims or “hypoallergenic” and “dermatologically tested”. Providing code rules on every conceivable advertising claim would render the Codes un-navigable and cumbersome, however the Codes do provide sensible rules on misleading advertising to which all advertisers must adhere. Advertisers that wish to make a claim about their product, including a scientific or allergy claim, must hold substantiation prior to making that claim. In particular, scientific claims must be supported by robust and independently verifiable evidence.

The burden of proof falls on the advertiser; it is not for the ASA to prove that the claim is untrue. I have enclosed a Help Note that has been drafted by CAP indicating the level of substantiation required under the Codes (see Annex 1). [not printed]

3.2 “Has the ASA had any previous experience of implementing these regulations?”

The ASA receives more than 20,000 complaints a year and approximately 75 per cent of these relate to misleading advertising. Although the ASA does not receive large numbers of complaints about allergy claims in advertising, it has investigated such claims in the past (see 3.3 below). Problems with misleading claims has led CAP to issue a Help Note providing guidance to advertisers on what can and cannot be stated in such ads (see Annex 2). CAP has also issued a Help Note on vacuum cleaner advertisements, which includes a section on allergy claims (see Annex 3). [not printed]

The ASA’s adjudications are published on a weekly basis and can be found on our website.

3.3 “Has the ASA ever received any complaints regarding the use of this terminology, and if so, were these complaints upheld?”

The ASA has received complaints about allergy claims in advertisements. These complaints have led to 24 published adjudications in the last five years, of which 19 were upheld fully or in part. I have enclosed some notable adjudications (see Annex 4).

The ASA considers each complaint on a case-by-case basis. If the Committee has concerns about any specific advertisements, we would be more than happy to look into their complaint. Complaints can be made via our website, or by email, fax, phone, or letter. I have enclosed a complaints booklet for your information.

3.4 The Unfair Commercial Practices Directive takes effect in April 2008. To what extent will this help the ASA regulate the use of misleading claims?

As the Committee is undoubtedly aware, the UCP Directive is a framework Directive, meaning that it primarily provides general legal principles with which business must comply ie businesses should not trade unfairly; should not mislead by action or omission and should refrain from aggressive business practices.

That said, the Annex I of the Directive does provide a list of commercial practices that are considered to be unfair in all circumstances. One of these practices is, “Falsely claiming that a product is able to cure illness, dysfunction or malformations” (annex practice 17). The DTI is expected to publish further information on 29 May 2007 on how this section of the UCP Directive can be enforced under UK law by statutory enforcers.

However, regardless of the DTI’s anticipated statement, the new provisions in the UCP Directive are unlikely to alter the ASA’s interpretation of what is or is not permitted in advertisements in relation to allergy claims. This is because the UK Advertising Codes and existing legislation have, for a long time, provided the level of consumer protection that the UCP Directive will, in future, provide for all EU citizens.

I do hope that this submission fully answers the Committee’s questions about advertising regulation in this area and reassures the Committee that the ASA is committed to protecting consumers and ensuring high standards in advertising.
Committee of Advertising Practice (Non-broadcast)

HELP NOTE ON ASTHMA AND ALLERGY CLAIMS IN MARKETING FOR DEVICES

CAP Help Notes offer guidance for non-broadcast marketing communications under the British Code of Advertising, Sales Promotions and Direct Marketing (the CAP Code). For advice on the rules for TV or radio commercials, contact the BACC www.bacc.org.uk for TV ads or the RACC www.racc.co.uk for radio ads.

These guidelines, drawn up by the Copy Advice team, are intended to help marketers, agencies and media interpret the rules in the British Code of Advertising, Sales Promotion and Direct Marketing as far as they relate to the subject discussed. They neither constitute new rules nor bind the ASA Council in the event of a complaint about a marketing communication that follows them.

Asthma and allergies affect people in different ways. Not only are asthma attacks and allergic reactions often triggered by different allergens, but one sufferer might have a much higher tolerance of an allergen than another. It is therefore difficult to predict the benefit, if any, to an individual of reducing the number of allergens in their environment by using devices such as specially designed vacuum cleaners, bedding and air filters.

1. Marketers who claim that their device can reduce the amount of allergens in the environment should hold relevant substantiation. Claims such as “Product X removes 99 per cent of house dust mite faeces” are likely to be acceptable if marketers can prove them.

2. Marketers who claim that reducing the amount of allergens in the environment can benefit the health of asthma or allergy sufferers should be able to support these claims with satisfactory clinical trials on human subjects. Claims such as “Product X removed 99 per cent of irritants”, “Product X removes 99 per cent of house dust mite faeces, providing relief . . .” and “Product X removes 99 per cent of house dust mite faeces, a common trigger for reactions” are unlikely to be acceptable in the absence of these clinical trials.

3. Marketers who have proved that their product can benefit the health of asthma or allergy sufferers equally should not imply that all asthmatics or allergy sufferers can benefit where this is not the case. It may be necessary to qualify a claim to reflect, for example, that only those sufferers whose reactions are triggered by house dust mite faeces might benefit.

Advice on specific marketing communications is available from the Copy Advice team. The CAP website at www.cap.org.uk contains a full list of Help Notes as well as access to the AdviceOnline database, which has links through to relevant Code rules and ASA adjudications.

August 1997
Revised: March 2003
Deal TV Limited
Portland Media Group Ltd

Date: 9 May 2007
Media: Television
Sector: Health and Beauty

Complaint

Monitoring staff viewed an ad for Miracle Spring Water and Miracle Olive Oil Soap on Deal TV, a teleshopping channel. The TV evangelist Reverend Peter Popo said viewers who called in to receive the Miracle Spring Water and obeyed the instructions would receive money, be offered a house, a car, be healed from allergy problems, chest pain, heart burn and high blood pressure and lose weight. He claims “Obey, move in obedience and you will literally see the angels of the Lord bring money to you . . .”

Reverend Peter Popo said “You’ve had pain, it’s because of a tumour in your stomach, right there by your navel, it’s more or less on the right side and there’s been pain. Four surgeries, I just believe now that Doctor Jesus is going to touch everything that’s not right and make it right, make it new . . . In the name of Jesus Christ of Nazareth I command these things to dissolve”. [Peter Popo puts his hand on woman’s head and she collapses].

An assistant said “She got the miracle spring water, she followed the instructions and just a little while later moved out of the slums into owning her very own home. Amen. God gave you a house.” The woman responded saying “Yes he did. Praise God. Yes he did.” The assistant said “Did you use the Miracle Spring Water?” The woman said “Yes, I followed the instructions and a couple of days later you wrote me and said I would get a house, I would get a car”.

A testimonial claimed “Since I received your Miracle Spring Water my mom was healed and can walk again after a bad fall. My son was healed from allergy problems and my 17 years of chest pain, finger pain and heart burn are all healed. I believe you are the 100 per cent prophet of God”.

Another testimonial claimed “I received your Miracle Spring Water when I saw you on TV. You said someone was going to get good news from the doctor. My blood pressure was 201/100. After the Miracle Spring Water my doctor said it [sic] was only a few days my pressure was down and I had lost 8 lbs”.

Reverend Peter Popo said “We are going to pray. We are going to send the anointed word out over the airwave. And Liz, so many people tell me that they’ve touched our hands as a point of contact and seen a miracle. We are going to believe God right now for a mighty miracle touch. Father in heaven, right now, in the name of Jesus I take authority over every sickness, affliction, infirmity and disease. I take authority over this onslaught of financial attacks that has come against the people of God right now. I bind the forces of the enemy now. And Lord Jesus I release abundant blessings until each and everyone who is watching right now in Jesus’s name. It’s done, Liz I can just feel the burdens rolling away I can feel bondages being broken I can feel healing power flowing, do you feel that? I feel that diabetes is going away”.

Another TV evangelist, Dr Paul Lewis, promoted the Doctor Paul Lewis Miracle Olive Oil Soap and gave examples of some healings. Harry and Harriet McCain were with him and reminisced about the healings. Harry McCain said “As a matter of fact you had given him a bar of soap because he had some things going on within his body. A lot of people don’t believe in the miracle olive oil soap. It works. It’s not a gimmick, it’s real. You told him to wash for several days and he had a back injury and he had some things going on in his stomach and all of that went away . . . He was totally blind to the point that his eyes were white when you took the sunglasses off. So you know that he couldn’t see anything. And so you prayed for him and you told him look, you’re going to see. And the whole place became silent. You could hear a pin drop. And he said you are going to see this night. After this night your sight after washing with the soap is going to get better and better and better until you can see totally. There’s something about the soap. Amen. We get so many calls about this soap saying what did you put in that soap? The amount of testimony we’ve been getting of people who’ve been healed from cancer, AIDS I mean AIDS! I mean doctors don’t have a cure for AIDS or cancer and the amount of testimony we are getting. Man of God, it’s real, Jesus it’s real”.

Dr Paul Lewis recounted how he had visited a mosque “that day in that temple about 10 of those Muslim got me down in that basement and we sit around and they say tell me a little bit about your Jesus. And I begun to tell them about my Jesus and can I tell you even to this day some of those Muslim, right now, is coming to my church”.

Harriet McCain said “You said to her believe woman, believe woman that you can get up out of that wheelchair. Raise yourself up and believe by the power of God that God can heal you. She hadn’t walked for years. She hadn’t walked for years, couldn’t move for years, for years. And you told her wise up
woman because you can do it—daughter of God, wise up . . . And she began to raise herself up and it took me back to the woman with the issue of blood, she did not want to miss her moment because if she’d have missed her moment Dr Paul, she would have missed her opportunity and then she would have missed her blessing and I can look at this woman’s face and she said I’m gonna get out of this wheelchair one way or the other and I am not going to miss my opportunity. And she raised herself up and it was, she got up out of that wheelchair and, when she got up out of the wheelchair she began to walk and then when she got up and she walked, she put you in the wheelchair and she begun to push you through the aisles, that’s the power of God. And that was the point of contact and you’ve been saying the point of contact and with this, this oil, this olive oil, that you have, the miracle olive oil that you offer free, free, free, it’s free”.

Chanice said “I’ve used the free olive oil soap and the pain that I had, Dr Paul, all through my body, all through her body, all through her body, has been gone. And listen to this Dr Paul. I’ve used the olive oil soap, the miracle olive oil soap, and I’ve even lost weight. You don’t have to go to the gym. You don’t have to go to the gym. So if you wanna lost weight. That’s right. Call for the miracle olive soap. Amen. Amen. O yeah. Come on call for it, and God will let you lose weight. Amen”.

Dr Paul Lewis said “James 5:14 said—Is any sick among you? Let him call for the elders of the church and he shall anoint him with oil, miracle olive oil soap, and the prior of the saints shall save the sick and the Lord will raise him up”. The on-screen text quoted from the Bible [Is any sick among you? Let him call for the elders of the church; and let them pray over him, anointing him with oil in the name of the Lord [James 5:14].

A testimonial said “Since I used the soap, the chemo makes my bones ache and I mean have no energy. I have had all the energy and haven’t had any bones aching, no muscles aching and I just thank God that I’m healed”.

Dr Paul Lewis said “Pick up the phone right now and call that number. It’s toll-free. You don’t even have to pay a penny”.

### ISSUE

Monitoring staff challenged whether the ads:

1. exploited vulnerable viewers;
2. expounded religious beliefs and referred to individual experiences associated with a doctrine;
3. claimed the products would cure cancer, AIDS, and other serious medical conditions;
4. made medicinal claims for products that did not hold a marketing authorisation under the Medicines Act 1968;
5. complied with rule 8.4.3 (Predictions of weight loss);
6. would cause serious or widespread offence against generally accepted moral or cultural standards;

Monitoring staff challenged whether:

7. evidence existed to substantiate the claims that people’s financial circumstances would change after receiving the Miracle Spring Water;
8. using the prefix “Doctor” for Paul Lewis implied a professional recommendation for the product;
9. offering the soap and water as treatment for various medical conditions was a breach of rule 8.2.6;
10. the channel had sought suitably qualified medical advice on the efficacy of the Miracle Spring Water and the Miracle Olive Oil Soap’s slimming effects;
11. the on-screen telephone number was “toll-free” as claimed.

### BCAP TV ADVERTISING CODE

10.13; 5.4.4; 10.8; 10.10; 5.1; 5.2.1; 5.2.2; 8.1.1; 8.2.9; 8.2.3; 8.4.3; 6.1; 8.1.2(a); 8.1.2(c); 8.2.6; 8.4.2; 5.3.1

### RESPONSE

Portland Media Group Ltd first said they had subleased the channel to a third party who had aired the ads on the understanding that they had been shown on other channels. Then, in a written response, they accepted that they had breached the Code and said that they had withdrawn the ads when the breach was brought to their attention. Later, they permanently stopped the broadcast of Deal TV and surrendered its Ofcom licence. They added that ads had been broadcast on two occasions only and, because of an isolated administrative
error, caused by the proposed re-location of parts of the business to the USA, the tapes had not been viewed by their compliance officer as standard. They believed that no-one had ordered the products as a result of the broadcasts.

**Assessment**

1. **Upheld**

The ASA considered that the references to healing, the testimonials of those who had been healed and references to people receiving “a miracle touch from God” if they called to order the Miracle Spring Water or the Miracle Olive Oil Soap breached the Code. We considered that the ads exploited vulnerable viewers.

The ads breached CAP (Broadcast) TV Advertising Standards Code rules 10.13 Vulnerable viewers and 5.4.4 (Testimonials).

2. **Upheld**

We considered that the quotes from the Bible, Reverend Peter Popoff’s reference to “We are going to pray, we are going to send the anointed word out over the airwave . . .” and his instruction that “it’s not the water that brings the miracle, it’s the obedience to the instructions of the servant of God that releases the miracle in your life” expounded doctrinal beliefs that were prohibited by the Code.

The ads breached CAP (Broadcast) TV Advertising Standards Code rules 10.8 (References to beliefs) and 10.10 (Benefit claims).

3. **Upheld**

We noted Deal TV had not sought independent medical advice on the safety and efficacy of the Miracle Spring Water or of the Miracle Olive Oil Soap and had not established whether reputable scientific evidence supported the claims.

The ads breached CAP (Broadcast) TV Advertising Standards Code rules 5.1 (Misleading), 5.2.1 (Evidence), 5.2.2 (Implications), 8.1.1 (Assessment of claims) and 8.2.9 (Cure).

4. **Upheld**

We considered that the claims that the Miracle Spring Water had healed people suffering from chest pain and heartburn and high blood pressure and that the Miracle Olive Oil Soap had healed a blind man and people with cancer and AIDS were medicinal claims.

The ads breached CAP (Broadcast) TV Advertising Standards Code rule 8.2.3 (Products without a marketing authorisation).

5. **Upheld**

We considered that the testimonial from the woman who claimed to have lost 8 lbs in a few days after receiving the miracle spring water did not comply with the Code because the rate of the weight loss was too rapid to comply with accepted good medical and dietary practice. We considered that the testimonial from Chanice who claimed to have lost weight from using the Miracle Olive Oil Soap did not comply with the Code because the period over which the weight loss was achieved was not specified.

On this point the ads breached CAP (Broadcast) TV Advertising Standards Code rule 8.4.3 (Prediction of weight loss).

6. **Upheld**

We considered that the reference to converting Muslims in their place of worship would cause serious or widespread offence.

The ad breached CAP (Broadcast) TV Advertising Standards Code rule 6.1 (Offence).
7. Upheld

No evidence was submitted to substantiate the testimonials that claims an improvement in financial circumstances after receiving the Miracle Spring Water. We concluded that the claims were misleading.

The ad breached CAP (Broadcast) TV Advertising Standards Code rules 5.1 (Misleading) and 5.2.1 (Evidence).

8. Upheld

We considered that referring to Paul Lewis as “Doctor” implied he was qualified to give professional advice on health matters. Also, we considered that the product’s name, “Dr Paul Lewis Miracle Olive Oil Soap”, was a reference to approval of or preference for the products by Dr Lewis.

The ad breached CAP (Broadcast) TV Advertising Standards Code rule 8.1.2 (a) and (c) (Impressions of professional advice and support).

9. Upheld

We considered that Reverend Peter Popo’s claim to “take authority over every sickness, affliction, infirmity and disease. I take authority over this onslaught of financial attacks that has come against the people of God right now. I bind the forces of the enemy now. And Lord Jesus I release abundant blessings until each and everyone who is watching right now in Jesus’s name. It’s done, this I can just feel the burdens rolling away I can feel bondages being broken I can feel healing power flowing, do you feel that? I feel that diabetes is going away” might give the impression that medical consultations were not necessary.

The ads breached CAP (Broadcast) TV Advertising Standards Code rule 8.2.6 (Conditions requiring medical attention).

10. Upheld

We noted Deal TV had not sought suitably qualified medical advice on the efficacy of the Miracle Spring Water and the Miracle Olive Oil Soaps slimming capabilities.

The ads breached CAP (Broadcast) TV Advertising Standards Code rule 8.4.2 (Requirements for medical advice).

11. Upheld

We noted the on-screen telephone number was an 020 7 number and so not free as claimed.

The ad breached CAP (Broadcast) TV Advertising Standards Code rule 5.1 (Misleading) and 5.3.1 (Accurate pricing).

We noted the two contradictory responses. We were concerned that, as the licence holders, Portland Media Group Ltd was not entitled to sublease a licensed service and was wholly responsible for that service and its compliance with the conditions of the Licence. We welcomed Portland Media Group Ltd’s prompt action in removing the ads and surrendering the Licence. We were concerned that the broadcaster had so seriously breached the Code and because of the seriousness of the breach, were minded to refer the Portland Media Group Ltd to Ofcom for the consideration of a statutory sanction. But, because the Licence had been surrendered, we considered that no other action was needed.

**ACTION**

The ads must not be shown again.

**Air Ion Technologies Ltd**

**Date:** 14 February 2007

**Media:** Magazine

**Sector:** Health and Beauty
COMPLAINT

A magazine ad, for Myairzone an air purifier, claimed “Clears the air of pollutants, dust mites, cold and flu bugs, fungal spores, pet and animal dander, smoke, moulds . . . What our customers say: From our 2006 customer survey, Myairzone is used for asthma, anxiety, bronchitis, hayfever, headaches, migraines, infection avoidance, odour removal, pet allergy, skin conditions, deepens sleep, smoke clearance, driving, working, dust mite allergy and mould . . .”.

ISSUE

1. The complainant challenged the efficacy of the product.
2. The ASA challenged whether the claim “What our customers say: From our 2006 customer survey, Myairzone is used for asthma, anxiety, bronchitis . . .”, misleadingly implied that the device could relieve, or treat, the symptoms of the listed conditions.

THE CAP CODE

3.1; 7.1; 50.1; 50.3

RESPONSE

Air Ion Technologies (Air Ion) explained that the purpose of the product was to claim the air in close proximity to the user; they said they believed it was analogous to a water purifier. They said the process had been tested in independent trials by the Workplace Environment Science & Technology Research Association (WESTRA) and the Universities of Surrey, Leeds, Southampton and Reading and its ability to clear the air of various particles had been demonstrated by WESTRA regularly by using a particle counter at clients’ premises. They also claimed that the product cleared the air of various micro-organisms and said this had been demonstrated by researchers at Leeds and Southampton Universities. They sent a presentation from the Healthy Buildings Symposium in June 2006 and a copy of their customer satisfaction survey as substantiation for the advertised claims. They pointed out that they had a 60-day money back guarantee that allowed purchasers to assess the value of the product for themselves and obtain a full refund, including postage, if they were not satisfied.

