

The Influence of the Pharmaceutical Industry

*A contribution to the Consultation
initiated by the Health Committee*

Submitted by the Maranatha Community
in association with the Council
for Health and Wholeness

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THIS DOCUMENT

This document has been prepared in response to the Consultation by the House of Commons Health Committee

‘THE INFLUENCE OF THE PHARMACEUTICAL INDUSTRY’

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THE MARANATHA COMMUNITY

The Maranatha Community is a Christian movement with many thousands of members throughout the country active in all the main churches. Its membership includes a substantial number of people involved in the health and caring professions and in a wide range of voluntary work. Since its formation 23 years ago, it has been deeply involved in work amongst children and young people, people with drug and alcohol problems, the disabled and disadvantaged. It has taken the initiative in a broad range of projects directly contributing to the health of the nation and it also has extensive international experience. The Trust is a registered charity number 327627.

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The Leader of the Community, which has ten thousand members throughout the United Kingdom, is Mr. Dennis Wrigley.

THE COUNCIL FOR HEALTH AND WHOLENESS

The Council is a multi-disciplinary body embracing doctors drawn from a variety of specialisms, nurses and various medical auxiliaries, counsellors, chaplains and others. It has close links with the healing ministry of the Christian church and is involved in a broad range of research projects.

The Council for Health and Wholeness is based in the offices of the Maranatha Community. Its medical co-ordinators are Dr. Hans-Christian Raabe & Dr. Linda Stalley.

INTRODUCTION

1. The Maranatha Community and the Council for Health and Wholeness welcome the inquiry by the Health Committee into the impact of the pharmaceutical industry.
2. While we recognize significant benefits through many products of the pharmaceutical industry, **we are increasingly concerned at the influence the pharmaceutical industry exerts** onto health care professionals, patients, health decision making and health systems as a whole.
3. The obvious – almost everyday – influence on doctors appears to be the ‘drug representative’, trying to encourage doctors, both in primary and secondary care, to prescribe the products of a certain company. The impact of this is shown by the **changing prescribing habits of doctors who regularly meet drug representatives** as opposed to those doctors who do not meet drug representatives.
4. However, a far more sinister influence is exerted by the distortion of research, the creation of a market for certain drugs and the **promotion of a simplistic and consumerist understanding of health and illness** based essentially on chemical and physiological processes which can be affected by drugs, but neglecting the nutritional, environmental, social, emotional and spiritual dimensions of health and illness.

BIASED RESEARCH

5. Far more research is carried out into drug treatment of chronic diseases funded by drug companies compared to research looking into treatment of chronic diseases based on ‘lifestyle’ interventions. **Drug companies are obviously more interested in selling their drugs – ideally, from a company point of view, to patients with often life-long “incurable” illnesses** such as IHD, hypertension, diabetes, asthma and others – than into the prevention and possibly even cure through nutrition and lifestyle changes.
6. Richard Smith, the Editor of the British Medical Journal writes in an editorial (31 May 2003): *“The pharmaceutical industry is immensely powerful. It is one of the most profitable of industries, truly global, and closely connected to politicians, particularly in the United States. Compared with it, medicine is a disorganised mess. **Doctors have become dependent on the industry in a way that undermines their independence and ability to do their best for patients.**”*
7. We are particularly concerned, that **medical practice is increasingly based on evidence gained from trials that are essentially funded by drug companies.** Due to the high costs of funding research, there has been a very worrying trend over past decades with more and more research being sponsored by drug companies and less research being funded independently. Researchers participating in research funded by drug companies usually have to sign an agreement which prohibits them from publishing results or data without the permission of the

drug company. It is therefore not surprising, that research funded by drug companies is far more likely to find in favour of the company's drug than independently funded research. *"Suppression of science is not an anomaly but is typical of, and produced by, the current economic, political, and social situation, and that is - money talks. It is the system; it is not just a few bad apples."* (Dr David Egilman, professor of medicine at Brown University, Providence, Rhode Island, quoted in British Medical Journal 17 July 2004)