ASSESSMENT

1. Upheld

The ASA considered that the claim “Clears the air” implied the product removed all airborne allergens. We noted the information Air Ion had supplied as substantiation was a short-term study on the impact of improved air quality on productivity and health in the workplace. Because it did not support the implication that the advertised product removed all pollutants and because it was not designed to be controlled for a placebo effect, we considered that the study was insufficient to support the claim. Furthermore, we noted Air Ion had not provided robust, placebo-controlled clinical studies that showed the product removed allergens from the surrounding air of the user’s homes, inside and outside, or for any specific irritant such as animal dander. We concluded that Air Ion’s submissions were insufficient to prove the efficacy of the Myairzone.

2. Upheld

We noted the customer satisfaction survey had a very high response rate and, from the graph provided, customers seemed to have enjoyed an improvement in their various symptoms. We nevertheless noted that it was impossible to know from the questionnaire whether any perceived change was directly attributable to the product. We considered that the claim implied the device could relieve, or treat, the symptoms of the listed conditions including the serious medical condition of bronchitis. Because Air Ion had not provided product-specific, clinically controlled trials on sufferers of these conditions to prove the efficacy of the product, we concluded that the claim was misleading. We were also concerned that the references to bronchitis and migraines, serious medical conditions, could discourage consumers from seeking help from a suitably qualified medical practitioner.

On points 1 and 2, the ad breached CAP Code clauses 3.1 (Substantiation), 7.1 (Truthfulness), 50.1 (Scientific substantiation) and 50.3 (Discouragement of essential treatment).
ACTION

We told Air Ion not to repeat the ad and advised them to consult the CAP Copy Advice team before advertising again.

Usave.tv t/a Save. TV
U Save TV Ltd

Publish Date: 22 November 2006
Media: Television
Sector: Retail

COMPLAINT

An ad for a silk-filled duvet on U Save TV claimed “It’s filled with 100 per cent silk and it’s got a very beautiful 100 per cent cotton casing as well. So it’s something that actually helps your body to breathe as you sleep at night. . . . Does that mean that it actually keeps you cool? Because I must admit when the summer starts coming I wake up sometimes in a hot sweat . . . Are you using the same duvet that you sleep with in the summer and the winter? You know, yes, I am actually. Well, you don’t have to worry about having a summer duvet or a winter duvet because the moisture will actually just evaporate. This is absolutely breathable. So this could actually be a summer duvet and a winter duvet? . . . The thing that I find quite amazing about this is the fact it keeps you warm in the winter yet it lets you breathe in the summer as well and so you actually save money on not having to buy a summer duvet and a winter duvet. You have this one all the year round. Absolutely, and so you don’t have to worry about storage so much because you’ve only got the one.”

“It’s great news for allergy sufferers as well . . . There are health properties along with this as well, real benefits for your health. Now because it doesn’t actually retain any moisture it means bed bugs can’t actually live in here. They are not welcome. It’s the bed bugs isn’t it that actually cause the problems. It’s the droppings of bed bugs which causes asthma and eczema and your itchy skin . . . It’s 100 per cent hypo-allergenic . . . it actually breathes with your skin . . . It will actually adjust to your temperature as well: so when you are sleeping in the winter it keeps you warm, in the summer it will keep you cool . . . It’s got great health properties as well: asthma sufferers, allergy sufferers, hello, this is for you!”

The voice-over on the offer page stated . . . including health properties which help relieve itching caused by skin conditions, 100 per cent breathable . . .”.

Another ad, for a memory pillow, claimed “this pillow is going to support your head. It’s going to mean there is less movement of the joints, the distribution of your weight is going to be maximised and, because you’re moving around less, if you’ve got any aches and pains or joints that are really achy, you’re going to possibly avoid that sort of problem. Do you know what else this is great for? If you’re a snorer . . . or you sleep next to a snorer and they keep you awake why don’t you get one of these for them? . . . Your head just rests so comfortably into this pillow, it’s supporting your neck. In fact it’s just lifting your neck very slightly, clearing your airways, so you can breathe air straight down into your lungs which could reduce your snoring”.

The text on the offer page stated that the pillow would “relieve pain and reduce snoring”.

ISSUE

BCAP staff challenged whether the duvet would:

1. help the body to breathe;
2. prevent bed bugs and their droppings and thereby help asthma and eczema sufferers;
3. be 100 per cent hypo-allergenic;
4. adjust to the body’s temperature and be warm in the winter and cool in the summer.
5. BCAP staff challenged whether the pillow would reduce snoring and help relieve pain.
Response

U Save TV submitted evidence of a study that demonstrated the effectiveness of a special sericin-free silk fabric in the treatment of young children affected by atopic dermatitis (AD). The study explained “silk also helps to maintain the body temperature, by reducing the excessive sweating and moisture loss that can worsen xerosis” although “the type of silk fabric generally used for clothes is not particularly helpful in the case and dressing of children with AD as it reduces transpiration and may cause discomfort when in direct contact with the skin”. The study stated “the clothes used in the present study are made of woven silk where the special properties of silk are enhanced: the fabric allows the skin to breathe and the sensation does not bother the wearer; it also has a high capacity to absorb sweat and serious exudates (up to 30 per cent of its weight without becoming damp)”. The study stated the fabric had a waterproof, durable, antimicrobial finish. The study noted that “recent studies have suggested that cotton may also present a roughness that irritates the skin of children affected by AD”. The study tested children wearing the special silk clothes against a control group that wore cotton clothing. The study concluded that “the use of sericin-free silk products would appear to alleviate the symptoms of AD”.

The study’s introduction stated that one of the many factors known to worsen AD was house dust mite.

The study explained that “the final textile products of silk are mostly non-allergenic”.

1. U Save TV explained that they had meant to state merely that silk was used as the ultimate breathable material; with its large fibres reducing thermo conductivity, either trapping air next to the skin to keep one warm in the cold or drawing it away from the body in hotter temperatures. The broadcaster admitted the statement could mislead.

2. U Save TV acknowledged that they did not have enough evidence to substantiate the claim.

3. U Save TV maintained that house dust mites were a frequent cause of allergic reactions and that one of their favourite locations was bedding. They claimed that house dust mites would not, or perhaps could not, live in silk. They added that, provided the rest of the bedding was washed regularly to keep it “mite-free”, that source of allergy could be controlled.

4. U Save TV maintained that silk-filled clothing was used by explorers in the Amazon jungle and in Alaska because of the silks natural properties. But they conceded that the claim was merely a suggestion and that it could apply also to other types of bedding.

5. U Save TV submitted no evidence and said the claim had been removed from the ad.

Assessment

1. Upheld

The ASA considered that evidence from a study on specially treated silk clothing could not be extrapolated to a duvet that was filled with a different type of silk and had a cotton casing. We considered that the claim was misleading.

2. Upheld

We noted that no evidence was presented to show that house dust mites were unable to live in silk-filled duvets or that a cotton-cased duvet would produce the improvements described in the study. We considered that the claims were misleading.
3. Upheld

Because no evidence was presented to show that house dust mites were unable to live in silk filled duvets and because the duvet had a cotton casing, we considered that the claim was misleading.

4. Upheld

We noted no evidence was presented to support the claim that the duvet would adjust to the body’s temperature or be warm in the winter and cool in the summer. We considered that the claims were misleading.

5. Upheld

We welcomed the broadcasters action but nevertheless considered that the claims were misleading.

We concluded that the ads breached rules 5.1 (Misleading advertising) and 5.2.1 (Evidence) of the CAP (Broadcast) TV Advertising Standards Code.

ACTION

The ads must not be shown again in their present form and the products should not be advertised without adequate substantiation for the claims made.

Sharp Electronics (UK) Ltd

Publish Date: 6 October 2004
Media: National press
Sector: Household
Public complaint from: London

COMPLAINT

Objection to a national press advertisement that was headed “I suffered allergies for 15 years. It only took two months to feel the difference”. It claimed “...Sarah has a job she loves... But since being a small child herself, she’d suffered badly with asthma and hay fever. Over the years she had learned that the most likely triggers were pollen, pets, and most especially, airborne mite allergens. Apart from irritation of the eyes, nose and throat, the severity of her allergy caused her actue breathing difficulties. Particularly at night, when it would become hard to get the restful sleep she needed to face the next busy day. As a result Sarah gave a trial to the new Sharp Healthcare air purifier... In as short a time as two months she began to notice a difference in her life. The severity of her symptoms was reduced and she was not able to sleep soundly right through the night... Introducing Plasmacluster Ion Technology. A scientific solution to airborne allergens... After lengthy research and development they [experts in the field of molecular biotechnology] have recently verified that they had identified a pro-active way to deactivate airborne mite allergens*, one of the most common asthma triggers... The Sharp Healthcare air purifier is the first device to incorporate a Plasmacluster Ion generator, the key to this revolutionary breakthrough in anti-allergen technology. This produces streams of positive and negative ions—which are natural components of healthy air—that quickly bond with water molecules, known as cluster ions. When these cluster ions are released into a room they actively seek out and surround airborne mite allergens. A chemical reaction takes place and the allergen is rendered harmless, robbed of its ability to provoke an allergic response even if breathed in... Plasmacluster Ion Technology is not in itself a cure for Asthma or other allergies. But for sufferers like Sarah, it may mean that they can now breathe in a purer air that isn’t laden with the active allergens that have caused them years of misery”. The complainant, who believed the product did not affect dust mite allergens, challenged whether the device benefited people who suffered from dust mite allergies.

Codes Section: (Ed 11: 3.1; 7.1; 50.1)
Adjudication

Complaint upheld

The advertisers said the device had been independently tested in Japan; they sent a press release that detailed the test results. They said, before the device was marketed in the UK, trials on allergy sufferers had been conducted by a specialist communication company on their behalf; they said the feedback from those trials had been mainly positive. The advertisers said they had selected two of the trials to form the basis of their advertising and sent a copy of one of the completed questionnaires from an allergy sufferer. The advertisers asserted the device had been awarded a “Seal of approval” by the British Allergy Foundation and that two professors, who were specialists in the field, had stated the effectiveness of the device in combating the triggers that caused allergic reactions.

The Authority took expert advice. It understood that the advertisers’ evidence showed the device provided effective air filtration and that the additional plasma cluster technology could inactivate allergens in the air. It nevertheless understood that, in the absence of a rigorously designed clinical study, corrected for any placebo effect, the efficacy of the device for providing actual clinical benefit to allergy sufferers was unproven.

The Authority considered that the advertisement implied the device would rid the air in people’s homes of virtually all airborne allergens and help those with medical conditions such as asthma. The Authority noted the results of the trials conducted on behalf of the advertisers, but considered that the results of those trials were not sufficient to substantiate that implication. In the absence of product-specific, clinically controlled trials on sufferers to prove the efficacy of the advertised product, the Authority concluded that the advertisement was misleading. It told the advertisers not to repeat the advertisement and advised them to consult the CAP Copy Advice team before advertising the device again.

Samsung Electronics UK Ltd

Publish Date: 16 June 2004
Media: Magazine
Sector: Household
Industry complaint from: Wiltshire

Complaint

Dyson Ltd objected to a trade magazine advertisement, for a washing machine, that was headlined “larger drum—less washing time”. Text stated “Effective, efficient and allergy free washing from Samsung . . . This powerful washing machine is not only a first for its size but also for its innovation. The unique Detergent Dissolver System dissolves the detergent faster and more effectively before it reaches the wash, minimising the residue left on your clothes which can cause skin irritation. And the impressive 7.5 kg load capacity, the largest in a standard UK size machine, ensures fewer loads to complete your washing . . .”. The complainants challenged whether:

1. the advertisement, especially the claims “larger drum—less time washing” and “not only a first for its size, but also for its innovation”, misleadingly implied that the advertisers’ machine had a larger drum than competitors’ machines;
2. the advertisement, especially the claims “larger drum—less time washing” and “not only a first for its size, but also for its innovation”, misleadingly implied that the advertisers’ machine washed more quickly than competitors’ machines and
3. the claim “allergy free washing” was misleading, because they understood that the advertisers’ machine performed poorly and less well than the Dyson CR01 on the IEC test, which measured the level of detergent left in the final rinse water.

Codes Section: (Ed 11: 3.1; 7.1; 19.1)

Adjudication

1. Complaint not upheld

The advertisers stated that the advertised washing machine was called Bigwash, because it had a larger load capacity and could wash large items such as duvets, towels and curtains. They stated that the Samsung Bigwash had a drum volume of 60 litres and a capacity of 7.5 kg; they said the 7.5 kg capacity was a first for its size and innovation, because no other brand provided that much washing capacity under European standard dimensions of 60 cm width, 60 cm depth and 82 cm height. They argued that they had never claimed that their
washing machine’s drum volume was the largest, merely that its load capacity was the largest for the European standard depth of 60 cm. The advertisers asserted that the complainants’ machine, the Dyson CR01, which had a depth of 71 cm, was oversized compared with European standard dimensions. The Authority noted although the Dyson CR01 had a drum volume of 78 litres, its load capacity was less than that of the advertised machine. It also noted the Dyson CR01 had a depth that was greater than the standard UK size machine. The Authority considered that the advertisement made clear the 7.5 kg load capacity of the advertised machine was the largest for a standard size machine. Because it noted the advertised machine could wash a larger load compared with other washing machines, including the complainants’ machine, the Authority concluded that the advertisement was not misleading on that point.

2. Complaint not upheld

The advertisers stated that a comparative test had shown that the Samsung Bigwash had a cycle time of 98 minutes (mins) compared with 118 mins for Miele, 124 mins for Bosch and Siemens and 145 min for Zanussi; they had not included the Dyson machine in the test because it was in a different size category. The advertisers asserted that no other brand had a shorter cycle time for a 7.5 kg load. The Authority noted, although it had a cycle time of 88 mins, the Dyson CR01 was larger than the standard size. The Authority noted the advertisement stated “. . . the impressive 7.5 kg load capacity . . . ensures fewer loads to complete your washing . . .”. It considered the consumers would infer from the advertisement that, because the advertised machine could wash heavier loads than other machines, they could complete their washing in fewer loads and thus spend less time washing, not that the advertised machine had a shorter cycle time compared with competitors’ machines. The Authority concluded that the advertisement was not misleading on that point.

3. Complaint upheld

The advertisers asserted that the Bigwash programs on the advertised machine, which no other manufacturer provided, focused on low detergent residues. They stated that WFK in Germany had conducted comparative tests to measure detergent residues; they said the results showed that the Samsung Bigwash 6 kg produced less detergent residue than Bosch, Hoover, Whirlpool and the Dyson CR01 washing machines. The advertisers asserted that, as well as the Bigwash programs, the Samsung Bigwash 7.5 kg had a “Detergent Dissolver System” to minimise detergent residue on laundry; the detergent powder was full dissolved and liquidised quickly to minimise residue that was not dissolved completely during washing. They asserted that their machine also had a “Shower Spinning” function that sprayed water onto the laundry during the spin cycle, thus helping to reduce skin problems. They said to ensure “allergy free washing” for sensitive people, their machine had a “Rinse Selection” option, which enabled consumers to increase the rinse cycle up to five times; they asserted that no other European brand had that feature. The Authority noted the results of the detergent residue tests and the features of the machine that the advertisers asserted reduce detergent residue. It nevertheless considered that the advertisers had not sent sufficient substantiation, including the results of clinical trials, to show that the advertised machine could provide a significant benefit to allergy sufferers. The Authority concluded that the claim was misleading and advised the advertisers to amend it with help from the CAP Copy Advice team.

Medivac Healthcare Ltd

Publish Date: 19 February 2003
Media: Leaflet
Sector: Health and Beauty
Public complaint from: Berkshire

Complaint

Objection to a leaflet for products for people with asthma, eczema and rhinitus. The leaflet stated“ . . . Swiss mountain air quality for your home or office. How does the Airwasher work? The new Swiss-designed Medivac Airwasher literally washes the air you and your family will breathe . . . The Airwasher has also been designed to help breathing difficulties during the drier months of the year when relative humidity levels are reduced . . . The modern design of the Medivac Airwasher will look good in any home or office. This appliance is strongly recommended for adults and children whose medical condition is influenced by exposure to common allergens, from dust mites, cats, traffic or any of the many airborne particles created by our modern lifestyles . . . Medivac has satisfied the United Kingdom’s [sic] HM Customs & Excise that Medivac Healthcare products are of such medical benefit to adults and children with asthma, eczema or rhinitus, that such individuals may purchase Medivac products free from Value Added Tax . . . The Airwasher is designed solely to protect adults and
children from airborne allergens . . . which can trigger asthma, rhinitis or eczema . . . ”... The complainant challenged the efficacy of the device.

Codes Section: (Ed 10: 3.1; 7.1; 50.1; 50.3)

Adjudication

Complaint upheld

The advertisers said their airwasher was an allergen avoidance product; they argued that the efficacy of allergen avoidance products had been proven by medical research institutions. They claimed that their product had two main features: it washed and it humidified air, both without the use of filters. The advertisers argued that temperature, air purity and moisture content of the air were all important factors in the maintenance of an ideal room climate. They explained how their product worked. The advertisers sent various references referring to studies about asthma prevention and the links between allergen exposure and respiratory allergy. They said they had no plans to promote the product again. The advertisers commented that they had received only one complaint about the product. The Authority considered that the leaflet implied the product would rid the air in people’s homes of virtually all pollutants and help those with medical conditions such as asthma. In the absence of results of product-specific, clinically controlled trials on sufferers to show the product worked as advertised, the Authority told the advertisers not to repeat the advertisement and advised them to consult the Committee of Advertising Practice Copy Advice team before advertising again.

Letter from the British Occupational Health Research Foundation

We do not have any research relating to non-occupational allergies and their impact on work and attendance. However, we are able to provide evidence pertaining to a specific allergy ie: occupational asthma from: Newman Taylor AJ, Nicholson PJ (Editors). Guidelines for the prevention, identification and management of occupational asthma: Evidence review and recommendations. British Occupational Health Research Foundation. London 2004.

The strength of evidence is identified as:

*** Strong evidence—provided by generally consistent findings in multiple, high quality scientific studies.

** Moderate evidence—provided by generally consistent findings in fewer, smaller or lower quality scientific studies.

* Limited or contradictory evidence—provided by one scientific study or inconsistent findings in multiple scientific studies.

We note that your letter refers to “The Provision of Allergy Services” Department of Health July 2006. One of the editors of the BOHRF Evidence Review was a member of the National Allergy Advisory Group associated with that review.

Defining the Problem:

What is asthma?

Asthma is a condition of chronic inflammation of the airways, characterised by widespread airflow limitation that is reversible, either spontaneously or with treatment over short periods of time. The inflammation results in hyper-responsiveness of the airways to many stimuli eg cold air, cigarette smoke, exercise, etc and in the clinical setting to methacholine and histamine. Symptoms include wheeze, cough, shortness of breath and chest tightness and are often worse at night or in the early morning.

Work-related asthma occurs when there is an association between symptoms and work. The two different types of work-related asthma are:

— work aggravated asthma, ie pre-existing or coincidental new onset adult asthma which is made worse by non-specific factors in the workplace, and

— occupational asthma ie adult asthma caused by workplace exposure and not by factors outside of the workplace.

Occupational asthma is subdivided into:

— allergic occupational asthma characterised by a latency period between first exposure to a respiratory sensitisier at work and the development of hypersensitivity symptoms, and
irritant-induced occupational asthma that occurs typically within a few hours of a high concentration exposure to an irritant gas, fume or vapour at work.

The evidence provided hereafter relates exclusively to allergic occupational asthma.

What is and what is not known about the origins and progression of occupational asthma?

Four risk factors have been identified including the predisposing factors of atopy and genetic predisposition, the causative factor of exposure to an agent at work and the contributing factor of cigarette smoking.

Atopy is a state characterised by the propensity to produce specific immunoglobulin IgE on ordinary exposure to common allergens in the subject’s environment.

*** Atopy increases the risk of developing occupational asthma caused by exposure to many high molecular weight agents that induce the production of specific IgE antibodies.