8. Whether a medical trial is sponsored by a drug company or not has a major impact on the outcome. **In an analysis of 370 studies, the drug under investigation was recommended as treatment of choice in only 16% of trials funded by independent organisations, but in 51% of trials funded by drug companies.** Trials funded by drug companies were over five times as likely to recommend the drug treatment as treatment of choice compared with trials funded by non-profit organizations. Studies of cancer drugs sponsored by not-for profit organisations were nearly eight times more likely to report unfavourable conclusions than drug company sponsored studies of the same drug. Studies sponsored by manufacturers of a newer class of antidepressants (Selective Serotonin Reuptake Inhibitors) favoured this drug class over the older tricyclic antidepressants more than non-industry-sponsored studies. It is therefore likely that conclusions in trials funded by drug companies are more positive due to biased interpretation of trial results. (*see Appendix A*)
9. With the advent of evidence-based medicine many reviews of the scientific literature include an assessment of how robust the published evidence is, based on the type of study used. For example, anecdotal evidence is considered to be less reliable than evidence from randomised trials. Whether or not a study has industry sponsoring or not is likely to affect the outcome of the trial. **We are surprised that there is no widely used scoring system, which classifies medical research according to the degree of independence from industry sponsoring. We strongly recommend the urgent introduction of such a scoring system.** We propose a scoring system starting from A (most reliable evidence, independent from industry sponsoring) to E ('expert' opinion with conflict of interest due to industry sponsorship). We suggest the introduction of a category W for 'warning' – that there is no research on a particular product independent from industry. (*see Appendix B*)
10. We are particularly concerned that **many experts involved in guideline development** for common conditions encountered in medical practice (such as hypertension, ischaemic heart disease, diabetes, asthma etc.) intended for General Practitioners or hospital doctors, **are not independent of the pharmaceutical industries.** Not surprisingly, these guidelines frequently favour a certain approach – for example drug treatment – over non-drug including nutritional approaches. Guidance on cholesterol-lowering issued by the US National Institutes of Health (NIH) in July 2004 calling for even lower cholesterol targets than previous guidance have been challenged very recently. The challenge follows the revelation, that eight of the nine authors of the guidelines had failed to disclose financial associations with the manufacturers of cholesterol lowering agents. This guidance would significantly increase the numbers of patients taking cholesterol-lowering drugs. While this is a US guidance, it is likely to have an impact on UK practice. (*see Appendix C*)

11. There is furthermore the danger that large **pharmaceutical conglomerates have an unfair interest on legislation affecting health**. An example of this is an EU Directive which may close down most of Britain's 2000 health shops. It is part of the huge programme of EU legislation which is being "fast-tracked". Pharmaceutical companies have been lobbying behind the scenes for years to introduce the "Herbal Medicines Products" Directive which seeks to apply to herbal remedies the principle of continental law that things can only be allowed when they are specifically authorised. (*see Appendix D*)

PRESCRIBING PRACTICE FOR CHRONIC DISEASES LIFESTYLE CHANGES OR DRUG TREATMENT?

12. Over the **past decades, we have seen a significant increase in chronic diseases** such as ischaemic heart disease, hypertension, stroke, asthma, obesity, diabetes and malignancies such as cancers of the breast, prostate and colon. The standard treatment of these conditions uses mainly drug treatment. However, there is strong evidence that a) many of these conditions are due to changes in lifestyle, b) that therefore lifestyle changes such as diet changes and exercise can have a major beneficial impact on those conditions and c) that lifestyle interventions therefore are more cost-effective than drug treatment.
13. It is likely that **many of the diseases we see currently in western societies are due to changes in our diet and change in lifestyle**: The dominating illnesses in modernised societies are new, or have become newly prominent, in the past 100-150 years. When traditional societies modernise, they, too, seem to develop these same 'modernisation diseases' within a few decades. These illnesses include cardiovascular diseases such as ischaemic heart disease, hypertension and stroke; respiratory diseases such as asthma, metabolic diseases such as obesity and diabetes, malignancies such as major types of cancer including cancers of the breast, prostate and colon, allergies, gastrointestinal conditions such as appendicitis, inflammatory bowel diseases, irritable bowel syndrome and coeliac disease and behavioural disorders especially in children such as childhood hyperactivity and 'autism'.
14. While it is possible that some of the above conditions are due to a 'westernised lifestyle', part of the 'westernised lifestyle' comprises a **'western diet' which in itself consists of increased intake of processed foods, including increased intake of fats, sugars, salt and an increased intake of total calories**. Obviously, other factors also contribute to a 'western lifestyle' such as reduced physical activity, increased exposure to toxins through for example pesticides or air pollution, exposure to electromagnetic fields, reduced amount of sleep and other influences. As two examples for this, see *Appendix E* on the causes of asthma and *Appendix F* on one possible factor in the epidemic of heart disease over the past century, the role of trans fats in our diet.
15. The medical treatment of many chronic lifestyle diseases such as ischaemic heart disease, hypertension, stroke, diabetes, asthma and cancer uses up most of the resources of the health service including drug budgets. **The anticipated increase in these conditions, especially**

obesity, diabetes and cancer is likely to financially crush the NHS. The cost of diabetes to the NHS is estimated at £5 billion per year. The economic cost of being obese or overweight is estimated in the region of £7 billion a year. The social, economic and health costs of heart disease is estimated to be another £7 billion per year. In addition to those costs, the social and economic cost due to incapacity, disability and death caused by these diseases can hardly be overestimated.

16. Currently, among the **highest prescribing drug costs in UK General Practice are cholesterol-lowering statins.** However, antihypertensives and inhalers for asthma/COPD also contribute very significantly to drug costs. Statins are currently prescribed to about 1.8 million people in the UK, at a cost of over £700 million a year. This is expected to rise to more than £2 billion a year by the year 2010. The figure of over £700 million a year spent on statins contrast with only £90 million spend by the NHS on dietetics.
17. The nutritional treatment of many chronic diseases is relatively cheap compared to drug costs. For example, one strategy for the secondary prevention of ischaemic heart disease (IHD) used a Mediterranean-style diet. This intervention led within three years to a 70% reduction in overall mortality rate, compared with the far more expensive statin treatment, which, over a five-year period led to a at most 30% reduction in overall mortality. Statin treatment is expensive. **For secondary prevention, statins costs in the range of £4,000- 9,000 per life-year saved. Primary prevention is even more expensive. Mediterranean diet is with a cost of around £300 per life-year saved only a fraction as expensive.**
18. Another study examined the impact of eating two or three portions of fatty fish per week on the survival of men with a previous heart attack. Within two years of the commencement of this simple diet change, a significant reduction in all-cause mortality was observed. This mortality reduction was similar to the reduction achieved in trials using statins for a period of over five years.
19. There has been a nearly fivefold increase in the prescription of lipid-lowering drugs, mainly statins, from 3.1 million to 17.6 million between 1996 and 2002. The cost to the NHS of prescribing lipid-lowering drugs rose from £93m in 1996 to £571m in 2002. Despite this massive increase in prescribing, there has been only a very modest reduction of admissions with myocardial infarction (MI) of less than 5% during the same period of time. **We are convinced that the currently adopted strategy of combating IHD with statins and neglecting more beneficial dietary interventions both for prevention and treatment is a grave misallocation of scarce public funds.** We are concerned that behind this is the influence of the pharmaceutical industry. (*see Appendix G*)
20. There is strong evidence from many studies that at least three dietary strategies are effective in preventing IHD: replace saturated and trans-fats with non-hydrogenated unsaturated fats, increase consumption of omega-3 fatty acids from fish or fish oils, and consume a diet high in fruits, vegetables, nuts, and whole grains and low in refined grain products. However the usual recommendation to simply reducing total fat in the diet is unlikely to reduce IHD. A recent review from Harvard University concluded: *“Substantial evidence indicates that diets using non-hydrogenated unsaturated fats as the predominant form of dietary fat, whole*

grains as the main form of carbohydrates, an abundance of fruits and vegetables, and adequate omega-3 fatty acids can offer significant protection against coronary heart disease. Such diets, together with regular physical activity, avoidance of smoking, and maintenance of a healthy body weight, may prevent the majority of cardiovascular disease in Western populations.”