** Some genes may predispose to occupational asthma for some agents.

Several hundred workplace agents are reported to cause occupational asthma. Those that induce allergic occupational asthma can be divided into those of high and low molecular weight. The former are usually proteins and appear to act through a type I, IgE associated hypersensitivity. Whilst some low molecular weight chemicals are associated with specific IgE antibodies, this is not the case for the majority.

*** The risk of sensitisation and occupational asthma is increased by higher exposures to many workplace agents.

*** The most frequently reported agents include isocyanates, flour and grain dust, colophony and fluxes, latex, animals, aldehydes and wood dust.

*** The workers most commonly reported to surveillance schemes of occupational asthma include paint sprayers, bakers and pastry makers, nurses, chemical workers, animal handlers, welders, food processing workers and timber workers.

** The workers reported from population studies to be at increased risk of developing asthma include bakers, food processors, forestry workers, chemical workers, plastics and rubber workers, metal workers, welders, textile workers, electrical and electronic production workers, storage workers, farm workers, waiters, cleaners, painters, plastic workers, dental workers and laboratory technicians.

** Cigarette smoking can increase the risk of developing occupational asthma with some sensitising agents.

** Occupational rhinitis and occupational asthma frequently occur as co-morbid conditions in IgE associated occupational asthma.

Occupational rhinitis is a risk factor for the development of occupational asthma, especially for high-molecular-weight sensitisers:

** Rhino-conjunctivitis is more likely to appear before the onset of IgE associated occupational asthma.

* The risk of developing occupational asthma is highest in the year after the onset of occupational rhinitis.

Generally, occupational asthma is reported to have a poor prognosis and to be likely to persist and deteriorate unless identified early and managed effectively.

*** The symptoms and functional impairment of occupational asthma caused by various agents may persist for many years after avoidance of further exposure to the causative agent.

Why does the UK in particular have such a high prevalence of occupational asthma?

The reported prevalence of occupational asthma in the UK is similar to other westernised countries.

*** Occupational factors are estimated to account for 9–15 per cent of cases of asthma in adults of working age, including new onset or recurrent disease.

*** The annual population incidence of occupationally related asthma ranges from an estimated 12 to 170 cases per million workers with an estimated mean of 47 cases per million workers.
What gaps exist in establishing the overall disease burden of occupational asthma and what are the barriers to filling the gaps?

One of the two reporting schemes (SWORD) is voluntary and the other (RIDDOR) requires patient consent. This leads to under-reporting in both.

* The population incidence of occupational asthma may be underestimated by as much as 50 per cent.

** Treatment and Management**

What is the effect of current treatments on the natural history of occupational asthma?

The pharmacological management of occupational asthma is no different to that of any case of adult asthma. What differs is the occupational health management.

A single small randomised-controlled trial has examined the effect of inhaled corticosteroids on the recovery from occupational asthma after cessation of exposure. Small but statistically significant improvements in some symptoms, peak flow and quality of life were reported.

Workers who remain in the same job and continue to be exposed to the same causative agent after diagnosis are unlikely to improve and symptoms may worsen.

What is the evidence base for pharmacological and non-pharmacological management strategies?

Complete avoidance of exposure may or may not improve symptoms and bronchial hyper-responsiveness. Both the duration of continued exposure following the onset of symptoms and the severity of asthma at diagnosis may be important determinants of outcome. Early diagnosis and early avoidance of further exposure either by relocation of the worker or substitution of the hazard offer the best chance of complete recovery.

*** The likelihood of improvement or resolution of symptoms or of preventing deterioration is greater in workers who have no further exposure to the causative agent.

** The likelihood of improvement or resolution of symptoms or of preventing deterioration is greater in workers who have relatively normal lung function at the time of diagnosis.

** The likelihood of improvement or resolution of symptoms or of preventing deterioration is greater in workers who have shorter duration of symptoms prior to diagnosis.

** The likelihood of improvement or resolution of symptoms or of preventing deterioration is greater in workers who have shorter duration of symptoms prior to avoidance of exposure.

Is the level of UK research into occupational asthma adequate?

BOHRF produced the world’s first evidence based guidelines for occupational asthma hence the UK is seen as a world leader in this area along with Canada, France and Spain. More research has been identified by the Health & Safety Executive examining in particular worker behaviour. Further research should be undertaken to assess the impact of evidence based guidelines and how their impact might be improved, and the most suitable components and frequency of health surveillance.

** Government Policies**

How effective have existing Government policy and advice been in addressing the rise in occupational asthma?

The Health and Safety Executive (HSE) estimate that 1,500 to 3,000 people develop occupational asthma each year. HSE estimates that the costs to society of new cases of occupational asthma are up to £1.1 billion over 10 years. HSE set up an Asthma Project Board in 2000 to help it reduce the incidence of occupational asthma by 30 per cent over 10 years. Data suggests that the incidence has reduced in the last three years.
Patient and Consumer Issues

What impact does occupational asthma have on quality of life of patients and their families?

There is consistent evidence that:

- Approximately one third of workers with occupational asthma are unemployed up to six years after diagnosis.
- Workers with occupational asthma suffer financially.

What can be done to better educate the public and to improve the quality of information that is available to patients and undiagnosed sufferers?

We believe that the BOHRF reviews and their practical lay guidance for the public, managers and safety professionals serve as a good model for communicating important messages as both hard copy and on the internet. Furthermore leaflets and internet based advice aimed at primary care staff serves to increase awareness to lead to earlier identification of cases.

Only one in eight of the UK workforce has access to comprehensive occupational health support. Making access more available is a key opportunity. As well as increasing the numbers of competent human resource, it would be useful to provide access to better online support, eg by making respiratory questionnaires accessible online.

Are current regulatory arrangements for private clinics satisfactory?

Any clinician may open and offer an occupational health service. Competence should be better defined and relate to qualifications and revalidation of providers.

Since many cases of occupational asthma first report to primary care, there is a need for better training in occupational medicine for GPs.

31 October 2006

Letter from the British Thoracic Society

Whereas the British Thoracic Society is strongly supportive of the overall direction of strengthening of allergy services (both clinical and research) within the UK we have little if any specific numerical data of our own.

We recognise allergy to be an increasing workload of primary care physicians, respiratory physicians, ENT specialists and dermatologists as well as specialised tertiary allergy referral centres. Respiratory physicians manage many patients with allergic associated diseases (such as asthma, occupational asthma, rhinitis, allergic alveolitis etc) and aspects of allergy are included in the specialty training curricula.

1. We have formally supported the concept proposed by the BSACI that there should be an Allergy clinic staffed by Specialist Allergists or Immunologists within each teaching hospital and that these should be equitably spread throughout the UK.

2. From the available data we have seen and on the BSACI website for the geographical location of the present Allergy clinics the present capacity and potential shortcomings of the tertiary Allergy/immunology services are unclear.

3. The exact number of patients with allergic conditions for example hay fever, asthma, eczema and food allergy/intolerance who are satisfactorily dealt within Primary care, Respiratory, ENT, storoenterology and Dermatology clinics without the need for referral to tertiary care is large, but the BTS has no figures for such workload within any specialty.

4. However within our own specialty the expenditure of asthma medications such as inhaled steroids are amongst the largest single drug spends within the NHS.

5. Undoubtedly there is a small but very important group of patients that our members would wish to refer to specialist tertiary allergy services and who currently get poor access by the limited number of such clinics and long waiting times but again we do not have exact figures to support this.

6. We hope that your committee would explore the current and future real and potential threats to the existing allergy services throughout the UK. Examples would be retirement of senior staff; a necessity for growth in training posts, capacity for training general practitioners and consultants in organ based specialties such as
our own and of course research which regrettably has a history of being under funded as far as respiratory medicine is concerned.

7. It would also be helpful to develop an ideal model for an allergy centre as far as specific staffing and support ie Consultants, SpR’s, Specialist Nursing, Secretarial support and the costing thereof. One could then test the present availability against the ideal model.

24 October 2006

Letter from Dr A T Clark, Consultant Paediatric Allergist and Dr P W Ewan, Consultant Allergist

House of Lords Science and Technology Committee: Allergy inquiry

We thought it might be helpful to put in context the recent media coverage, including a slot on “Today”, on severe food allergy, as it gave a misleading impression. This followed an article in the British Medical Journal (BMJ) by Professor Colver, titled “Are the dangers of childhood food allergy exaggerated?” The message was that they are exaggerated.

This debate was based on data published by Professor Colver in 2002 (Archives Disease of Childhood). This was criticized by 2 groups (of international experts in childhood allergy), published later in the same journal. Similarly there were published criticisms of the recent BMJ article.

This highlights two issues. There is debate and we do not have enough data to inform routine clinical decisions; so high quality clinical research to answer basic questions in allergy is much needed. Second, the author is commenting from the position of a non expert in allergy (his expertise is in community child health), and selectively quotes from the literature. Colver’s original study was poorly designed and biased, by both failing to recruit children from major allergy centres and setting inappropriately restrictive criteria for inclusion (for example a child requiring one injection of adrenaline is not included—yet a child would usually be very ill before adrenaline was given). Colver’s conclusions and much publicized opinions are therefore based on flawed study design and misinterpretation of the findings.

An analysis of our data on 1,500 children with nut allergy revealed a severe reaction rate of 1.93 per 100,000 population per year, a figure 10 times that suggested by Colver for all foods.

Media publicity of poorly conducted studies is misleading.

7 October 2006

Memorandum by Coeliac UK

1. Introduction

1.1 Coeliac UK is the only national charity supporting people with coeliac disease. It was formed in 1968 as The Coeliac Society to provide support and advice to people with coeliac disease.

1.2 Coeliac disease is a life-long auto-immune disease caused by an intolerance to gluten. Left untreated it can lead to life-threatening malnutrition or other serious complications such as osteoporosis and bowel cancer. It can only be controlled by a strict gluten-free diet for life. Therefore, in identifying and managing the condition the issues are comparable to those surrounding allergies and other intolerances.

1.3 Studies show that 1 in 100 people in the general population have coeliac disease but only 1 in 8 will have been clinically diagnosed. Of these Coeliac UK has over 70,000 people as members. It is the oldest and largest coeliac society in the world; and a leading source of information on coeliac disease.

1.4 Besides supporting our members and the broader coeliac community, the charity provides information to healthcare professionals who use our services to provide information to their patients.

1.5 We have a Helpline telephone service run by registered dietitians providing advice and support to members, health care professionals, food manufacturers and the general public.

1.6 We also work closely with the leading gluten-free food manufacturers and retailers to provide advice and promote choice and availability.

1.7 We are also providing funding for invaluable research into the causes, nature and treatment of coeliac disease.
2. **Defining the Problem**

**What is the definition of food allergy?**

2.1 An allergic reaction to a food can be described as an adverse reaction by the body’s immune system to the ingestion of a food that in the majority of individuals causes no adverse effects. Allergic reactions to foods vary in severity and can be potentially fatal. In food allergy the immune system does not recognise as safe a protein component of the food to which the individual is sensitive (such as some peanut proteins). This component is termed the allergen. The immune system then typically produces immunoglobulin E (IgE) antibodies to the allergen, which trigger other cells to release substances that cause inflammation. Allergic reactions are usually localised to a particular part of the body and symptoms may include asthma, eczema, flushing and swelling of tissues (eg the lips) or difficulty in breathing. A severe reaction may result in anaphylaxis (as with severe peanut allergy) in which there is a rapid fall in blood pressure and severe shock. Food allergy is relatively rare, affecting an estimated 6–8 per cent of children and 1–2 per cent of adults, and is often wrongly used as a general term for adverse reactions to food.

**What is the definition of food intolerance?**

2.2 Food intolerance is the general term used to describe a range of adverse responses to food, including allergic reactions (eg peanut allergy or coeliac disease), adverse reactions resulting from enzyme deficiencies (eg lactose intolerance or hereditary fructose intolerance), pharmacological reactions (eg caffeine sensitivity) and other non-defined responses. Food intolerance reactions are usually reproducible adverse responses to a specific food or food ingredient, which can occur whether or not the person realises they have eaten the food.

2.3 In any consideration of allergies and intolerances, however, coeliac disease should also be considered as it affects 1 in 100 of the population and people with the disease face the same issues and challenges as people with allergies or food intolerances. These include the difficulties of obtaining early accurate diagnosis, the need to maintain a nutritional diet, management of that diet, access to affordable food alternatives, the safe selection of food, and the dangers of cross-contamination in cooking and food preparation.

**Incidence and prevalence**

2.4 Studies have shown that the prevalence of coeliac disease in the general population is 1 in 100. This seems to be true across Europe. It may appear to be raising in comparison to earlier studies but it is more likely that it is simply better recognised than in the past and that there is a greater awareness of coeliac disease. The development of screening tools in antibodies tests specific to coeliac disease (i.e endomysial antibodies—EMA- and tissue transglutaminise -tTGA) have improved diagnosis rates in recent years.

**Socio-economic impact**

2.5 It is difficult to assess the overall burden of coeliac disease due to the absence of recorded information on diagnosis rates. There is a need for a central register of coeliac disease patients.

2.6 As a health problem, coeliac disease has an impact on both the individual and the community because of high prevalence and long-term complications due to late diagnosis. The development of osteoporosis or bowel cancer therefore has an impact for the individual, the community and the health service. Even in the short-term the absence of diagnosis has a socio-economic impact.

2.7 According to an independent study commissioned by Coeliac UK in 2006, just under half (46 per cent) of people with coeliac disease who had been wrongly diagnosed believed that their job or career suffered due to their condition prior to diagnosis.

3. **Treatment and Management**

3.1 Better understanding and greater familiarity is needed among GPs for coeliac disease to be diagnosed earlier. The disease needs to be recognised before the patient can be treated. Coeliac disease needs to be higher in the GP’s consciousness and earlier testing is essential to diagnose or eliminate coeliac disease from diagnosis early on.
3.2 GPs need to recognise that, once diagnosed, patients need to be referred to a registered dietician to help advise on the management of their diet. In the YouGov study of diagnosis conducted in February 2006, 43 per cent of respondents were not referred to a dietician despite the fact that the condition can only be controlled by following a strict gluten-free diet.

3.3 Dieticians and other healthcare professionals, namely GPs, need continuing professional development to ensure that they are aware of the current guidelines on coeliac disease and information on the gluten-free diet.

3.4 A survey conducted by Coeliac UK of registered dieticians showed that there is a wide variation nationally in the level of provision of dietetic expertise for patients with coeliac disease. The current level of provision is in the region of one third of what would be required to provide diagnosed coeliacs in the UK with basic support and annual review.

4. Government Policies

4.1 There is a continuing cost to the health service in repeat visits to their GPs by people with undiagnosed coeliac disease.

4.2 Furthermore, left untreated or undiagnosed it can lead to more serious complications such as bowel cancer and osteoporosis which will require a bigger drain on health service resources in the longer term.

4.3 Coeliac UK recognises the competing demands upon health service resources and budgets but coeliac disease is a disease that is easily controllable once diagnosed. It is a disease that can potentially be self-managed if diagnosed early enough in life.

4.4 Government policy needs to acknowledge the scale of coeliac disease’s impact across a large segment of the population. Policy also needs to take into account the potentially serious nature of the disease, the cost in financial terms and suffering for the undiagnosed and therefore recognise the importance of early diagnosis. In particular measures could be taken to:

- address the lack of awareness of the disease and to provide a framework to ensure that GPs receive the appropriate training and resources. This would enable them to better recognise and more accurately diagnose the disease and thus increase the speed of diagnosis and improve diagnosis rates.
- and to provide ongoing training to enable GPs to give better care in the community for patients with coeliac disease.

Importance of prescriptions

4.5 As coeliac disease can only be controlled through a gluten-free diet, which restricts intake of the staple foods, it is essential that patients with coeliac disease are able to buy gluten-free food substitutes for the staple foods like bread, flour and pasta in the diet.

4.6 Many gluten-free foods and food ingredients are more expensive than their gluten-containing alternatives. To many people on low incomes, especially the vulnerable young and old, the cost of some gluten-free foods could be prohibitive. For example:

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Normal price</th>
<th>Gluten-free price</th>
</tr>
</thead>
<tbody>
<tr>
<td>White loaf of bread (400g)</td>
<td>35p</td>
<td>£2.49</td>
</tr>
<tr>
<td>Plain white flour (250g)</td>
<td>22p</td>
<td>£1.99</td>
</tr>
<tr>
<td>Penne pasta (500g)</td>
<td>31p</td>
<td>£3.20</td>
</tr>
</tbody>
</table>

* This is based on a comparison between Dietary Specials gluten-free products available in shops and Tesco’s own brand.

4.7 The Department of Health provides guidance which enable coeliac patients to receive prescriptions to obtain gluten-free food and so maintain a healthy diet.

4.8 Recently, in an effort to make cost-savings, some Primary Care Trusts have sought to restrict the number of gluten-free prescriptions that are being issued and have issued guidance to GP Surgeries to cut down on the number of prescriptions or restrict them to staples. This may include bread, flour and bread mixes but may not include pasta which to many people these days (particularly with children) is now a staple. There has been an inconsistency in the policies or recommendations put forward by PCTs across the country.
**Allergy: Evidence**

4.9 In recent years we have seen great improvements in the labelling of food containing gluten particularly in light of the recent implementation of the European Commission Directive on allergen labelling (2003/89/EC). This is a great advance and Coeliac UK has been working closely with the Food Standards Agency.

4.10 However, for many people there is still some confusion as to what the labelling means. Coeliac UK owns the trademark of the Crossed Grain symbol which manufacturers can licence to brand their products to indicate that they are gluten-free. The Crossed Grain symbol is globally recognised and provides a reassurance to people with coeliac disease that the product they are buying is gluten-free and safe to eat.

5. **Patient and Consumer Issues**

*The problem for the patient*

5.1 The first problem for the patient with coeliac disease is the lack of knowledge at primary care level. GPs do not always recognise coeliac disease when confronted with the symptoms. It is often diagnosed as some other ailment and the patient frequently finds themselves making repeated visits to their GP as their symptoms persist. This causes both distress to the patient (as coeliac disease can be a debilitating illness if left untreated) and a cost to the health service in terms of the repeated visits to the GP.

5.2 A survey conducted for Coeliac UK shows that one third of coeliac patients visit their GP seven or more times before receiving a correct diagnosis. One fifth were only diagnosed after everything else had been “ruled out” and two fifths were not tested for coeliac disease until a year after first visiting their GP with the symptoms.

*Quality of life*

5.3 People with coeliac disease can experience bloating, exhaustion, diarrhoea, anaemia, headaches, weight-loss, mouth ulcers and skin complaints. It can be a distressing and debilitating illness.

5.4 In the recent survey of members undertaken by IPSOS MORI for Coeliac UK 56 per cent considered coeliac disease to have limited their life to a “fair amount or a great deal”. This was also borne by a survey undertaken by YouGov for Coeliac UK, which showed that among a representative sample of diagnosed coeliacs 59 per cent of respondents believed that their social life suffered as a result of their illness prior to diagnosis.

5.5 Furthermore, in the YouGov survey 68 per cent of men and 52 per cent of women felt that before diagnosis their condition had left them too tired or ill to participate in sports or exercise.

5.6 One fifth believed their sex life suffered before diagnosis.

*How to educate the public and improve quality of information available to patients and undiagnosed sufferers*

5.7 The Government could generally help to raise awareness of coeliac disease by:

- providing better training and resources for GPs;
- ensuring that healthcare professionals are aware of recent advances in diagnosis and management; and
- taking measures to encourage better provision of gluten-free meals in institutions such as schools, hospitals and care homes.

6. **Conclusion**

6.1 We welcome the Select Committee’s decision to investigate allergies and allergic diseases. We hope that it will broaden its scope to consider the policy implications for coeliac disease which is a diet-managed disease where early diagnosis and safe selection of food are key issues.
6.2 Coeliac disease is comparable to allergies and intolerances in its impact on the individual, their wider community and the socio-economic impact.

6.3 With 1 in 100 of the population believed to have the disease; with currently only 1 in 8 diagnosed; and in view of the possible serious long-term complications that can arise from a lack of diagnosis the identification, diagnosis and treatment of coeliac disease has implications for policy and resources that we hope the Select Committee will consider.

REFERENCES (not printed)

3 November 2006

Memorandum by the Faculty of Homeopathy

1. BACKGROUND

1.1 The Faculty of Homeopathy was incorporated by an Act of Parliament 1950 and represents statute-registered healthcare professionals who have trained in and integrate homeopathy into their practice. The majority of Faculty members are doctors (specialists working in the five NHS homeopathic hospitals, GPs or independent practitioners) though there are also growing numbers of nurses, pharmacists, dentists, podiatrists and vets.

1.2 Homeopathy is the only complementary therapy to have been part of the NHS since its inception in 1948. Today there are five NHS homeopathic hospitals—Bristol, Glasgow, Liverpool, London and Tunbridge Wells. These are consultant-led services, which take referrals from GPs and specialists and are staffed by doctors who have trained and qualified in homeopathy and other CAM (Complementary and Alternative Medicine) therapies such as acupuncture.

1.3 Clinical outcome studies from the hospitals consistently demonstrate a high level of patient satisfaction with patient-reported improvement rates of over 70 per cent even though many of the patients referred have not improved with the conventional treatment they have usually tried at length before coming to homeopathy.

2. THE HOMEOPATHIC TREATMENT OF ALLERGIES

2.1 Homeopathy

In homeopathy there are a number of therapeutic strategies for the treatment of allergic disorders. These are commonly termed “local”, “constitutional” or “miasmatic” strategies. Local prescribing is a strategy based on the patient’s actual allergic symptoms. The advantage of this strategy is that it can be achieved in a standard GP appointment or even through self-prescribing. Constitutional prescribing is based on a more in-depth consultation which takes into consideration the patient’s allergic symptoms and, additionally, their unique patterns of coping with any disease. Miasmatic prescribing is based on an elaboration of the patterns of allergic disease which can be seen to run through certain whole families. This approach can be particularly appropriate in complex allergic conditions.

2.2 Isopathy

Isopathy is similar to homeopathy but the main difference is that the treatment is selected solely on the basis of the patient’s proven allergies (as shown, for example, by skin testing). It involves giving a patient a substance to which they are allergic in a homeopathic potency, usually orally, for a short course of a few days in order to reduce the allergic response. All the common allergens such as pollens and dusts are available in potentised form from the specialist homeopathic pharmacies and it is also possible to have customised medicines made.

2.3 All of these approaches involve prescribing homeopathic or isopathic medicines which are safe, not addictive and have no side effects. However in some cases there may be a temporary worsening of symptoms immediately after the patient receives the treatment—the phenomenon known as “aggravation”. This does not entail any risk of anaphylactic shock. Treatment options are individually tailored and rely on sensitive history-taking and a flexible response by the practitioner, including careful consideration of diet and lifestyle.
3. **Why Patients Choose Homeopathy**

3.1 The homeopathic approach differs from conventional medicine in that rather than suppressing the allergic symptoms, the medicines stimulate the body’s ability to cope with exposure to the allergens. The benefits are therefore longer-lasting and free from the side effects associated with conventional treatments. A homeopathic medicine taken before the hay fever season begins can act prophylactically protecting the patient and so reducing the need for medicines such as antihistamines.

3.2 Many patients and doctors are concerned about the long-term use of conventional drugs such as corticosteroids and anti-histamines and for some patients a conventional approach has not helped so they seek more holistic advice and care.

4. **Specialist Allergy Services at the Homeopathic Hospitals**

4.1 All the NHS homeopathic hospitals receive referrals for patients with allergy problems. Glasgow and London have special allergy clinics.

4.2 *Glasgow Homeopathic Hospital, North Glasgow University Hospitals NHS Trust*

Dr Jacqueline M Mardon MBBS MPhil MRCGP MFHom

4.2.1 Allergy is a frequent reason for people to be referred to Glasgow Homeopathic Hospital by their medical practitioner. The Allergy Clinic has been running for many years and is funded as 26 clinical sessions/year. Originally set up on a research basis, it is currently run by one experienced medical practitioner who is on the Faculty of Homeopathy specialist register and who regularly attends conventional medical allergy seminars and updates.

4.2.2 Children and adults are accommodated in either a general out-patient clinic or, in particular if there is a strong indication of atopy or a complicated history such as anaphylaxis or multiple sensitivities, in the specialist allergy clinic. Sometimes a patient is referred elsewhere in the homeopathic service from the clinic, for example for in-patient care. A wide range of allergic conditions and morbidity is seen.

4.2.3 The clinical approach includes an emphasis on careful history taking and assessment may include skin-prick testing to a wide range of allergens, performed in the clinic. Treatment is with a variety of methods: homeopathic constitutional prescribing, symptom alleviation using homeopathic remedies and isopathy which can often be prophylactic or curative where specific allergens are identified. Advice about preventative measures and a supportive approach in complex cases in particular is also a mainstay of treatment.

4.2.4 Using this approach, one is able to address complex emotional issues which are so often involved (aetiologically and as a result of the disease). Patients often find it easier to accept advice about allergy from the homeopathic hospital, which can steer them away from the more extreme (and expensive) fringes of untested alternative treatments. This can be of particular benefit with food sensitivities and allergies or multiple sensitivities.

4.3 *Royal London Homeopathic Hospital, University College London NHS Trust*

Dr Saul Berkovitz MRCP MFHom MCPP

4.3.1 Allergy clinics at the RLHH are run by a consultant physician with a postgraduate diploma in Allergic Disease from the University of Southampton. There are three consultant sessions per week and two clinical assistant sessions. Classical allergic diseases are managed with avoidance advice, conventional treatment where appropriate, dietary advice, homeopathic medication, Western Herbal Medicine, and also (uniquely in the NHS) with a form of desensitisation treatment called enzyme-potentiated desensitisation (EPD). The clinic is also one of the very few centres able to effectively manage patients with “food intolerance” in all its manifestations.

4.3.2 EPD is a therapeutic technique in which low dose allergens (in concentrations of $10^{-12}$ molar, comparable to skin prick test doses) are injected intradermally to desensitise patients with atopic diseases. It was first introduced by McEwen in the early 1970s. Mixed allergens (inhalants, foods or both) are given intradermally after mixing with the enzyme beta-glucuronidase, which is thought to enhance the desensitising effect of the low dose allergen. Unlike conventional immunotherapy, EPD is an extremely safe technique, with a very low rate of anaphylaxis and other major adverse effects. Injections are given two- to three-monthly instead of weekly. Thousands of injections have been given at the RLHH over the last thirty years with no systemic allergic reactions. It is not used for IgE-mediated food allergy.
4.3.3 Several clinical trials involving small numbers of subjects, conducted mostly in Italy over the last two decades, suggested safety and effectiveness of EPD in hay fever and asthma and house dust mite allergy in children. The results in hay fever, however, were not confirmed by a larger clinical trial recently performed in the U.K. All the studies used the same mixture of inhaled allergens. Positive results using mixed food allergens have also been shown for childhood attention deficit disorder and childhood migraine. Despite the conflicting research evidence, many allergy patients continue to benefit from this treatment. It is hoped to demonstrate this with a program of prospective audit.

4.3.4 The clinic is fortunate to have a dietician who is expert in food allergy and intolerance, a rarity in such services. This enables patients to be treated who have adopted an unnecessarily restricted diet on the basis of spurious “food allergy tests” available on the high street, gradually broadening such diets, offering authoritative advice, checking nutritional status and advising on supplements. It is also possible to effectively manage conditions known to be variably improved by elimination dieting (including irritable bowel syndrome and rheumatoid arthritis) without compromising overall nutrition.

4.3.5 The Royal London Homeopathic Hospital hopes to expand its allergy services in the near future, with an increased emphasis on conventional as well as complementary management of allergy in order to provide a truly integrated service.

REFERENCES (not printed)

5. THE EVIDENCE BASE FOR HOMEOPATHY IN THE TREATMENT AND MANAGEMENT OF ALLERGIC CONDITIONS

5.1 Thirteen randomised controlled trials (RCTs) published in the peer-reviewed literature have studied the effect of homeopathy in allergic conditions. Clinical areas of investigation have been limited to seasonal allergic rhinitis (11 RCTs) and allergic asthma (two RCTs); 12 of them were placebo-controlled studies, the other was an equivalence trial.

5.2 Nine of these trials reported statistical analyses in favour of homeopathy, one found homeopathy to be inferior to placebo, and three observed no significant differences between patient groups. This overall positive conclusion from RCTs of homeopathy in allergy has support in the findings of six systematic reviews. Summary details of the nine RCTs with positive findings are listed below:

<table>
<thead>
<tr>
<th>Authors and Date</th>
<th>Main Results Reported in Publication</th>
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<tr>
<td>1 Aabel S, Laerum E, Dølvik S, Djupesland P (2000)</td>
<td>Verum group had fewer and less serious symptoms during a certain period of the birch pollen season. Single-day P values ranged from 0.41 to 0.02, ie for some days the differences between verum and placebo were statistically significant.</td>
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<td>2 Kim LS, Riedlinger JE, Baldwin CM, et al. (2005)</td>
<td>Significant positive changes from baseline to 4 weeks in the verum group compared with the placebo group (P = 0.032 for rhinoconjunctivitis symptoms, P = 0.031 for activity impairment, P = 0.04 for reported health transition).</td>
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<td>3 Reilly DT, Taylor MA (1985)</td>
<td>Maximum clinical improvement in verum group in weeks 3 and 4, with maximum statistical significance in week 3 (P = 0.002). Substantial reduction in average consumption of antihistamine tablets in verum group compared with placebo at that time.</td>
</tr>
<tr>
<td>4 Reilly DT, Taylor MA, McSharry C, Aitchison T (1986)</td>
<td>Mean change of VAS scores was –17.2 in verum group and –2.6 mm in placebo group (P = 0.02). Doctor-assessed scores showed similar reduction: –27.7 in verum group vs. –12.2 in placebo group (P = 0.05). Use of antihistamines lower in the verum group than in controls: total 11.2 cf. 19.7 tablets (P = 0.03).</td>
</tr>
<tr>
<td>5 Reilly D, Taylor MA, Beattie NGM, et al. (1994)</td>
<td>Difference in visual analogue score in favour of homeopathic immunotherapy appeared within one week of starting treatment and persisted for up to 8 weeks (P = 0.003). Similar trends in respiratory function and bronchial reactivity tests.</td>
</tr>
<tr>
<td>6 Taylor MA, Reilly D, Llewellyn-Jones RH, et al. (2000)</td>
<td>Homeopathy group had significant objective improvement in nasal airflow compared with placebo group (mean difference 19.8 l/min, 95 per cent CI 10.4 to 29.1 (P = 0.0001).</td>
</tr>
</tbody>
</table>
5.3 Evidence is also available from non-randomised studies that homeopathy can be an effective treatment in allergic conditions. An international, prospective, multi-centre study compared homeopathic treatment with conventional medical care in 456 patients with respiratory tract complaints including allergies. The primary outcome measure was the number of patients who were cured or had “major improvement” after 14 days of treatment; homeopathy was found to be at least as effective as conventional treatment. A similar study carried out in Germany on 178 children with mostly allergic conditions reported significantly greater improvement after homeopathic than conventional treatment. Large-scale clinical observational studies in primary or secondary care in Europe have indicated a high proportion of follow-up patients with allergic complaints achieve good outcome from homeopathy. A report from a single clinic in Israel showed that homeopathic intervention led to modest economic savings and reductions in the use of medicines commonly used to treat allergies and their complications. Finally, high dilutions of two homeopathic medicines used for the treatment of allergic diseases (Lung histamine and Apis mellifica) were observed to have a significant effect on human basophil degranulation in-vitro.

6. IS THE LEVEL OF UK RESEARCH ADEQUATE?

6.1 One of the arguments levelled against homeopathy is that its evidence base is weak. Problems with inappropriate study design and a lack of funds mean that there is strong but not unequivocal evidence to demonstrate the effectiveness of homeopathy in clinical trials and much more research is needed. Homeopathic medicines do not attract pharmaceutical funding because they cannot be patented and there is consequently very little financial impetus. Non-commercial funding is extremely limited and good research proposals often fall by the wayside due to lack of resources, often relying on small charities with an interest in CAM. This situation needs to be addressed.

6.2 The Science & Technology Committee’s report on CAM in 2000 recommended the creation of a stronger research infrastructure for CAM and the DH allocated limited funds. None of these has been directed towards research into the homeopathic treatment of allergies.

6.3 The homeopathic approach has much to offer but at present is limited to a smaller number of centres of excellence and individual practitioners. A great opportunity is being missed, particularly in view of the potential for savings on allopathic medicines with potentially serious side-effects, such as corticosteroids.

7. MOST PROMISING AREAS OF RESEARCH INTO PREVENTING OR TREATING ALLERGY

7.1 Research is needed to confirm unequivocally whether specific homeopathic medicines are more effective than placebo in the treatment of particular allergic conditions. It is also important to demonstrate convincingly with further pragmatic RCTs that homeopathy has clinical effectiveness at least as good as conventional medical care. Since the mechanism of homeopathy’s in-vivo effects remains to be elucidated, the study of allergy...
might afford an opportunity for hypothesis-driven clinical research in this area: it has been proposed, for example, that homeopathy may help to regulate the Th1/Th2 lymphocyte imbalance that characterises allergic disorders.

REFERENCES [not printed]

Memorandum by Dr Nigel J N Harper, Royal College of Anaesthetists

ANAPHYLACTIC REACTIONS OCCURRING DURING ANAESTHESIA

BACKGROUND

Severe anaesthetic anaphylaxis is relatively uncommon. The incidence in the UK is not known accurately. The true incidence probably lies between 1:10,000 and 1:20,000 anaesthetics. Approximately 5 million anaesthetics are administered per annum in the UK for a wide variety of healthcare procedures including major surgery, childbirth and radiological imaging. Many individuals require repeated anaesthetics.

Modern anaesthesia takes advantage of the specific attributes of several different drugs, each administered for a specific purpose. Thus, a typical anaesthetic may comprise an induction drug, a maintenance drug, a potent analgesic, a muscle relaxant drug, an anti-emetic drug, reversal agents and synthetic intravenous fluids. In addition, the surgical procedure may necessitate the administration of antibiotics, radiological contrast agents and drugs which manipulate blood coagulation. All these drugs are administered in large doses, directly into the circulation and are capable of eliciting life-threatening anaphylaxis. The anaesthetic environment also includes latex and skin-antiseptics which may precipitate anaphylaxis during anaesthesia. The severity of anaesthetic anaphylaxis varies from the appearance of a rash, a moderate fall in blood pressure or the onset of treatable wheeze, to catastrophic hypotension, intractable bronchospasm, and cardiac arrest.

The majority of these reactions are not fatal but there are approximately 5-10 deaths per annum. A considerably larger number of patients suffer with a range of permanent disabilities as a result of cerebral or cardiac hypoxia during the anaphylactic reaction, for example; poor memory, loss of balance, poor spatial awareness and permanent cardiac damage.

The incidence of anaesthetic anaphylaxis appears to be increasing in line with the general increase in allergy. Previous exposure to the culprit anaesthetic drug is not a pre-requisite for anaesthetic anaphylaxis. Components of the molecular structure of many drugs given during anaesthesia are found in everyday life, for example in detergents, cosmetics or cough medicines. There is considerable cross-sensitivity between some anaesthetic drugs, especially muscle relaxant drugs. Following a relatively minor anaphylactic reaction, a second exposure may be life-threatening.

Although the incidence of proven anaesthetic anaphylaxis is approximately only 1:10-20,000, many more patients require investigation because the clinical signs of anaesthetic anaphylaxis can be imitated by more common and benign events. For example, a significant fall in blood pressure may be the result of the interaction between the hypotensive effect of the anaesthetic induction agent and long-term anti-hypertensive medication. Severe wheeze during anaesthesia may be the consequence of the mechanical effects of tracheal intubation in a patient with irritable airways through asthma or heavy smoking. Most anaesthetists would see these events several times a year. The consequences of not investigating these phenomena may be serious. If these clinical events were, indeed, caused by allergic anaphylaxis, it is likely that future exposure to the anaesthetic drug, or an anaesthetic drug with a similar molecular structure, would endanger the patient’s life. A recent case in law emphasised the responsibility of the anaesthetist to refer this group of patients for expert investigation and diagnosis (Eastwood v Wright 2005).

ISSUES

It is important that every case of suspected anaesthetic anaphylaxis is investigated by an expert team to:

(a) Identify the causative agent so that it can be avoided in future.
(b) Establish whether there is cross-sensitivity with other drugs.
(c) Enable recommendations to be made concerning future anaesthesia on an individual patient basis.
(d) Gather data concerning the patterns of allergy to individual drugs (a worthwhile report to the Medicines Control Agency can be made only when the causative agent has been established).
(e) Establish whether certain factors predispose to anaesthetic anaphylaxis.

(f) Identify optimal resuscitation management protocols.

The expertise required for investigation anaesthetic anaphylaxis is required in a relatively small number of centres in the UK, but that expertise should be readily available to all patients. A number of immunologists, allergists and anaesthetists have expertise in the investigation of anaesthetic anaphylaxis. A high proportion of patients are required to travel long distances to their nearest specialist clinic, and waiting times are long. It is not unusual for a patient to have to travel 30 miles. Many cases of anaesthetic anaphylaxis are not referred for immediate investigation.

Because of the complexities of modern anaesthesia it is necessary for patients to be seen by an anaesthetist with a special interest in anaphylaxis at the same time as seeing an immunologist or allergist. The author started the first combined anaesthesia and immunology clinic in the UK in Manchester in 1997 but expansion of bi-specialty clinics has been relatively slow and, currently, there are only 3 similar combined clinics. There are approximately six additional uni-specialty clinics in which patients are seen only by an immunologist or allergist. Nevertheless, progress has been made and The Association of Anaesthetists of Great Britain and Ireland (AAGBI) has set up a working group to update its 2003 publication “Suspected Anaphylactic reactions Associated with Anaesthesia” in collaboration with the British Society of Allergy and Clinical Immunology and The Royal College of Anaesthetists. These bodies will shortly announce a national database for anaesthetic anaphylaxis, with on-line reporting. The Royal College of Anaesthetists runs an educational programme on anaesthetic anaphylaxis. Focused resources are needed to expand the number of bi-specialty clinics for the investigation of anaesthetic anaphylaxis.

Memorandum by the Latex Allergy Support Group

BACKGROUND

1. The UK Latex Allergy Support Group (LASG) is a voluntary self-help organisation founded in 1996, with 300+ members. The aims of the Group are to raise awareness of latex allergy, provide support for those affected, and promote the safe and appropriate use of latex products and equipment. An advisory panel provides advice on medical and technological issues.

2. Allergy to natural rubber latex (NRL) was first described in 1979 and, as with other allergies related to an underlying atopic susceptibility, the past 15 years has seen its recognition as a health issue of increasing importance. Latex allergy is thought to affect less than 1 per cent of the general population, although it is commoner in certain groups who are regularly exposed to latex such as healthcare workers from widespread use of protective gloves, and most notably patients with spina bifida who have been exposed to NRL gloves and catheters.