21. There are examples of community-based intervention programmes, such as the **Finnish North Karelia Project, which influence diet and other lifestyles** that are crucial in the prevention of cardiovascular disease. Broad community organisation and the strong participation of people were the key elements. Following this, the diet of the population has changed and these changes have led to a major reduction in average serum cholesterol and blood pressure levels. Following this, **ischaemic heart disease mortality has declined by 73%** in North Karelia. The project was based on low-cost intervention activities, where people's participation and community organisations played a key role.
22. There is therefore overwhelming evidence showing that the majority of ischaemic heart disease can be prevented through lifestyle and diet changes. If ischaemic heart disease is established, nutritional and lifestyle treatment are far more cost effective than drug treatment. In view of this, it is **surprising that the major focus regarding prevention and treatment of ischaemic heart disease, based on guidance distributed to general practice is on drug treatment**. While there is a mention of lifestyle interventions in guidance, these appear to take second place to drug treatment. We strongly suspect that the reason for this imbalanced approach is the influence of the pharmaceutical industry wanting to create and maintain a significant market for their drugs.

Conclusion

23. By virtue of the enormous financial resources at their disposal, **major pharmaceutical companies exercise an undue and unhealthy influence on medical research and practice**.
 24. The greatest care needs to be exercised **by the Government to counterbalance the influence of powerful pharmaceutical companies on public policy and academic research**.
 25. Whilst recognizing that the pharmaceutical industry plays a fundamental and often beneficial role in the health service, there is a **real danger of commercial interests generating long-term dependency on those medicaments which contribute most to profits**.
 26. It is imperative that wherever possible **professional appointment to public advisory bodies making far-reaching recommendations regarding treatment should not be directly or indirectly linked to companies operating in the pharmaceutical industries**. Where this is unavoidable, actual or potential conflicts of interest must be declared.
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APPENDICES – SUPPORTING EVIDENCE

Appendix A

Research into the effects of industry sponsoring shows that funding affects the outcome of research. Industry-sponsored trials are significantly more likely to come to a positive conclusion regarding a certain drug treatment than independently sponsored trials.

- In an analysis of 370 studies by different sponsors it was found that the experimental drug was recommended as treatment of choice in 16% of trials funded by nonprofit organizations, 30% of trials not reporting funding, 35% of trials funded by both nonprofit and for-profit organizations, and 51% of trials funded by for-profit organizations. **Trials funded by drug companies were 5.3 times more likely to recommend the experimental drug as treatment of choice.** (Als-Nielsen B et al. Association of funding and conclusions in randomized drug trials: a reflection of treatment effect or adverse events? JAMA. 2003; 290: 921-8.)
- **Pharmaceutical company-sponsored studies in oncology were less likely than nonprofit-sponsored studies to report unfavorable qualitative conclusions (1/20 [5%] vs 9/24 [38%]; P = .04).** (Friedberg M et al. Evaluation of conflict of interest in economic analyses of new drugs used in oncology. JAMA. 1999; 282: 1453-7.)
- **Studies sponsored by selective serotonin reuptake inhibitor (SSRI) manufacturers favoured SSRIs over tricyclic antidepressants more than non-industry-sponsored studies.** Studies sponsored by manufacturers of newer antidepressants favoured these drugs more than did non-industry-sponsored studies. Studies of antidepressants reveal clear associations of study sponsorship with quantitative outcome. (Baker CB et al. Quantitative analysis of sponsorship bias in economic studies of antidepressants. Br J Psychiatry. 2003; 183: 498-506.)

Appendix B

A system of classifying evidence based on the quality of the research quoted is widely used in guidelines development. As an example, see the Scottish Intercollegiate Guidelines Network (SIGN) classification (<http://www.sign.ac.uk/guidelines/fulltext/50/section6.html>)

Levels of evidence (SIGN)

1++	High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1 -	Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2 -	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

Grades of recommendation (SIGN)

A	At least one meta analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+

It is surprising that no such system is in use to classify research in the degree of independency from industry. The evidence in Appendix A shows the degree to which industry sponsoring affects the results of research. Industry sponsoring therefore has to be treated like research bias and needs to be reported as such.