3. Latex allergy is a reaction to the constituent proteins of NRL and is an example of an “immediate” Type I IgE-associated reaction, where symptoms generally appear within minutes of exposure. This is quite different from allergy to chemicals used in the manufacture of rubber, which is a “delayed” Type IV hypersensitivity reaction taking some hours or days to manifest clinically. These two quite separate conditions are often confused by the public, and also by healthcare staff. Similar confusion often exists between “glove allergy” (which is usually a non-immunological irritant reaction) and latex allergy.

4. The clinical effects of latex allergy are similar to those from peanut allergy in that most will have relatively mild local reactions, some will have more troublesome local and respiratory problems and a few will be at risk of potentially fatal anaphylactic reactions. It is not possible at present to predict which individuals may progress from mild reactions to anaphylaxis, or when a more severe reaction may occur. The greatest potential danger to an allergic individual comes from mucosal contact (surgical/medical/dental/obstetric gloves must be avoided) or from inhalation of latex (carried in the air by powder from glove or balloon). Patients presenting with anaphylactic reactions during surgery or with occupational asthma may be found on subsequent investigation to be latex allergic.

5. A diagnosis of latex allergy may have profound consequences for the patient from worry about the ubiquitous nature of NRL in the environment together with its potential for serious reaction. In addition, proper investigation of latex allergy is itself not without hazard. It is therefore important that patients with suspected latex allergy are referred to appropriately trained practitioners for accurate confirmation of the diagnosis (or equally important exclusion of this) and sound advice to be given, generally by an allergist, dermatologist or other clinician with a sub-speciality interest.
6. There is an overlap between NRL (a plant product) allergy and food (usually fresh fruit) allergy due to common / cross-reacting antigens. An allergic reaction to banana, kiwi or avocado (for example) may be the first clinical presentation of a previously undiagnosed latex allergy.

**Quality of Life**

7. Although there is an extensive published literature on latex allergy, there has been surprisingly little investigation into the impact of this condition on Health Related Quality of Life (HRQoL). Two surveys have been conducted in the UK.

8. The first study of 50 latex-allergic adults from Wales showed that some had experienced severe impairment of HRQoL as a result of their NRL allergy. Twenty five per cent required to change the nature of their work as a direct result of their allergy, this varying from transfer to a “latex-safer” environment within healthcare to the necessity for full career change. Thirty three per cent experienced difficulties when visiting doctor or dentist, such as having to explain necessary precautions or supplying their own latex-free gloves.

9. A further specific latex allergy HRQoL questionnaire survey of 153 adult LASG members showed that the highest scoring questions (ie having most impact on QoL) related to worry, mood and situations where latex avoidance could be problematic. Eighteen per cent were not working and 25 per cent had required to change jobs because of their latex allergy.

10. The same survey of 28 child LASG members showed that their highest scoring questions related to restriction of diet, play and sports, whereas for their parents worry about possible anaphylaxis or other severe physical reactions to latex had the most impact on QoL. Nine children had experienced difficulty at school because of their latex allergy.

11. The employment difficulties reported above contrast with studies from other countries where affected individuals have been accommodated more easily, suggesting that with careful case management the effects on employment can be mitigated. This perhaps reflects a lack of support from or understanding of latex allergy by UK employers or line managers.

**Healthcare**

12. Visits to healthcare settings are a major concern for patients with latex allergy because of the widespread presence of NRL (mainly gloves) together with frequently reported lack of healthcare staff knowledge or understanding of this condition. In the survey of 153 LASG adult members mentioned above, 80 per cent reported reactions to NRL-containing medical equipment, 60 per cent had experienced at least “some difficulty” in obtaining medical and/or dental care due to their latex allergy, and only 5 per cent were confident that they would be cared for in a latex-safe environment if they were to be admitted to hospital.

13. NRL is a hazardous substance for the purposes of the Control of Substances Hazardous to Health (COSHH) Regulations 2002, and healthcare organisations are expected to have in place robust policies, both to minimise the development of latex allergy in the workforce, and also to provide a latex-safe environment for allergic patients and staff. The UK Health and Safety Executive (HSE) have a web-site on latex allergy aimed at healthcare employers and employees which explains about latex allergy and how staff and patients may be protected http://www.hse.gov.uk/latex/index.htm


   (a) local organisations should ensure that they have a comprehensive working policy on the use and purchasing of latex products, supported by efficient management arrangements (only 60 per cent had such a policy at the time of the survey—although this had risen to 85 per cent by 2006, continuing frequent reported incidents relating to communication and documentation suggest lack of education and/or enforcement).

   (b) products and packaging containing latex need to be easily identifiable—labelling and catalogue descriptions need to be unambiguous and clear (identification of latex content of medical equipment continues to be a problem and there is at present no European latex symbol for industry to adopt).

   (c) there is a need for greater choice of effective and cost-effective latex-free products and equipment—this remains a concern for many NHS purchasers and managers.
15. Natural rubber latex has many positive attributes. Comfort, strength, biological protection and low cost have made latex gloves the standard choice for use within healthcare. Recognition of the problem with latex allergy has led manufacturers to reduce protein content and remove powder from medical gloves, although it is not yet possible to completely remove all NRL allergens.

16. Although reduction in NRL allergen content of medical gloves appears to have substantially reduced the number of healthcare staff acquiring latex allergy, the need remains to provide a safe environment within healthcare for those who are already allergic, a few of whom react to even tiny amounts of NRL in the environment. The recent NPSA survey and ongoing reports of adverse incidents show that there is still much to do to safeguard affected individuals.

17. Non-latex (synthetic) gloves are now readily available for allergic staff and patients, and advances in technology are making these a viable alternative to latex gloves for all staff. Some healthcare establishments have already effected such a change, although concern has been expressed in some quarters on issues relating to synthetic glove supply, degree of protection and potential for adverse reaction.

18. The Partnership Support Unit of the Scottish Executive Health Department released a document in 2005 giving guidance on glove choice for staff working in NHS Scotland. This advised that latex gloves may continue to be used when justified by risk assessment, but that unnecessary routine use of latex gloves should be identified and discouraged.

19. Otherwise within the UK, there has been no clear agreement or guidance on whether healthcare organisations should:

(a) continue with routine use of latex gloves, except for those who are already sensitised or allergic, because their benefits outweigh the risk of causing allergic reactions; or

(b) eliminate the risk of latex allergy by switching to synthetic gloves, considering the allergy risk to be greater than the risk of blood-borne virus infection or synthetic glove reaction

This decision has been left up to each individual healthcare organisation to make. LASG feels that this is unsatisfactory, and that clearer advice on this issue should be provided at national level, and be subject to regular review in the light of ongoing experience and technological advances.

20. A further issue within healthcare relates to the use of NRL in the manufacture and presentation of medicines, eg rubber vial stoppers. Sourcing information of NRL content and latex-free alternatives (eg vaccines) can be problematic. An accurate and up-to-date national database would assist healthcare staff in safe choice of medication for patients with NRL allergy.

Balloons

21. Another significant concern for individuals with latex allergy is NRL balloons. In a recent LASG survey of 109 members (83 adults, 26 parents of children), 21 had required to use adrenaline following exposure to these. Sixty nine had experienced symptoms just from being in an enclosed area containing balloons and 81 said that their presence restricted access to public premises, from which 90 thought that balloons should be banned. Although scientific evidence is lacking on this issue, LASG has recently petitioned the European Commission to examine balloon safety, ways of improving this and to look at the question of labelling.

22. In 1998, The Medical Devices Agency (MDA) issued a Safety Notice informing healthcare organisations of the increased risk of allergy from powdered latex gloves, and these were subsequently removed from national contract two years later. As NRL balloons are also powdered, it does not make sense for healthcare organisations to permit these on their premises (eg for displays), having already removed powdered gloves for safety reasons. Some hospitals have taken steps to meet COSHH regulations and ban NRL balloons, although not many to our knowledge.

Other Issues

23. There is a dearth of available data, but anecdotal evidence suggests that latex gloves are widely used out-with the healthcare setting, for example in garages, restaurants and hairdressing salons. We do not know how allergenic these gloves are, but the need to minimise costs is likely to mean that many are cheap, powdered and highly allergenic. If this is the case, the gloves will be a risk both for those who wear them (from developing allergy) and also for their customers (eg from transfer of latex allergens to car interior or food). It is possible that widespread use of highly allergenic gloves in such occupations will produce a similar outbreak of overt allergy that has already been encountered in healthcare, and further study is required.
The Health and Safety Executive have recently produced a web-site aimed at hairdressers, entitled “Let’s cut out dermatitis” (70 per cent hairdressers suffer from this skin condition) http://www.hse.gov.uk/hairdressing/index.htm.

Non-latex gloves are specifically recommended by HSE, and LASG would welcome similar guidance to be issued to catering and automobile industries.

24. Similar concerns exist for latex glove use in care homes, where controls may be laxer than is the case within hospitals. In addition, there is some evidence that powdered latex gloves may commonly be used in schools for eg science, home economics and waste recycling, thus unnecessarily exposing substantial numbers of atopic children to NRL on a regular basis. Again, further study is required.

25. Although the Industrial Injuries Advisory Council recommended in 2003 that NRL be added to the list of prescribed causes of occupational rhinitis, that NRL be recognised as a cause of occupational asthma, and that anaphylaxis resulting from NRL allergy in healthcare workers be considered as a prescribed disease, there still appear to be difficulties for patients obtaining benefits or compensation for occupationally induced latex allergy.

Diagnosis and Information

26. Investigation and management of patients with suspected latex allergy can be time-consuming. Lack of trained personnel and competing demands on time in specialist clinics will inevitably compromise optimal management for some. A recent survey of 202 UK dermatology and allergy consultants who investigate for NRL allergy http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD= search&DB= pubmed showed substantial variation in diagnostic procedures, pointing to a need for robust guidance to assist more consistent practice across the country. Furthermore, patients referred with suspected latex allergy may subsequently be found to have rubber chemical allergy (see paragraph 3), and investigating physicians must have knowledge of and access to appropriate investigation for each condition.

27. The same survey showed that provision of basic information to help allergic patients cope with what can sometimes be a very daunting prospect is neither standard nor consistent. LASG has produced both basic http://www.hse.gov.uk/latex/pdf/patientinfosheet.pdf and comprehensive http://www.bad.org.uk/public/leaflets/bad_patient_information_gateway_leaflets/latex/index.asp web-based patient information for hospital departments, although it is not clear how accessible this is for the general public.

28. Nearly 30 years on, there remains much confusion and misinformation about latex allergy.

LASG sees the education of all healthcare staff, managers, employers and the general public as absolutely central to addressing this issue.

We would welcome investment in key trained personnel in order to deliver and maintain the correct information, education and advice that is required throughout the country.

31 January 2007

Memorandum by the Patent Office

Executive Summary

The Patent Office is responsible for the administration of intellectual property rights. In addition, as part of the DTI Science and Innovation Group we are committed to playing an important role in supporting innovation in the UK. We are pleased therefore to support the House of Lord’s Select Committee on Science and Technology enquiry into allergic disease in the UK. Patenting is a key marker of innovative activity. In the following report we have endeavoured to provide information in the context of six of the questions outlined in the Call for Evidence:\footnote{http://www.parliament.uk/parliamentary—committees/lords_s_t__select/allergies.cfm}

— What is allergy?
— What is the difference between allergy and intolerance?
— What is and what is not known about the origins and progression of allergic disease?
— Treatment and management?
— What is the evidence-base for pharmacological and non-pharmacological management strategies?
— Is the level of UK research into allergy and allergic disease adequate?
— What are the most promising areas of research into preventing or treating allergy?

A detailed analysis of patent information in a database containing patent records from all major industrialised countries was conducted. The report shows:

— Chronological filing trends by country.
— Trends in particular technologies, for example organic compounds, biotechnology and foodstuffs—globally, chronologically and by country.
— The top 10 companies world-wide and top 10 UK organisations ranked by their patent activity.
— An analysis of the top 50 inventors filing at the UK Patent Office, their associated organisation and the relationships between those organisations.

A significant body of world-wide patent filings on allergy derives from UK based pharmaceutical companies. The majority of this UK patent activity is on classical heterocyclic chemical pharmaceuticals. Whilst a number of UK organisations show innovative activity in the biotechnological aspects of the treatment of allergy, this area is less extensive than classical organic chemistry.

1. Introduction

Reference to “patents” relates to both patent applications and granted patents unless otherwise indicated. For this study the European Patent Office (EPO) database EPODOC was used which encompasses published patent documents derived from the majority of leading industrialised countries and patent organisations, for example the World Intellectual Property Organisation, EPO and the African Regional Industry Property Organisation (ARIPO). This report includes data in the period from 1996 up to and including 2005. However, it is pointed out that the apparent down-turn in 2005 may be due to the incompleteness of the database. Since patents are usually published eighteen months after filing, the data reflects the time when the information became available rather than when the research was carried out.

The Patent Office is currently trialling patent information analysis software, supplied by Thomson Scientific™. The two pieces of software used to generate the data presented in this report are Thomson Data Analyser (TDA) and Aureka™.

2. What is Allergy?

Question 1

Our study was based on a broad definition of allergy as “an inappropriate or exaggerated immunological response of the body to a substance”. The International Patent Classification system (IPC) now provides six “marks” specifically catering for allergy: allergens and pollen allergens, anti-allergic agents, antiasthmatics, antipsoriatics and ophthalmic antiallergics.

2.1 What is the difference between allergy and intolerance?

We considered intolerance to relate to “a defect in the processing of substances within the body, particularly gastro-intestinally” which is distinguished from allergy because it does not necessarily require the significant involvement of the immune system. Food intolerances are often caused by enzymatic deficiencies. Patents relating to food intolerance enzymes and medicines that promote digestion also have specific marks in both international and domestic classification systems.

Immunological intolerance is the physiological status quo relating to foreign material and characterised by a normal immune response. In this respect allergy is distinguished from immunological intolerance by the magnitude and often acute level of response. Both domestic and international classification systems provide marks for the identification of immunosuppressants and immunostimulants.

3. What is and What is not Known about the Origins and Progressions of Allergic Disease?

Question 2

There is a wealth of patent information on allergy. Nearly thirty thousand patents were identified. Over one third of these have been published in the last five years (Figure 1). In common with journal articles, individual patents are likely to outline and discuss contemporary theories surrounding a disease. The relative increase in patent filings in allergy this century reflects an overall trend in the patent activity in the area of biotechnology,
pharmaceuticals and organic chemistry in general. This expansion of patent activity may to some extent reflect the increase in knowledge about underlying disease mechanisms as well as corporate intellectual property strategies.

**Figure 1**

*Figure 1: Chronological trends in patent records relating to allergy*

**Figure 2: Chronological trends in patent records in biotechnology, pharmaceuticals and organic chemistry*
4. Treatment and Management

Question 6

There is a lag time between patent filings and time taken to get to market for therapeutic products. Nonetheless, a range of therapeutic strategies can be identified in a variety of patent classification areas: organic compounds, particularly nitrogen-containing heterocyclic compounds, recombinant genetic technology and antibody engineering (Figure 3).

Clearly the most prominent area of patent activity is in nitrogen-containing heterocyclic organic molecules. Within the biotechnology area, particularly notable is that the European Patent Office classification scheme provides a specific term for antibodies against IgE indicating a significant level of patent activity in the area of limiting the allergic response by engineering antibodies (anti-idiotypic antibodies) against IgE. The other biotechnological area showing significant activity is in T-cell receptor-based inventions and the engineering of proteins making up that receptor or associated with it.

Strategies for diagnosis appear in genetic-based testing and immunoassays and these can also provide information about disease mechanisms. About 6 per cent of patents on allergy are concerned with genetic diagnostics and a similar number with immunoassays.

Figure 3: Distribution of patent documents by technology term

5. Evidence-base for Pharmacological and Non-pharmacological Management Strategies

Clearly the abundance of patent information relates to pharmaceuticals and the majority of these are organic compounds. About 4 per cent of allergy-associated patents are found in the area of food modification. Direct genetic engineering based therapies comprise a small number, less than 30, of the overall therapeutic patents; notably half of these have published in the last five years.
6. **Is the Level of UK Research into Allergy and Allergic Disease Adequate?**

UK-based companies GlaxoSmithKline™ and Pfizer™ rank first and third, respectively, in terms of the number of patents on allergy worldwide in the last 10 years (See Figure 4).

![Figure 4: World-wide patent activities in allergy by organisation](image)

6.1 *Global patent activity in allergy*

Looking at the country distribution of the gross number of patent records in the last five years it is apparent that the UK ranks third behind America and Japan\(^\text{67}\) (see Figure 5).

A comparison of the number of patent filings over the last five years measured against Gross Domestic Product in 2005 shows that the UK falls lower than Japan and the USA but is ahead of Germany (Table 1). Other European countries were not considered here because it is likely that organisations in these countries do not predominantly file directly in the country of origin but instead make first filings at the European Patent Office.

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<th>Country</th>
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\(^{67}\) The data was extracted from priority patent filings—that is the country where the first patent filing was made as an indicator of filing in that country. In extracting this data European Patent designations were not counted.

\(^{68}\) World Bank- World Development Indicators Database, 1 July 2006.
6.2 Technology activity across the globe

A more detailed analysis of national activity by technology area is given in Figure 6. This plot indicates that the relative level of patent activity in the main technology areas for the UK is similar to US and Japan.
6.3 UK patent activity on allergy

An assessment of activity within the UK was conducted. The top 50 companies and top 50 inventors appearing on GB patent specifications were analysed (Annexes 1 to 3) (most of the inventors are based in the UK but where a company has an overseas location, ie USA, some of the inventors are based in that country).

Two universities, University of Southampton and the University of Oxford (ISIS Innovations) which include spin-off organisations from them rank among the top 10 UK-based organisations filing in the field of allergy. Seventeen UK Universities/Medical Schools have filed at least one patent application on allergy. Of the top fifty organisations twenty have collaborated on patent filings.

### Top 10 Organisations Filing UK Patent Applications in Allergy

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<td>Isis InnovationTM</td>
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</table>

7. What are the Most Promising Areas of Research into Preventing or Treating Allergy?

**Question 10)**

A chronological analysis of technology terms (Figure 7) indicates that, whilst patent activity in pharmaceuticals and heterocyclic organic compounds continued to rise this century, activity in biotechnology appears to have slightly decreased. However, this could in part be due to changes in filing strategies by biotechnology organisations. Nevertheless biotechnology patent activity is higher than it was 10 years ago. Patenting in the area of non-cyclic organic therapeutic compounds appears to be relatively flat.
7.1 Top 50 Inventors filing in UK; their relationship with companies and field of activity

To gain an insight into current patent activity two strategies were used:

(i) analysis of 10 most cited patent applications; and
(ii) analysis of the top fifty inventors filing patents in UK and to group these with their corresponding companies (Annexes 1 to 4).

The 10 most cited patents all concern nitrogen-containing heterocyclic compounds. Analysis of the most recent patent filings from each company (see Annex 1) revealed a more diverse spread of activity within three main areas: (a) heterocyclic organic compounds; (b) biotechnology and (c) environmental allergen deactivation.

7.1.1 Nitrogen containing heterocyclic compounds

The most abundant patent filings by GSK™, Merck™, Pfizer™, Novartis™, AstraZeneca™ and CellTech™ all concerned nitrogen-containing heterocyclic compounds:

— Knowles et al and Jones et al (GSK) phosphodiesterase inhibitors;
— Macoss et al (Merck)—tachykinin receptor antagonists;
— Lethwaite et al (Pfizer)—bronchodilatory β2agonists;
— Warrellow et al (CellTech)—anti-inflammatotary phosphodiesterase inhibitors;
— Danahay et al (Novartis)—synergistic anti-asthmaic compounds; and
— Stocks et al and Baxter (AstraZeneca)—modulation of chemokines (interleukins and chemoattractants) with pyrazinyl phenylsulphonamides.
7.1.2 Biotechnology-based inventions

- Ames et al (GSK)—recombinant peptides as therapeutic agents; Wheeler et al (also Allergy Therapeutics Ltd)—the surface modification of allergens;
- GSK and Peptide Therapeutics collaborated on engineering protein vaccines (mimitopes) to neutralise IgE antibodies;
- Moffat et al (ISIS)—recombinant proteins associated with IgE–mediated atopic disorders; and
- Lamb et al (Lorantis)—modification of T cell interactions via cell signalling proteins (Notch) ligands.

7.1.3 Allergen deactivation

The Reckitt BenckiserTM/University of Southampton collaboration produced patent applications on the deactivation of dust mite allergens with dispersable deactivants such as terpene hydrocarbon oils.

8. Conclusions

There is an abundance of world-wide patent information relating to allergy. The main findings of this report are:

1. Patent trends in allergy mirror those of the biotechnology and pharmaceutical sectors.
2. GDP indicators suggest the level of patent activity in the UK is less than in the USA or Japan but at least as strong as Germany.
3. There is a substantial body of patent information emanating from the UK on classical organo-chemical pharmaceuticals relating to allergy. There are several UK institutions generating patent filings in biotechnology but the level of innovation is not as extensive as for classical organo-chemical pharmaceuticals.
4. UK private sector companies make a significant contribution to the patent landscape on allergy. Two UK university entities rank in the top 10 UK organisations in the field of allergy.
5. Patent databases provide the opportunity to perform a detailed analysis of the information and patent trends relating to particular molecules in the molecular pathways involved in the allergic response and also about particular companies and individuals involved in this area.
At least one inventor in each cluster is based in the UK. Where a company has an overseas location, ie USA, some of the inventors shown may reside in that country. The number of patents is indicated by the size of the dot. The bold lines indicate over 75 per cent collaboration. Dotted lines indicate less than 25 per cent collaboration.
Annex 2

UK-based companies or companies collaborating with UK-based companies
The number of patents is indicated by the size of the dot. Bold lines indicate over 75 per cent collaboration. Dotted lines indicate less than 25 per cent collaboration.

### Annex 3

**NUMBER OF PATENT RECORDS FOR TOP UK-BASED COMPANIES OR COMPANIES COLLABORATING WITH UK-BASED COMPANIES**

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ANNEX 4

NUMBER OF PATENT RECORDS FOR TOP UK-BASED INVENTORS OR INVENTORS COLLABORATING WITH UK-BASED INVENTORS

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Memorandum by Research Councils UK

Key Points

1. Allergy is driven by immune mechanisms that range from acute (short-term) responses that can be potentially fatal to chronic (long-term) diseases such as asthma, eczema and rhino-conjunctivitis. The high prevalence and morbidity associated with these long-term illnesses can inflict a poor quality of life on sufferers and a high burden to the economy and the health service.

2. RCUK’s major contribution to research into allergy comes in the form of grant funding provided by the MRC and the Biotechnology and Biological Sciences Research Council (BBSRC). The MRC currently invests £5.14 million pa on research and training into allergy and the BBSRC £1.6 million pa. BBSRC also invests in allergy research via the Institute of Food Research.

3. In the UK, research into the underlying mechanisms of allergy and allergic disease is restricted to a few centres, but most of these groups are world-leaders in their field. Therefore, whilst research in this area needs to be encouraged, the existing researchers are of high international standing and the research funded is of excellent quality.

4. In 2004, the MRC carried out an analysis of its respiratory research portfolio. It concluded that its research spend on respiratory diseases, including asthma, was low in relation to morbidity. The MRC identified respiratory research as a strategically important priority. As a result of this, and through partnering relevant charities, the MRC has markedly increased its funding of research in this area from 6 awards (£0.5 million pa) to 15 awards (£2.0 million pa). Notwithstanding this, the UK Clinical Research Collaboration (UKCRC) subsequently identified that the research spend from all funding bodies on respiratory diseases, including asthma, is low in relation to morbidity.

5. MRC believes that working with partners will help tackle the broad challenges posed by allergic diseases. In addition to the collaborations with charities, the MRC has created partnerships with Universities in Edinburgh, London and Birmingham, to create Centres of research excellence into the allergic mechanisms of disease, inflammation and associated immunological processes.

Defining the Problem

6. The incidence of allergy in the UK is high and increasing, for example, more peanut hyper-sensitivity cases have been reported in the UK suggesting that peanut allergy is becoming more prevalent. Chronic allergic disease is now common, affecting 20 per cent of households in the UK. Effective treatments for allergy are few and can be toxic. This is a driver for an increased research effort which the RCUK has responded to through major investments in UK research.

7. From the patient’s perspective, allergy embraces conditions such as rapid sneezing, itching, rash, shortness of breath, and in its most extreme form, anaphylactic shock, which can be fatal if not treated quickly. From a research perspective, the term allergy is used to describe a hypersensitivity that results from altered or heightened reactivity of the immune system in response to external or “foreign” substances. These foreign substances are called allergens and examples include grass pollen, weed and tree pollens, house dust mites, fungal spores, animal proteins, certain foods (eg peanuts) and chemicals.

8. Allergens enter the body where they may come into contact with certain types of white blood cells known as mast cells and basophils. The allergen binds to a molecule on these cells known as IgE. Binding of IgE on these cells causes them to release histamine and other chemicals stored within the cell. These other chemicals, known as cytokines and chemokines, attract other types of white blood cells known as leukocytes to the area. The activation of these leukocytes, together with the initial activation of mast cells and basophils, is known as the inflammatory response and this produces marked changes in the muscles and blood vessels in the affected area. It is this response that produces the characteristic symptoms associated with an allergic response.

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69 Allergens enter the body by inhalation, injection or through contact with food. They bind to specific IgE which itself is bound to high affinity receptors (FcsR1) on the surface of mast cells and basophils. There also exists a low affinity IgE receptor (FcER2) but its role is unknown.

70 Symptoms differ depending upon the target tissue eg in asthma—contraction of smooth muscle causes bronchoconstriction and wheezing. In allergic rhinitis—nerve stimulation, vascular swelling and mucus secretion cause sneezing, rhinorrhoea and nasal obstruction. In anaphylaxis, systemic activation of mast cells and basophils causes massive release of mediators into the circulation leading to cardiovascular failure.
9. Coupled with this rapid response is the more, long-term, activation of a different white blood cell known as the T helper 2 (Th2) cells. The activation of Th2 cells directs the production of more IgE molecules, produces more cytokines and chemokines and so attracts more leukocytes.\footnote{Th2 lymphocytes initiate isotype switching of B lymphocytes to IgE synthesis, augmenting recruitment of secondary leukocytes such as eosinophils through the secretion of specific cytokines eg interleukins (IL) – 4, – 5, – 13 and GM-CSF and chemokines eg the eotaxins and RANTES.} This chronic response is important in orchestrating the immune system in allergic disease. Continued activation contributes to the persistent symptoms of allergy, for example, persistent airflow obstruction, that requires regular anti-inflammatory treatment often with corticosteroids. Chronic inflammatory conditions are of most concern as they can impose on sufferers a low quality of life, a high burden on the Health Service and a heavy economic impact due to working days lost.

10. There are also conditions caused by external substances that stimulate the immune system and Th2 cells without involving IgE-dependent cell activation. Examples include some forms of drug allergy, occupational asthma and some types of dermatitis. The mechanisms of Th2 cell activation in these diseases are unknown. Some forms of sensitisation, for example, contact dermatitis, involve a different type of immune response known as the delayed-type hypersensitivity response.

11. Finally, there are also conditions caused by external factors such as foodstuffs which are not mediated by known immunological pathways and are often referred to as intolerances; these include disorders such as Irritable Bowel Syndrome and migraine. There are also conditions that are confusingly described as “allergic”, for example Attention Deficit Hyperactivity Disorder, chronic fatigue syndrome (CFS, ME) and multiple chemical sensitivity syndrome, where the evidence for an allergic basis is weak.

12. In summary, from a research point of view, an allergic response can be distinguished from intolerance as having its basis in an immunological process involving Th2 cell and (usually) IgE activation. Through complex pathways and mechanisms, this can lead to a specific type of chronic inflammatory response. Scientists supported by RCUK are working hard to discover the mechanisms by which the immune system is activated. This includes studies of Th2 cells, mast cells and the chemicals these cells release. Also, why the resulting inflammation can in some cases continue indefinitely leading to chronic and debilitating disease. The current state of allergy research might be broadly described as extensive knowledge about the underlying mechanisms of the complex pathways that lead to disease, but as yet too few effective therapies. This is why a focus of MRC research strategy is currently to translate basic research knowledge into the development of new prophylactics and cures.

THE BBSRC’S CONTRIBUTION TO RESEARCH INTO ALLERGY AND INFLAMMATION

13. The Biotechnology and Biological Sciences Research Council (BBSRC) funds work on allergy through studies on basic immunology and on food allergies at the Institute of Food Research. Six relevant projects funded at BBSRC-supported Institutes in 2005–06, cost £672,935 and in 2006–07, £741,859 was invested in three projects. The Institute of Food Research will be making a separate submission to the House of Lords Select Committee.

14. The BBSRC also currently funds University-based research totalling £193,828, as well as four studentships, for research training directly relevant to the study of allergy. In addition, both BBSRC and MRC support a significant amount of research on basic immunology which may be relevant to the mechanisms underlying allergic responses.

THE ESRC’S CONTRIBUTION TO RESEARCH INTO ALLERGY AND INFLAMMATION

15. The Economic and Social Research Council (ESRC) is the UK’s leading research funding and training agency addressing economic and social concerns. We have an international reputation both for providing high-quality research on issues of importance to business, the public sector and government and for our commitment to training excellence, which produces world-class social scientists.

16. The ESRC’s funding of research into allergy is less central to our strategic objectives than some other Research Councils. However, we do fund research addressing an as yet largely un-explored area of the social implications and consequences of the rise in allergies, in particular focusing on food allergies and food intolerance. Very little is known about how lay and professional people define or explain food allergies and intolerance, how people live with them, or how those who cater for people’s food and health needs in a variety of institutional settings manage this growing challenge.
17. In addition, the ESRC funds a wider range of research relevant to the area including research on the social contexts of risk and individual and social responses to risk, genomics and genomic identity, the environment and public understanding of science.

THE MRC’S CONTRIBUTION TO RESEARCH INTO ALLERGY AND INFLAMMATION

18. The MRC funds research aimed at improving human health and has supported some of the most significant discoveries in medicine in the UK. The Council is committed to funding the highest quality proposals and has recently increased its investment in understanding inflammation especially in the respiratory system. Our current investment in this research is of the order of £ 5.1 million pa covering both immunology and inflammation research. The portfolio is summarised briefly at Annex 1.

19. The MRC’s research strategy in this area is further developed in Annex 2. The MRC believes that forming partnerships is an important approach to tackling the challenges posed by allergic diseases as evidenced through MRC partnerships with Universities to develop Centres of Research Excellence. The MRC is also partnering Asthma UK, the British Lung Foundation, the British Thoracic Society and the Morriston Davies Trustees in funding studentships that will build research capacity in this area.

RESPONSES TO SOME HOUSE OF LORDS COMMITTEE QUESTIONS

What is allergy? What is the difference between allergy and intolerance?

20. This has been addressed in paragraphs 6 to 10.

What is and what is not known about the origins and progression of allergic disease?

21. This is covered in some detail in the Royal College of Physicians (RCP) Report “Allergy, the unmet need”. There is also an increasing literature on the origins of allergy. For diseases such as atopic dermatitis (eczema), food allergy and asthma, it would appear that the onset of the allergic state is in early childhood, possibly intra-uterine or during the first few months of life. Sensitisation to specific allergens has a strong genetic component but the rising trends in allergy worldwide is likely to be due to changes in the environment (Asher M I et al, Lancet 2006; 368: 733 – 43).

22. While exposure to new and/or previously uncommon allergens, such as peanuts, tropical fruits etc may in part explain some of the increased allergy seen in childhood, it does not explain it all (Bioschoff SC, Curr Gastroenterol Rep 2006; 8: 374 – 82). Considerable interest has been generated in the role of diet (antioxidants, polyunsaturated fatty acids, unpasteurised milk and probiotic bacteria) and exposure to rural environments as protective against allergy possibly by programming the early life response to allergens (Perkin MR, Strachan DP, J Allergy Clin Immunol 2006; 117: 1,374 – 81).

23. Prospective studies from pre-conception to adulthood will be needed to address some of these issues. A number of human study cohorts already exist; for example, the MRC together with the Wellcome Trust, is a funder of the Avon Longitudinal Study of Parents and Children (ALSPAC) and the UK Biobank, both of which may be resources for such studies. MRC has contributed £4.5 million over five years toward the ALSPAC cohort and has committed £28 million for the recruitment phase of UK Biobank, planned to end in 2010. The MRC, in partnership with the University of Southampton, also funds the Southampton Women’s Survey. Their aim is to learn more about the dietary and lifestyle factors that influence the health of women and their children—including the effect of these on allergies.

What gaps exist in establishing the overall disease burden for all types of allergy and what are the barriers to filling these gaps?

24. Three comprehensive enquiries into allergy and allergy services in the UK have been published.72 All of these have highlighted the lack of information about individual diseases and their burden, as well as commenting on service provision relating to allergy. It is clear that more information is required in this area so that health economic calculations can be undertaken.

25. It is not appropriate for MRC to comment on the provision of health services to those suffering from allergic disorders.

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In addition to the impact on the Health Service what is the overall socio-economic impact of allergic disease?

26. The socio-economic impact of allergy maybe much greater than is commonly appreciated largely because allergy rarely occurs in a single organ and manifests through multiple organs. For example asthma and rhinitis occur together in over 80 per cent of patients with asthma (Demoly P and Bousquet J, Lancet 2006; 368: 711 – 3). The combined morbidity imposed by this multi-organ expression of allergy requires further research. A second element that needs to be taken into account is the effect of allergic disease on patients’ lives. Recent studies have shown a large impact of diseases such as asthma, hay fever and atopic dermatitis on quality of life.

What is the effect of current treatments on the natural history of allergic disease?

27. It would appear that anti-inflammatory therapy for diseases such as asthma, rhinitis and atopic dermatitis do not affect the natural history of these disorders. Specifically, corticosteroids have a marked suppressive effect on the inflammation with control of symptoms, but as soon as the steroids are withdrawn the disease appears again sometimes more aggressively than before. The only therapy so far that has been shown to influence the natural history of allergic diseases is immunotherapy, a treatment not yet extensively used in the United Kingdom due to fears over side effects, amongst other issues (Frew AJ, Clin Exp Allergy 2006; 36: 251 – 3). The only other factor that has been shown to influence the natural history of allergic disease is avoiding contact with the offending antigen. This is only useful in certain instances, such as occupational asthma eg that experienced by small animal handlers. Interestingly, clinical trials have shown that allergen avoidance in children genetically at risk of asthma, either fails to influence the development of allergy or leads to even greater sensitisation (Simpson A & Custovic A, Curr Opin Allergy Clin Immunol 2004; 4: 45 – 51). This observation suggests that allergen reduction strategies in children may remove protective agents from the domestic setting as well as those leading to sensitisation. Thus, in summary, apart from limited allergen avoidance and immunotherapy, there are no current therapies that are known to influence the natural history of allergic disease or allergy in general.

What is the evidence base for pharmacological and non-pharmacological management strategies?

28. As stated above, most allergic diseases are managed by drugs that either treat the symptoms or suppress inflammation, but they do not influence the natural history of the disorder. There is evidence to suggest that allergen specific immunotherapy has beneficial effects on the allergic immune and inflammatory responses in patients. This involves giving patients allergens or modified allergens by injection, or more recently, sub-lingually and has shown promise in allergic rhinoconjunctivitis and venom allergy. The benefits of this approach have not yet been tested in large scale clinical trials.

Is the level of UK research in allergy and allergic disease adequate?

29. It is worth noting firstly that although research in this field is limited to a few centres, the UK is a world leader in many specific aspects of research into the underlying mechanisms of allergy and allergic disease. 30. The UK Clinical Research Collaboration (UKCRC) analysis has identified that there is an imbalance in research funding for all respiratory diseases, including allergic diseases such as asthma, compared to the severity of disease as measured by the disability adjusted life years (DALYs). This did not surprise the MRC who had already issued a Highlight Notice (see Annex 2) and had started working closely with the British Thoracic Society, Asthma UK and British Lung Foundation to encourage the respiratory research community to bid for funding. The added value and agility of this partnership approach has been successful in stimulating new interest. The number of applications increased markedly between April 2005 and March 2006 and the number of awards rose from 6 awards (totalling £0.5m per annum) in 2004 to 15 awards (£2.0 million per annum) in 2006.

What are the most promising areas of research in preventing or treating allergy?

31. It is important to pursue several avenues of research to combat allergic disease. The MRC has funded several research programmes at the forefront of research into allergy, some of which are at Annex 2. Broadly speaking these can be broken down to: 1) genetic studies to identify the genes responsible for allergies, 2) cellular studies to find out more about how the cells of the immune system function in health and disease and 3) new treatment evaluations such as oral immunotherapy. Other avenues of future research include studies (http://www.ukcrc.org/PDF/UKCRC Health Research Analysis Report.pdf).
into environmental aspects of allergy such as identifying new allergens, determining the effect of reducing or increasing allergen exposure on allergy and the effectiveness of pro-biotics as a treatment for allergic diseases.

32. Of special interest is the shaping of the early life immune response towards or away from allergy via pattern recognition receptors such as Toll-like receptors. Ligands that stimulate these receptors may have potential preventative and therapeutic potential. The production of recombinant allergens that generate protective immune responses without triggering an allergic reaction is another promising area of research.

33. The following questions posed by the House of Lords Science and Technology Committee have not been addressed as they lie outside of the remit of the Research Councils:

**Government policies**
- How effective have existing Government policy and advice been in addressing the rise in allergies?
- How is current knowledge about the causes and management of allergic disease shared within Government? For example,
- Do housing policy and regulations governing the indoor environment pay enough attention to allergy?
- How effectively are food policy and food labelling regulations responding to the rise in food allergies?

**Patient and consumer issues**
- What impact do allergies have on the quality of life of those experiencing allergic disease and their families?
- What can be done to better educate the public and to improve the quality of information that is available to patients and undiagnosed sufferers?
- Are current regulatory arrangements, for example, those governing private clinics offering diagnostic and therapeutic services and the sale of over the counter allergy tests, satisfactory?

Annex 1

**SUMMARY OF MRC FUNDING IN ALLERGY AND IMMUNOLOGY**

**Allergy**
The MRC currently spends £5.14 million pa on allergy research.
This is comprised of:
- £3.15 million for MRC grants to academic researchers in universities.
- £1.44 million for direct support in MRC Units and Institutes.
- £0.55 million for research training.

**Immunology Research Underpinning Research into Allergy**
The MRC currently spends a further £15.3 million pa on research into basic immune function.
This is comprised of:
- £5.7 million for MRC grants to academic researchers in universities.
- £7.9 million for direct support in MRC Units and Institutes.
- £1.7 million for research training.

Annex 2

**MRC RESEARCH STRATEGY**
1. The MRC recently highlighted the need for more research on respiratory disease—a manifestation of many allergic and inflammatory diseases by issuing a call for innovative research proposals. This call highlighted perceived barriers to progress in this area, such as the need for animal and/or human models of disease. Such models can be used to study disease mechanisms and pilot novel therapies. The call also highlighted the need
to perform longitudinal studies to establish aetiology of disease. As a result, there has been a recent and significant increase in the MRC portfolio of funded research into allergy and related conditions of the respiratory system.

2. The commercial arm of MRC, MRC Technology (MRCT), is sponsoring major “showcase” events in 2007, on the subject of immunology, infection and inflammation. These will highlight the work of MRC-funded scientists to members of the pharmaceutical and biotech industries. It is hoped that this will increase partnerships between academia and industry and promote the translation of more basic research into therapy.