We therefore propose the following classification system for research as a basis for discussion:

Proposed Levels of evidence – Industry dependence

1++	High quality meta analyses, systematic reviews of RCTs, or RCTs without industry sponsorship (funded by independent sector)
1+	Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias due to some industry sponsorship, however research and writing of paper independent of industry
1 -	Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias due to industry sponsorship
2++	High quality systematic reviews of case-control or cohort studies High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal independent of industry
2+	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2 -	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4+	Expert opinion without conflict of interest
4-	'Expert opinion with conflict of interest due to links with pharmaceutical industry

Proposed Grades of recommendation

(ind) stands for independence from industry

A (ind)	At least one meta analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B (ind)	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
C (ind)	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
D (ind)	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+
W (ind)	(Warning) that there is no research on this subject independent of industry.

Appendix C

Cholesterol lowering guidelines issued in July by the US National Institutes of Health (NIH) are being challenged by a consumer organisation that is petitioning the NIH to appoint an independent panel to review them. The petition, organised by the Center for Science in the Public Interest, a consumer advocacy organisation funded by subscribers to its newsletter and by individual donors, has asked the NIH to "create an independent review panel free of conflicts of interest to review all the data in the five studies that led to [the July] update... If warranted, [the NIH] should issue revised conclusions."

The request follows the revelation that eight of the nine authors of the guidelines had failed to disclose financial associations with the manufacturers of cholesterol lowering agents (BMJ; 31 July 2004;429: 247). The guidelines, devised by the national cholesterol education programme of the NIH's National Heart, Lung, and Blood Institute, were endorsed by the American Heart Association—which also receives funding from the makers of statins. "This [petition] isn't just based on conflicts of interest," said Merrill Goozner, director of the Integrity in Science project at the Center for Science in the Public Interest. "It's based on anomalies in the science. The update went too far, and we want independent experts to do a systematic reanalysis of the data." The new guidelines recommend lowering the threshold for treating low density lipoprotein cholesterol levels from 130 mg/dl (3.4 mmol/l) to 100 mg/dl for patients without heart disease and from 100 mg/dl to 70 mg/dl for patients with previously existing heart disease. But primary prevention is unproved even in patients with multiple risk factors—including diabetes, argued the consumer group. The group's petition claims that the guidelines, which cited the heart protection study as showing that statins were beneficial for primary prevention for diabetics, "ignore the three other studies under review that found that statins did not provide significant benefit to people with diabetes." The new guidelines will radically increase the number of people taking cholesterol lowering drugs, said Dr John Abramson, clinical instructor at Harvard Medical School, Boston, Massachusetts, author of *Overdosed America: The Broken Promise of American Medicine*, and one of the signatories to the petition. He told the BMJ: "In the one group that could benefit, men aged under 65 with multiple risk factors, you'd have to treat 238 men for one year to prevent one heart attack, and to prevent one death you'd have to treat 526 patients for one year." "While statins are clearly beneficial in certain high risk individuals," said Dr Abramson, "exercising, eating a healthy diet, and not smoking each individually appear to give more protection against heart disease, as well as the added benefit of preventing diabetes, osteoporosis, and multiple other diseases. One can't help wondering whether the ties between the authors and the statin makers contribute—consciously or unconsciously—to their focus on drugs." Dr Barbara Alving, acting director of the National Heart, Lung, and Blood Institute, issued a statement in response to the petition, saying that the institute "stands behind" the guidelines and that "several clinical trials in high risk individuals are currently under way." Dr Alving added that the National Heart, Lung, and Blood Institute was working on further "refining the process for management of potential conflict of interest." (Jeanne Lenzer. *British Medical Journal*; 2nd October 2004; 329: p.759.)

Appendix D

Pharmaceutical companies wanting to close down the sale of herbal remedies.