3. In November 2005, the MRC participated in a joint-funded workshop attended by other major stakeholders (the Wellcome Trust, Department of Health and the major charitable supporters of respiratory medicine: Asthma UK, the British Lung Foundation and British Thoracic Society) to encourage research in the field and identify any tractable barriers to progress. Several key individuals including the Director of the Wellcome Trust (Dr Mark Walport), the Department of Health’s Director of R&D (Professor Sally Davies); and the MRC’s Chief Executive (Professor Colin Blakemore) made keynote speeches on their current portfolios in the area. The 72 participants included senior scientists and a report has been published on the BTS website. Since this workshop, the MRC has also been very active in working with the respiratory charities to encourage high quality applications and increase the participation of the research community in new funding initiatives, such as the recent MRC call for funding of Experimental Medicine.

4. The MRC intends to work closely with the newly established UK Respiratory Research Strategy Committee. This Committee has been set up to promote the need for world class research into respiratory disease. It will produce updates for research strategy in consultation with its constituent groups and other outside bodies.

MRC Centres of Excellence

5. The MRC funds Centres of Excellence in partnership with UK Universities. This unique type of funding supports scientific strategy that links and reinforces existing work as well as fostering new lines of research. MRC funding for these Centres helps UK Universities develop and sustain research with a clear strategic direction in areas of importance for knowledge and health. Allergy research has benefited from three such centres.

6. The MRC-Asthma UK Centre in Allergic Mechanisms of Asthma was launched in September 2005. The Centre is funded by the MRC and Asthma UK with a grant of £0.9 million over three years and directed by Professor Tak Lee, King’s College London and Professor Tim Williams, Imperial College London. The three main aims of the Centre are:

   (1) to advance the understanding of allergic mechanisms in order to inform the development of new, effective and targeted treatments;

   (2) provide high-quality, basic and clinical research training in allergy and asthma; and

   (3) provide quality public information on allergy and asthma in conjunction with stakeholders and partners.

7. The University of Edinburgh/MRC Centre for Inflammation Research (CIR) was established in 2000 with an MRC grant of £1.113 million over 5 years and is headed by Professor Chris Haslett. The Centre comprises 10 major groups and over 150 investigators to pursue co-ordinated interdisciplinary research into three key control points of inflammatory disease—the initiation, regulation and resolution of inflammation. The Centre brings together a critical mass of internationally outstanding researchers in inflammation harnessing the skills of both basic and clinical scientists. There is a keen interest in research training in the molecular cell biology of inflammation, which has been particularly successful in nurturing young clinical scientists, adding vital capacity to this research area.

8. The MRC also funds The University of Birmingham/MRC Centre for Immune Regulation directed by Professor Eric Jenkinson, contributing £1.5 million over five years. This Centre brings together 16 internationally regarded research groups, with complementary skills in studying the different facets of immune responses and their regulation. It links basic research on immune regulation with the study of relapsing and remitting inflammatory conditions associated with immunological damage to joints or blood vessels.
OTHER EXAMPLES OF MRC-FUNDED RESEARCH

9. The MRC has a well-established commitment through intramural funding for research into allergy. Professor Sir Philip Cohen, Director of the MRC Protein Phosphorylation Unit in Dundee, is a world expert on the intracellular mechanisms involved in immune- and inflammatory-cell activation. The steps involved in this activation may offer new targets for drug interventions to prevent allergic disease. Professor Dan Cutler in the MRC Cell Biology Unit, London, has been investigating the mechanisms by which white blood cells move from the blood vessels towards sites of inflammation and specific targets that can be attacked to prevent inflammation. Dr David Jackson from the MRC Human Immunology Unit, Oxford, has been studying blood cell trafficking in inflammation and how these cells are controlled by the proteins released during inflammation. They have discovered that during inflammation, some white blood cells will actively bind inflammatory proteins and so cause their own activation.

10. The MRC also funds a number of novel, cutting-edge programmes of research looking at inflammatory mechanisms in the lung. For example, MRC Professor Stephen Holgate and his team from the University of Southampton have been studying the cells lining the airways of the lungs and have shown that in asthmatics, these cells are more susceptible to injury. They have also shown that levels of a powerful immune system chemical, tumour necrosis factor (TNF) are much higher in the lungs of people with severe asthma compared to non-asthmatics. This raises the question as to whether drugs that TNF would be an effective treatment for asthma and the Southampton team are carrying out these studies.

11. IgE-dependent mechanisms in allergic diseases such as asthma are clearly of fundamental importance in our understanding these diseases. The MRC is funding research at Kings College London led by Professors Brian Sutton and Christopher Corrigan to study the structures of these molecules and their receptors. Based upon these structural studies, they are designing small molecules to inhibit receptor interactions and control the allergic response.

6 October 2006

Memorandum by the Royal College of Physicians

The Royal College of Physicians (RCP) plays a leading role in the delivery of high-quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training, and support throughout their careers. As an independent body representing over 20,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

1. In 2003 the Department of Health was advised by the Royal College of Physicians (supported by patients, their allergy organisations and other relevant professional organisations) in the enclosed report “Allergy: the unmet need”—that:

   — The UK is exposed to an epidemic of allergic illness; one third of the population is directly affected; the growth in severe allergy, allergy which expresses itself in novel forms and multiple allergy are especially concerning.

   — The NHS is not responding to the increased need for services (at any level of care); and people with unmet needs are being diverted into inappropriate care pathways.

   — Whereas a comprehensive service development plan is ultimately required, the first and essential step is to get properly qualified clinical staff into the front line of service provision. This requires a strategic investment in training—initially and primarily in the training of specialist allergy doctors who can take leadership roles in the development of the specialty.

2. In 2004 these findings and advice were endorsed by the House of Commons Health Committee.

3. The DH responses (DH Command paper January 2005, and subsequent Review, July 2006) were initially disappointing as they did not recognise the scale of need.

4. The DH has now conceded the need for improvement, and that there is enough known to move forward; but have allocated responsibility to PCTs and SHAs. However, it is far from clear if these bodies have access to experts in allergy.

5. The College, at a round table chaired by the then President, Dame Carol Black, reached a consensus on referral pathways and models of care with potential providers of allergy care (specialists in allergy, physicians in other specialties, and other colleges especially paediatrics, RCPCH, and primary care, RCGP).
6. Underpinning this consensus was the training of more specialists in allergy, who could provide specialist care and support developments and improved education in primary care, and, working in partnership, across the NHS. An absolute requirement is the creation of more new training posts in allergy (beyond the current eight available nationally).

7. Research and developments in clinical care are essential to improve patient care for allergy sufferers in the UK. Research needs to have a particularly clinical focus. However, without a more robust specialist clinical service, with well studied patients and more doctors who specialise in allergy this will not happen. At present there are few allergy specialists (26.5 whole time equivalents in adult and paediatric allergy in the UK) and many of these are supported by academic funding, so these posts may not continue beyond the tenure of the current post holders.

Letter from the Royal Pharmaceutical Society of Great Britain

The role of community pharmacists in allergic conditions

Community pharmacists provide support to people with allergic conditions in a variety of ways:

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- By supplying and advising on appropriate over-the-counter medicines. The choice of anti-allergy products is vast and potentially bewildering for allergy sufferers: the pharmacist can help them recognise symptoms, identify allergy triggers and select appropriate products. By developing an ongoing relationship with these patients, pharmacists can take a proactive approach by, for instance, encouraging patients to begin hay fever treatments before symptoms start. Pharmacists can also warn patients about side effects and interactions with other medicines e.g. for high blood pressure.  

- By providing advice on how to take prescribed medicines for allergic conditions.

- By providing specialist medicines management services for allergic conditions.

- By prescribing and supplying prescription-only medicines for allergic conditions (this would apply to pharmacists who have successfully completed accredited training courses to become supplementary or independent prescribers).

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I have attached at Appendix 1 a paper prepared especially for this response by Shailen Rao on the role of pharmacists in the management of allergic conditions. It reflects the personal perspective of a pharmacist who has been involved in medicines management and pharmacy development in the NHS.

Some pharmacies sell diagnostic tests for allergies. However, these test kits may also be stocked in non-pharmacy areas of larger retailers, e.g. with a range of other health-related items, and in those circumstances the sale will not be supported by the advice of a pharmacist.

The RPSGB has recently conducted detailed research on the contribution of pharmacists to managing three long-term conditions—asthma, diabetes and coronary heart disease. Key findings of the research included the following:

1. The average community pharmacy serves around 450 patients with asthma (based on national prevalence figures).  

2. Ten intervention trials of community-pharmacy based asthma services were identified and reviewed.

3. Seven of the 10 trials showed positive effects on asthma control.

4. The most effective use of community pharmacy resources will be to focus on those whose asthma is less well controlled, or could become uncontrolled.

5. Several models of community pharmacy based asthma care are offered in the UK, usually on a pilot basis.

6. Community pharmacists have identified asthma as an area in which they would like to offer a more clinical service.

7. Some other countries have been sufficiently convinced by the evidence of pharmacists’ effectiveness to fund a pharmacy based asthma service.

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74 Bokma A (2006). Clearing the air for allergy sufferers—pharmacists ease patient confusion. Pharmacy Practice Canada 22(6); A13–A15.

75 The role of pharmacists in advising patients with allergies was recognised in the Department of Health’s 2006 review of allergy services—Pharmacists need to advise public about allergies. Pharmaceutical Journal 277; 124, 29 July 2006.

76 http://www.rpsgb.org.uk/pdfs/tcondintegcommphsumm.pdf

77 http://www.rpsgb.org.uk/pdfs/tcondintegcommphreptl.pdf

78 http://www.rpsgb.org.uk/pdfs/tcondintegcommphrept3.pdf
What formal training do pharmacists receive in allergy at pre- and post-graduate level?

Registration as a pharmacist requires successful completion of a four-year MPharm degree, a further year of pre-registration training within a pharmacy workplace, followed by a registration examination. At undergraduate level, the pathological and immunological basis of allergy is covered, as is treatment for symptoms with prescribed and over-the-counter (OTC) medicines. Details of the relevant parts of the pre-registration programme and registration examination syllabus are attached at Appendix 2.

At postgraduate level, we are not aware of a compendium of courses, so to identify higher education courses of relevance to allergy would require examining the prospectuses of individual higher education providers. The Centres for Pharmacy Postgraduate Education in England, Scotland and Wales have programmes that include allergy in several forms—as a discrete topic such as asthma and also as part of a wider topic—eg eczema in skin disease.

CPPE (England) does not have any specific courses on allergy, but it is building one this year with Allergy UK (no further details are available at this stage). It has an open learning programme on respiratory disease which covers asthma (about 1,000 are sent out each year) and one on skin disorders which looks at atopic eczema (about 1,500 per year of these have been sent out). It hosts an allergy workshop but very few of these have been run in the last few years.

Do pharmacists feel they receive enough information and support in order to competently advise the general public about allergic diseases?

The RPSGB has produced a range of resources which pharmacists would find helpful advising the public about allergic diseases, eg

— Practice guidance on the care of people with asthma and COPD.

The RPSGB provides a Technical Information Service staffed by experienced information specialists. The Society also provides a Legal and Ethical Advisory Service. Questions from pharmacists about allergic disease would normally be dealt with by the technical information service. The Society does not have statistics on the volume of enquiries on specific medical conditions such as allergy.

Two departments of the Society, the Technical Information Service and the Research and Development Division, undertook literature searches for this response on the topic of pharmacists and allergy. Additional references which do not appear in the footnotes are attached at Appendix 3.

The Pharmaceutical Press (an imprint of RPS Publishing, which is owned by the RPSGB) produces a wide range of textbooks for pharmacists and pharmacy students. Those of relevance to allergic conditions include Asthma in Focus (2006) and Non-Prescription Medicines (2006). We have not found any evidence that pharmacists feel they have insufficient knowledge or support to competently advise the public about allergic disease. Allergies are among the most common conditions for which the public visit pharmacies and seek the advice of pharmacists, so pharmacists are likely to be familiar with allergic conditions and their management.

The Department of Health told this Committee that a new regulatory framework for pharmacists should be introduced this year. What will this involve? Does the Royal Society welcome this? What benefit will this have to the general public?

The RPSGB has welcomed the Pharmacists and Pharmacy Technicians Order 2007, which was made on 7 February 2007. The new legislation will overhaul and modernise pharmacist and pharmacy technician regulation and will update, strengthen and clarify the RPSGB’s powers to protect, promote and maintain the health and safety of the public.

The main provisions of the Order are:

— Improved capacity to address fitness to practise issues and health matters.
— Reform of the Society’s registration process.
— Updated provisions for education, training and continuing professional development (CPD).
— Statutory registration of pharmacy technicians in England and Wales.

The Order has been developed as a result of close co-operation between the Department of Health, the Royal Pharmaceutical Society of Great Britain and the UK devolved administration health departments. There are separate arrangements for the regulation of pharmacy in Northern Ireland.

**Which treatments are most commonly bought in pharmacies for the treatment of allergic conditions?**

The Proprietary Association of Great Britain provides total sales figures (supplied by Information Resources Inc) for OTC medicines but the figures do not distinguish sales from sales in other outlets. Most of the categories used in the figures do not distinguish allergic from non-allergic conditions. However, they show that £79.1 million was spent on OTC hay fever remedies in 2005, a rise of 4.5 per cent compared to the previous year. The total OTC sales of hay fever remedies have doubled in the past six years. Hay fever remedies are sold for a range of allergic conditions and sales take place all year round.

Another information provider, IMS Health, has supplied figures for this inquiry. For the year March 2006 to February 2007, pharmacy sales of OTC medicines used for allergic conditions totalled £47,574,208, a rise of 5.45 per cent in the total value of sales compared to the previous year. The sub-totals for the four categories of medicines making up that total are:

— Asthma remedies (£490,122).
— Respiratory and general anti-allergics (£25,634,167).
— Skin irritation including topical antihistamines (£14,756,075).
— Eye anti-allergies and anti-inflammatories (£6,693,845).

The figures are for pharmacy independents and multiples but do not include mass market channels such as Boots, Superdrug and the supermarkets.

**What diagnostic tests are available over the counter for allergies and does the Royal Society recommend these?**

The RPSGB’s Technical Information Services published guidance on diagnostic testing in community pharmacy in 2006. It includes information on providers of allergy and food intolerance testing. The Society does not make recommendations as such regarding particular tests or suppliers of tests. Additional information on diagnostic tests for allergies is attached at Appendix 4.

The RPSGB also produces general guidance on diagnostic testing and health screening in its Code of Ethics (Service Specification 14).

**APPENDIX 1**

**The Role of Pharmacists in the Management of Allergic Conditions**

**Background**

Community Pharmacists currently provide a wide range of services and support to patients with allergic conditions and associated conditions eg allergic asthma. The main role at present is the over the counter (OTC) diagnosis and supply of medicines to manage mild allergic respiratory and skin conditions eg hay fever and allergic contact dermatitis. Recent changes in NHS policy and a drive to extend the rota of health care professionals eg practice based commissioning, extended prescribing and the new pharmacy contract provide an opportunity to further enhance the role of pharmacists in the management of allergic conditions.

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85 http://www.pagb.co.uk/pagb/downloads/marketinformation/FINAL%202005%20OTC%20Data%20for%20PAGB.pdf
86 Personal communication, IRI, 17 April 2007. IRI compiles a comprehensive database of OTC medicine sales from all the major pharmacy multiples and supermarkets. It provides “top-line” data to PAGB but more detailed information is available at a charge, eg on the sales of particular OTC medicines and where they were brought.
87 IMS Health, 23 April 2007.
88 http://www.rpsgb.org/pdfs/rpspspecidiagnost.pdf
89 http://www.rpsgb.org/pdfs/coe060524.pdf
**The Current Service**

Pharmacists are already recognised by the public as a key resource in the treatment of mild allergic conditions. They are regularly consulted by patients who present with symptoms of allergy. Many of these patients prefer to see a pharmacist rather than to take time off work to visit a GP. In the first instance, many patients will not know that the condition is allergic in nature. Pharmacists are well skilled in using over the counter questioning techniques to establish potential allergic conditions and also have at their disposal a wide and growing range of first-line treatments, without the need for a prescription. These include oral antihistamine therapy, topical skin preparations eg hydrocortisone cream and cromoglicate eye drops. Pharmacists also provide information and education on prevention and minimisation of symptoms. Many of these patients will continue with over the counter treatment and others will see their GP for future treatments. Pharmacists also provide a very important role in referring patients suspected as having more serious conditions to their GP eg asthma and eczema.

By providing this comprehensive and patient centred OTC service, a huge number of GP consultations are probably avoided each day across the country. In addition, OTC purchasing by patients rather than seeking a GP prescription reduces the burden on the NHS drugs bill.

In some areas, allergic conditions are included as part of Minor ailments schemes commissioned locally by PCTs. In these schemes, patients with symptoms of minor illness are directed to pharmacies by GP practice reception staff. The pharmacist is enabled to triage the patients and either provide treatment or refer to the GP. Many patients with allergic conditions will be on regular medication eg antihistamines. However, in many cases, compliance is likely to be poor, often caused by a lack of knowledge about the condition or the medication. Pharmacists could be well placed to utilise medicines use reviews (MURs), which are part of the national pharmacy contract, to improve adherence to medication. It is probably unlikely that this is being explored as a specific opportunity as yet.

In addition to community pharmacy, prescribing advisers in GP practices have been involved in the management of allergic conditions. This includes advice to GPs on drug choice and running audits within practices to review use eg antihistamines. In recent times, a number of prescribed antihistamines have come of patent and therefore reduced in price. Pharmacist involvement at practice level has helped GPs to endure that treatment remains cost-effective. Hospital pharmacists play a key role in identifying allergies, specifically drug allergies; recommending safer alternatives and ensuring appropriate use of medicines during hospital admissions. Pharmacist led NHS medicines information services also provide information and advise on identifying and managing patient drug allergies; for healthcare professionals and the general public.

**A Potential Future Pharmacy Service in Allergy**

Whilst pharmacists already provide a valuable role, it would be possible to enhance the value they add by better integration of within local NHS service delivery. A number of recent initiatives and policy documents would empower such a role:

- The pharmacy contract.
- Practice based commissioning (PBC)
- Extended prescribing rights.
- Practitioners with specialist interests (PwSIs).
- Choosing “Health Through Pharmacy”.

Pharmacists could become a first port of call and specialist medicines support service, recognised by patients and health care professionals across the whole health economy. In order for this to happen, a local service specification would need to be drawn up.

A brief description of an example specification is given below:

1. Patients could continue to present over the counter (as they do now).
2. Pharmacists would run regular health promotion campaigns to raise awareness of allergies and the presence of pharmacy as a resource. This could fulfil part of the requirement to run health promotion campaigns under the pharmacy contract.
3. GPs would refer patients with allergies to be managed by the community pharmacist. This could be done either by use of a patient group direction (PGD) or where possible by utilising independent/ supplementary prescribing. The pharmacist could then continue the management of the patient ensuring that the patient is complying and altering medication as required.
4. Patients already being treated by their GPs could be referred to the pharmacist for support with prescribed medication. The pharmacist could utilise MURs to ensure that the patient is gaining benefit whilst also minimising the potential for wastage caused by unused or unwanted medication.

5. The service could be broadened to include patients with allergic asthma. Pharmacists would be well placed to provide support on the use of inhaled medications.

6. In the future, it may be possible to commission an allergy testing service through pharmacy. Some pharmacies already provide a testing service but at present these tests are not always of a standard recognised by other health care professionals.

Potential Benefits of the service:

1. Improved access to services for patients.
2. Improved patient knowledge and understanding of the condition and treatments options.
3. Cost-effective utilisation of pharmacists—some of these resources eg MURs, health promotion campaigns are already funded but may be under utilised.
5. Improved working relationships between GPs and pharmacists.
6. Reduced workload for GPs.
7. Improved effectiveness of prescribed medication and reduced wastage.

Conclusion

Pharmacists in all sectors of the health community are a valuable source of identifying and managing allergies, specifically drug related ones. Community pharmacists currently provide an extensive service in the management of allergic conditions. In the main, this is an OTC service dependent on the patient self-presenting in the pharmacy. Some patients will either suffer in silence with conditions that could readily be treated, whilst others will present at GP practices and possibly even in hospital.

With the changing NHS agenda, there is now a move to utilise a wider range of healthcare professionals, especially in primary care settings. These initiatives provide the means for engaging primary care pharmacists to improve the management of allergic conditions.

In order, for the potential to be realised, NHS organisations should be encouraged to develop care pathways for allergic conditions and explore how pharmacy services could be integrated within them. Although additional funding may be required, it is possible that much of the existing resource eg MURs and GP practice prescribing budgets could be better utilised making such a service cost-effective at the same time as being high quality.

APPENDIX 2

PRE-REGISTRATION EDUCATION AND TRAINING REQUIREMENTS FOR PHARMACISTS OF RELEVANCE TO ALLERGIES

Dr Nicola Tyers, Preregistration Manager, RPSGB

1. PRE-REGISTRATION PERFORMANCE STANDARDS (LEARNING OUTCOMES OF THE PRE-REGISTRATION YEAR)

Although there is not an explicit requirement for MPharm students to specifically cover allergy, this topic will definitely be covered within the area of Pharmacy Practice and specifically in Responding to Symptoms, and Clinical Pharmacy training.

Also, in the pre-registration Performance Standards there is not an explicit requirement for trainees to cover allergy, other than C2.10, which deals with emergency first aid. It is not realistic to provide a list of all topics that trainees should cover as part of their core Performance Standards, but rather a list of outcomes in dealing with differential diagnosis and recommendations of treatment.

Trainees are not specifically trained in diagnosis. The following Performance Standards do amount to assessing situations and providing solutions.

Trainees must show that they:
A3.1 Recognise and define actual or potential problems.*
  * Problems include difficulties, minor and serious, needing resolution.

A3.2 Identify workable options to resolve the problem.

A3.3 Select the best solution, based on sound analysis* and appropriate evidence.
  * Sound analysis will include:
    — Exploring the strengths and weaknesses of options.
    — Considering barriers to resolving the problem.
    — Discussion with others.

A3.4 Suggest and, if appropriate, implement solutions to problems.

A3.5 Evaluate the outcome of the solution after implementation, and if necessary redefine the problem (see A3.1).

B1.11 Provide information and advice appropriate to the needs of the recipient(s)*.
  * Recipients must include individuals, groups and those with particular needs, eg people with diabetes, asthma etc.

Unit C—Medicines and health standards encompass aspects of performance and behaviour that are specific to pharmacy practice and cover responding to symptoms. I would suggest that an integral part of dealing with responding to symptoms would be the diagnosis and treatment of allergy.

In this Unit, trainees must demonstrate their ability to provide an effective pharmaceutical service.

Development of the following characteristics will underpin their future role as a provider of pharmaceutical care:

— identifying health needs and understanding the opportunities for health promotion as well as treatment and care;
— working with patients and carers, to manage their medicines and ensure that they can play an active part in the decisions and choices affecting their treatment or care;
— understanding and making the most of the whole health and social care system—for the benefit of patients.

For this unit to be achieved, trainees must have experience or awareness of the following:

— supply of medicines from both community and hospital;
— provision of advice about medicines and health;
— use of patient medication records and histories.

Performance Standard C2—Provide additional clinical and pharmaceutical services Trainees must demonstrate the application of their clinical and pharmaceutical knowledge. Trainees must show that this knowledge is up-to-date. It must be used effectively in the following areas:

— the management of prescribed medicines, long term conditions and common ailments;
— the promotion and support of healthy lifestyles;
— the provision of advice and support to patients and other healthcare professionals.

Competence in this element will underpin trainee’s ability to manage medicines and provide pharmaceutical care in the future.

Trainees must show that they:

C2.1 Provide considered and correct answers to queries, founded on research-based evidence*.
  * Evidence sources will include clinical textbooks, journals and pharmaceutical company information (whether paper-based or electronic).

C2.2 Pro-actively* assist patients** to obtain maximum benefit from their treatment.
  * This will include identifying opportunities to assist, providing information, positive reinforcement, reassurance, testing understanding and encouraging recipient to ask questions.
  ** Directly or via their representatives.

C2.6 Use medication histories correctly*.
  * Access existing information, record new information and apply the information.
C2.7 Recognise possible adverse drug reactions, evaluate risks and take action* accordingly.
* This may include advising and informing patient or representative, discussion with colleagues and reporting to CSM.

C2.8 Provide appropriate information and advice on the management of minor and common ailments*.
* Information and advice must incorporate both appropriate self-medication and appropriate non-drug actions.

C2.9 Effectively use opportunities* to promote and support healthy lifestyles and prevent disease.
* With individual patients and at formal events such as presentations to patient or public groups.

The above includes Performance Standards that could be used to test differential diagnosis. Items highlighted in bold should cover allergy. It is important to remember that allergy could also include an allergic response from a medication.

2. Registration Examination Syllabus

Items highlighted in bold below should cover allergy, although not specifically mentioned.

**SYLLABUS SECTION 2—CLINICAL AND PHARMACEUTICAL PRACTICE**

**Part I—Clinical Practice**

(a) Evidence-based practice You must be able to demonstrate an understanding of:
— The principles of obtaining and applying evidence to inform and enhance practice.

(b) Action and uses of drugs You must be able to demonstrate an understanding of:
— The mechanism of action, administration, absorption, distribution, metabolism and excretion of commonly prescribed and purchased licensed medicines.
— The principle uses of these medicines.
— Correct dosages and dose adjustments for patients with particular needs because of their age or condition.

(c) Non prescription remedies You must be able to demonstrate an understanding of:
— The actions and licensed uses of medicinal products available without prescription that are commonly used to treat minor ailments.

(d) Differentiating minor illness from more serious disease You must be able to identify and to demonstrate an understanding of:
— The symptoms of conditions that require referral to a medical or other healthcare practitioner.
— Conditions not requiring referral and how they may appropriately be treated by non-prescription medicines, by short-term action that does not involve medication or by lifestyle change.

(e) Adverse effects of medicines (see also section 3, item e) You must be able to demonstrate an understanding of:
— the recognised adverse effects of commonly prescribed and purchased medicines.

(f) Contra-indications You must be able to demonstrate an understanding of:
— the circumstances in which commonly prescribed and purchased licensed medicines are contra-indicated.

(g) Drug interactions You must be able to demonstrate an understanding of:
— the principle interactions that can occur between medicines, prescribed and purchased, and between these medicines and foods or other substances.
(h) Counselling requirements

You must be able to identify and demonstrate an understanding of:

— circumstances or situations in which patients or other clients require information.

— the nature of that information and the most appropriate way to provide it to the individual.

(i) Optimising patients’ drug therapy

Understanding of:

— The purpose and principles of medicines management and pharmaceutical care.

(j) Interpretation of test results

You must know, demonstrate an understanding of and be able to interpret:

— The normal ranges for blood pressure and key blood components.

— The normal ranges for therapeutic blood levels of drugs with a narrow therapeutic index.

— The normal ranges for key parameters of bodily function.

— The implications of figures outside these ranges.

(k) Health promotion and disease prevention

You must be able to demonstrate an understanding of:

— The concepts of health promotion and health education.

— Recommendations for key health parameters.

— The basis for health improvement programmes.

— The social, environmental, lifestyle and dietary factors that influence health.

— How awareness of the stages of behavioural change can help the pharmacist to make interventions appropriate to the individual.

— Actions the pharmacist and pharmacy support staff can take to promote health and prevent disease.

Asthma is only mentioned as an example in the standards. We deliberately do not have a definitive list of topics as things are always changing. Trainees will be exposed to learning about allergy in practice.

The overarching information about Performance Standard C2 does state that trainees must know about the management of prescribed medicines, long-term conditions and common ailments. I would expect this to cover allergy in its broadest sense of both short and long duration. The assessment standards under C2 (below) would also cover this. The knowledge requirements under C2 deal with inhalers, which are integral to asthma treatment.

C2 Assessment requirements

Evidence that your trainee provides for assessment should include:

— proof that she has been involved in the provision of pharmaceutical services in both community and hospital practice.
— proof that she has provided advice or supplied non-prescribed medicines for a wide range of conditions, including those affecting:

— the respiratory tract;
— the gastro-intestinal tract;
— the oropharynx;
— the skin;
— the ear(s);
— the eye(s);
— musculoskeletal and connective tissue;
— women;
— babies and children;
— elderly patients;
— patients with long term health management needs.

C2 Knowledge requirements

Most of the knowledge represented by the whole registration examination syllabus is needed to underpin these standards.

In addition, your trainee must show that she has a working knowledge of, and can apply, the following:

Compliance aids—availability and use.
Use of inhalers and other devices.
Dispensing for residential and nursing homes.
Emergency first aid.
Government healthcare priorities.
Local healthcare priorities.
Patient information leaflets.
How to evaluate literature and data.
Referral agencies in emergency or for provision of further advice.
Roles of healthcare professionals.
Sale of medicine protocol in your pharmacy (where the pharmacy sells medicines).
Techniques for effective questioning.
Information sources.

It must be remembered that none of the Performance Standards should be viewed in isolation, a trainee would not learn about inhalers in isolation—they would also learn about providing information to the patient about asthma management. I have attached the full list of Performance Standards including the underpinning assessment and knowledge requirements for your information.

APPENDIX 3

ADDITIONAL REFERENCES—PHARMACISTS AND ALLERGY/ALLERGIC CONDITIONS

Pharmacy practice

GSK Website www.pharmassist.gsk.co.uk/en120.htm


Education
RPSGB Pre-registration Performance Standards http://www.rpsgb.org.uk/pdfs/preregtrwb06-07.pdf

Centre for Pharmacy Postgraduate Education courses:
Skin Conditions, the Management and treatment of http://www.cppe.manchester.ac.uk/Bookings/Details.asp?TemplateID=Dermat%2DD%2D02&OnTab=0&Format=D
Pharmaceutical Care of the Eye http://www.cppe.manchester.ac.uk/Bookings/Details.asp?TemplateID=EYE%2DD%2D02&OnTab=0&Format=D

OTC Diagnostic Testing
Royal Pharmaceutical Society. RPS e-PIC References on; Diagnostic testing in community pharmacy www.rpsgb.rpsgb.org/pdfs/rpsepicdiagest.pdf

APPENDIX 4

ADDITIONAL INFORMATION ON DIAGNOSTIC TESTS FOR ALLERGIES
Consulting areas for Superdrug stores, Pharmaceutical-Journal 2003: 270: 465 (5 April). Superdrug is to introduce screened consulting areas to its stores following positive feedback from customers about the 20 stores that have private consulting rooms. Superdrug currently uses its consulting rooms for services from blood pressure monitoring to allergy testing. http://www.pjonline.com/Editorial/20030405/news/superdrug.html
Moss offers food intolerance tests, Chemist-and-Druggist 2002: 257: 20 (20 April). Moss Pharmacy is offering food intolerance and allergy tests in its 800 branches. The tests are approved by the British Allergy Foundation and produced by York Nutritional Laboratories.
Home allergy test kits for asthmatics, Chemist-and-Druggist 2002: 257: 28 (16 March). A range of home test kits has been designed to help asthma sufferers to diagnose their specific allergies. Individual test kits have also been developed to confirm cat, house dustmite, egg, milk and pollen sensitivity.
Imutest home allergy test, Pharmaceutical-Journal 2001: 267 (14 July): 48. Clinical Diagnostic Chemicals has launched Imutest, a range of six home testing kits for checking sensitivity to allergens. Imutest Allergy Check is for checking patients’ sensitivity to allergens and is useful in those who have no idea what the causes of their symptoms are. Other products in the range test for five of the most common allergies: cat, egg, hayfever, house dustmote and milk. An allergy care nurse is available to provide support for users of Imutest.
Lloyds offers food intolerance tests. Pharmaceutical-Journal 2001: 266 (24 February): 243. Lloyds Pharmacy Ltd is offering its customers a food intolerance testing service which will allow them to change their diets to avoid foods they might be allergic to. Two types of test service are available. A 40-food screen (£99 sterling) tests groups of foods, such as citrus fruits, for reactions and provides results for the most commonly eaten foods. A 93-food screen (£245 sterling) offers more precise measurements for individual foods. The food testing is undertaken by York Nutritional Laboratory Ltd.
Unfortunately there is not a comprehensive list of diagnostic tests available for allergies; some of the products available are:

- Home allergy test kit (Clinical Diagnostic Chemicals).
- Imutest self tests for allergy (Clinical Diagnostic Chemicals).
- Yorktest (Yorktest Laboratories).
- Food Allergy and Food intolerance test kits (www.mypharmacy.co.uk—testing is carried out by Exeter Nutritional Clinic).

Memorandum by The Royal College of Midwives

The Royal College of Midwives (RCM) is the professional organisation and trade union representing 95 per cent of all practising midwives in the United Kingdom. Virtually all practising midwives work within the NHS, and the RCM is recognised in every Trust that provides a midwifery service.

Comments

The key issue here is about reducing the risks of a child developing an allergic condition.

Hygiene

- To regularly vacuum carpets and wash floors. Preferable to have simple wooden/laminate floors that can be easily washed—most family homes with young children now have this; this is a trend.
- Avoid quilts/pillows made of feathers or polystyrene materials.
- Consider the type of mattress that the child sleeps on and change regularly as can be afforded/possible.

Reducing the collection of dust mites in mattresses/carpets etc.

Clothing

- Cotton is advisable—avoid nylon as far as possible.
- Bed linen/sheets—should consider cotton.
- Regular change of bed linen.
- Wash clothing and bed linen with non-bio washing powder.

Skin Care

- Simple, non-perfumed soap/lotion for washing/bathing.

Environment

- Caution/avoidance of pollen laden areas in high season.
- Caution around pets!!!
- Avoid smoking in the home or near children/do not take children to smoke filled environments.

Foods

- Exclusive breastfeeding for the first six months without the introduction of supplements or solid foods. Breast feeding contains specific immunological properties; while this may to a certain extent protect children from certain diseases, especially asthma, the home and environmental factors play a significant part. Parents can continue on to two years if they are able to; especially if the child is diagnosed with an allergy or there is a familial history of allergies/asthma.
- Avoid the early introduction of cow’s milk, particularly below six months.
- Introduce child to solid foods from family’s own diet/foods after six months. It is therefore important that family chooses/eats healthy/fresh food with fewer additives, colours etc.
- Caution if familial history of nut allergies.
— Parents should not give their children replacement foods/products/cut out dairy unless they have been diagnosed as having specific food allergies by a physician.
— If they suspect that the child has symptoms similar to allergies; always consult a doctor/seek specialist medical advice and not try to self-treat.

Prevalence
— The evidence is suggesting 25–30 per cent.
— The most common allergies are around foods; lactose intolerance nut and other minor foods. However, parents should not self-treat/give replacement foods which can result in sensitisation of the child.
— Other allergies include atopic diseases such as eczema, allergic rhinitis and asthma.

Education/Treatment/Gaps
— Needs education particularly around foods/healthy eating and environmental factors. Good public health education on how to reduce risks of allergies.
— Referral for specialist medical opinion—treatment should be dependent on the allergy and its causes.

Gaps
— Late diagnosis as parents attempt to self-diagnose particularly around foods or have their children sensitised/desensitised by non-medical specialists.
— Poor/lack of knowledge.

Memorandum by the Wellcome Trust
1. The Wellcome Trust is pleased to make a response to the House of Lords Science and Technology Committee call for evidence on allergy and allergic diseases.
2. The Wellcome Trust is an independent research-funding charity, established under the will of Sir Henry Wellcome in 1936. It is funded from a private endowment, which is managed with long-term sustainability and growth in mind. The Trust is the second largest biomedical research funding foundation in the world with a mission to “foster and promote research with the aim of improving human and animal health”.
3. The Trust has funded over £20 million of research into allergies and allergic diseases since 2000, through a number of its funding streams.
4. A wide range of academics and research centres have been supported by the Trust in this field. As requested by the Clerk of the Committee, we would like to draw the Committee’s attention to some individuals who we feel would offer valuable insight into allergies and allergic diseases. The Trust has also supported the majority of the researchers that have been contacted by the Committee namely:
   — Professor Stephen Holgate;
   — Dr Seif Shaheen;
   — Professor Tim Williams;
   — Professor Tak Lee;
   — Dr Pamela Ewan;
   — Dr Glenis Scadding;
   — Dr Clive Robinson;
   — Professor John Britton;
   — Professor Anthony Frew;
   — Professor Adnan Custovic; and
   — Professor Douglas Robinson.
5. Outlined below are details of the researchers and their current projects supported by the Wellcome Trust. The Trust would be happy to supply further details about these projects if the Committee feels it would be useful.
6. The MRC-Asthma UK Centre in Allergic Mechanisms of Asthma at King’s College London and Imperial College London

Dr Clare Lloyd, Imperial College London University

Current research

Dr Lloyd and her colleagues have developed a murine model of allergen induced airway inflammation and remodelling, and used this model to identify key interactions leading to the development of pathology. The model recapitulates many of the features characteristic of the human disease, including eosinophilic inflammation, airway hyperresponsiveness, mucus production, extracellular matrix deposition, airway secretion. Importantly, the changes to smooth muscle cell proliferation, and TGF to airway structure were sustained in the absence of further allergen challenge.

Current studies of the team aim to delineate molecular and cellular pathways involved in the resolution of allergen induced airway inflammation and remodelling. They plan to manipulate pathways thought to play a regulatory role in the immune system in order to promote resolution of established airway remodelling. The effects of these manipulations on development of AHR, inflammation, and parameters of airway remodelling such as collagen deposition and mucus production will then be assessed.

In addition they are investigating the contribution of resident lung cells to airway remodelling. They will investigate the ontogeny of fibroblasts during the development of airway remodelling in vivo.

Dr Lloyd is a current Wellcome Trust Senior Basic fellow (from 1999).

7. Professor Peter Friedmann, Professor of Dermatology, University of Southampton

Current research

Dr Friedmann’s current research includes the: investigation of xenobiotic disposition in the development of allergic contact hypersensitivity; mechanisms of adverse reactions to therapeutic drugs and contact sensitisers; the generation of inflammatory mediators in skin—a microdialysis study; and the functional role of vasoactive mediators in allergic contact hypersensitivity responses in human skin in vivo.

Prof Friedmann was awarded in 2004, a Wellcome Trust Science Research Investment Fund (SRIF), for a new superdivision of Infection, Allergy, Inflammation and Repair at Southampton General Hospital.

8. Professor Hugh Miller, University of Edinburgh

Current research

The Miller Group’s primary research interest is in mast cells, their recruitment to the epithelium and how mucosal mast cell specific proteases, which are produced in abundance by rodents, function within the affected mucosa. A key role for the proteases may be in regulating epithelial tight junctions, thus controlling epithelial permeability.

Further to this, they are employing current methods for global analysis of gene transcription (micro-arrays) and protein expression (proteomics) to discover novel molecules and patterns of expression in allergic reactions and parasite rejection. A group of candidate molecules, including intelectin, resistin-like molecule beta and acidic mammalian chitinase are being studied in more detail. By understanding how natural immunity to parasites works, their hope is to be in a better position to augment these processes and design effective vaccines.

Professor Miller has received Wellcome Programme Grants to support this work.

September 2006