There now appears no chance of stopping an EU Directive which will close down most of Britain's 2000 health shops. It is part of the huge programme of EU legislation which is being "fast-tracked". Pharmaceutical companies have been lobbying behind the scenes for years to introduce the "Herbal Medicines Products" Directive. It is a specifically British initiative, championed by our Medicines Control Agency and seeks to apply to herbal remedies the principle of continental law that things can only be allowed when they are specifically authorised. This reverses the British tradition that everything is allowed unless specifically prohibited. Under the directives such herbal remedies as Hypericum, Rhodiola and Echinacea, used by 5 million people in Britain for a wide range of conditions, could only be sold if they had been through the MCA's prohibitively expensive licensing procedures. Thousands of safe herbal products will have to be removed from the market. There are no health reasons for banning the 3,000 herbal preparations currently on sale in Britain. Almost all adverse reactions linked to herbal remedies (infinitely fewer than those due to synthetic drugs made by pharmaceutical firms) are caused by preparations made up by Chinese practitioners, but these are specifically exempted from the Directive. (Sunday Telegraph 21.7.02)

Appendix E

Asthma as an example of a chronic condition that is associated with 'western lifestyle' including 'westernised diet'.

In this submission, we maintain that many of the chronic medical conditions currently encountered in the health service are due to lifestyle changes, following the adoption of a 'westernised lifestyle' which includes a 'westernised diet'. One condition, that has increased dramatically over the past decades is asthma. While perhaps the impact of diet and lifestyle in the aetiology of many chronic diseases such as hypertension, obesity, ischaemic heart disease etc. is well recognised, we believe that there is far less awareness about the contribution of diet and lifestyle in the aetiology of asthma. There is a lot of evidence, however that asthma, too, is a lifestyle disease that accompanies the westernized way of living.

Because of lack of space, we want to use asthma as only one example of a condition, where western diet and lifestyle play an important role in aetiology. We believe that there is sufficient evidence to show that this is the case too for many other conditions such as obesity, hypertension, ischaemic heart disease, diabetes and others. Obviously, an understanding of the aetiology of those chronic conditions – including asthma – could lead to their prevention and treatment.

In this context we deplore that the conventional treatment of most of the chronic medical conditions mentioned above does not take dietary and lifestyle aspects sufficiently into account. There appears to be too much emphasis on the pharmacological treatment of these conditions using drug therapies. This is also the case with asthma. This raises the suspicion that there are strong financial interests in research aimed at the treatment rather than the prevention of asthma and most other chronic diseases. Obviously it is far more lucrative for the pharmaceutical industry to treat a chronic and frequently lifelong condition with medication than it is to prevent its onset or find a cure in the first place.

- There is a **significant increase in the prevalence of asthma**. The increase has been substantial in many developed countries. In the UK, asthma has more than doubled among adults over a 20-year period. One-third of UK schoolchildren aged 12-14 report wheezing in the past year and one-fifth reported ever having a diagnosis of asthma. In developing countries, **this increase is associated with the degree of affluence** in the population. This suggests, that lifestyle changes ("westernised lifestyle") including changes in nutrition play a part in this. (Upton MN et al. Intergenerational 20 year trend in the prevalence of asthma and hay fever in adults: The Midspan family study surveys of parents and offspring. *BMJ* 2000; 321: 88-92. Kaur B et al. Prevalence of asthma symptoms, diagnosis, and treatment in 12-14 year old children across Great Britain (international study of asthma and allergies in childhood, ISAAC UK). *BMJ* 1998; 316: 118-24. Carey OJ et al. The effect of lifestyle on wheeze, atopy and bronchial hyperreactivity in Asian and white children. *American Journal of Respiratory and Critical Care medicine*. 1996; 154: 537-40.)
- **Evidence linking nutritional and lifestyle factors but also environmental factors with the increased incidence of asthma** are the following (Brostoff, J and Gamlin, L. *Asthma, the complete guide*. London 1999; p79 ff.):
 1. **Among Black South Africans moving to Cape Town the rates of asthma in the next generation are 20 times higher than in the rural villages, where the people originated.**
 2. Chinese people in Taiwan who have stayed in the same place but gradually adopted a Westernised lifestyle now have eight times more cases of childhood asthma than they had in 1974.
 3. **Children in West Germany – despite breathing cleaner air - had far more allergies and asthma than children living in areas in East Germany with heavy air pollution.**

4. Children aged 6-7 who eat kiwi or citrus fruit rich in Vitamin C five to seven times per week compared with those who eat fruit less than once per week have a significantly reduced risk of wheeze, cough and shortness of breath (Forastiere F et al. Consumption of fresh fruit rich in Vitamin C and wheezing symptoms in children. *Thorax* 2000; 55: 283-8.)
 5. In a group of schoolchildren followed up since 1964 the risk of **bronchial hyperreactivity** (a marker of how susceptible a person is to asthma) **was increased seven-fold among those with the lowest intake of Vitamin C, while the lowest intake of saturated fats gave a ten-fold protection.** The risk of adult-onset wheezy illness is increased fivefold by the lowest intake of Vitamin E and doubled by the lowest intake of Vitamin C (Seaton A and Devereux G. Diet, infection and wheezy illness: lessons from adults. *Pediatric Allergy and Immunology* 2000; 11: (Suppl). 1337-40).
 6. Lower dietary intake of Zinc and Magnesium has been found to increase the risk of asthma in a Scottish study. The lowest intake of Vitamin C and Manganese were associated with more than five-fold increased risk of bronchial reactivity. **The observed reduction in antioxidant intake in the British diet over the last 25 years is considered to be a likely factor in the increase in asthma over this period** (Soutar A et al. Bronchial reactivity and dietary antioxidants. *Thorax* 1997; 52: 166-70)
- There are many possible causes for the asthma epidemic including **change in diet, less ventilation, more heating and more carpets** in houses (encouraging growth in moulds and **house dust mites**), more time spent indoors, **soft toys, maternal/parental cigarette smoking, increasing prevalence of obesity, lead toxicity**, changing pattern of childhood illnesses, early introduction of solids and **reduced rate of breastfeeding, antibiotic prescribing in early childhood**, frequent (i.e. daily or weekly) **paracetamol use** and others. For a detailed discussion of these issues – including allergen avoidance – please see Professor Brostoff's review (Brostoff, J and Gamlin, L. *Asthma, the complete guide.* London 1999)
 - Current thinking on asthma focuses on the role of inflammatory processes in the lung. Airways inflammation is thought to be the major cause of hyper reactive airways in asthma causing bronchoconstriction The balance between oxidants and antioxidants is vital in this respect. An decrease in antioxidants may render individuals more susceptible to developing lung disease, especially asthma, but also pulmonary fibrosis, respiratory distress syndrome and cystic fibrosis (Rahman I and MacNee W. Oxidative stress and regulation of glutathione in lung inflammation. *European Respiratory Journal* 2000; 16: 534-54.).
 - Even though some studies do not find an association between diet and asthma (Picado C et al. Dietary micronutrients/antioxidants and their relationship with bronchial asthma severity. *Allergy: European Journal of Allergy and Clinical Immunology* 2001; 56: 43-9.), overall there is quite a lot of evidence linking diet and asthma prevention – (for two recent reviews see Fogarty A and Britton J. The role of diet in the aetiology of asthma. *Clinical and Experimental Allergy* 2000; 30: 615-27. Smit HA. Chronic obstructive pulmonary disease, asthma and protective effects of food intake: from hypothesis to evidence? *Respiratory Research* 2001; 2: 261-4.)
 - **People who eat more fruit have better spirometry values and are less likely to develop asthma and emphysema.** Population studies involving over 2800 adults found a positive association between fresh fruit consumption and lung function with a 78 ml lower FEV1 (forced expiratory volume in one second – a measure of lung function) for adults who have fresh fruit less than once a week during winter. In a population of 2650 children aged 8-11 those who never ate any fresh fruit had a FEV1 of 79 ml (4.3%) lower than those who ate fresh fruit more than once a day. In a Dutch study, fruit intake was inversely related to the development of chronic lung disease over a 25-year period. Smokers who reduced their level of fresh fruit consumption the most lost 167 ml (non-smokers 101 ml) more of FEV1 over a 7-year period than those who did not reduce their fresh fruit consumption. (Strachan D et al. Ventilatory function and winter fresh fruit consumption in a random sample of British adults. *Thorax* 1991; 46: 624-9. Cook DG et al. Effect of fresh fruit consumption on lung function and wheeze in children. *Thorax* 1997; 52: 628-33. Miedema I et al. Dietary determinants of long-term incidence of chronic non-specific lung diseases: the Zutphen study. *American Journal of Epidemiology* 1993; 138: 37-45. Carey IM et al. Effects of changes in fresh fruit consumption on ventilatory function in healthy British adults. *American Journal of Respiratory and Critical Care Medicine* 1998; 158: 728-33.)
 - Flavonoids are substances widely found in many plants such as fruits and vegetables but also plant products such as tea and wine. They have anti-inflammatory and antioxidative effects. They are thought to reduce the risk of heart disease and cancer and have been associated with healthier lungs. A high intake of Flavonoids – mainly from tea and apples - has been associated with a higher FEV1 and reduced risk of breathlessness and chronic cough. **Eating five or more apples per week is associated with a 138 ml higher FEV1 compared to non-consumers.** This association was independent of both Vitamin C and Vitamin E intake (Tabak C et al. Chronic obstructive pulmonary disease and intake of catechins, flavonols, and flavones. The MORGEN study. *American Journal of Respiratory and Critical Care Medicine* 2001; 164: 61-64. Butland BK et al. Diet, lung function, and lung function decline in a cohort of 2512 middle aged men. *Thorax* 2000; 55: 102-8.)
 - Intake of Vitamin C can prevent asthma. Vitamin C is a powerful antioxidant and can reduce the inflammation in airways. In some - however, not all - studies, it has a positive effect on lung function, airways reactivity and frequency of respiratory infections. In a population study in Nottingham, a 40 mg increase in vitamin C intake was associated with a 25 ml increase in FEV1. In a Dutch population study a 53 ml increase in FEV1 between the lowest and highest vitamin C intakes has been found. Effects of Vitamin C supplementation in short-term studies included a reduction in exercise-induced bronchospasm and decreased bronchial reactivity. In a long-term study a reduction in severity and frequency of asthma attacks over a 14 week period was noted. Vitamin C also leads to the

production of a natural bronchodilator. (Bucca C et al. Effect of vitamin C on histamine bronchial responsiveness of patients with allergic rhinitis. *Ann Allergy* 1990;65:311-4. Bielory L and Gandhi R. Asthma and Vitamin C. *Annals of Allergy* 1994; 73: 89-99. Britton JR et al. Dietary antioxidant vitamin intake and lung function in the general population. *American Journal of Respiratory and Critical Care Medicine* 1995; 151: 1383-7.)

- Magnesium relaxes airway muscles and a high intake of magnesium (found in dark green vegetables, cereals, nuts and dairy products) is associated with healthier airways. **A 100 mg/day higher magnesium intake is associated with a 27.7 ml higher FEV1 and on average 18% reduced risk of hyper reactive airways.** Asthmatics may have low serum magnesium, and asthmatics with a low serum magnesium are three times more likely to be hospitalised. However more commonly, only the intracellular magnesium is reduced (while serum magnesium is normal), as evidenced by reduced red cell magnesium. Intravenous magnesium has been successfully used in the treatment of asthma attacks, often improving symptoms within minutes. Intravenous magnesium led to an 130 ml increase in FEV1 in stable asthmatics and oral magnesium supplementation (300 mg/day) decreased bronchial reactivity. Taking 400 mg of magnesium per day for three weeks reduced asthma symptoms significantly, however no change in lung function was observed. A positive effect has also been observed in exacerbation of chronic obstructive airways disease (COPD). (Britton J et al. Dietary magnesium, lung function, wheezing, and airway hyper reactivity in a random adult population sample. *Lancet* 1994; 344: 357-62. Emelyanov A et al. Reduced intracellular magnesium concentrations in asthmatic patients. *European Respiratory Journal* 1999. 13: 38-40. Skobeloff EM et al. Intravenous magnesium sulfate for the treatment of acute asthma in the emergency department. *JAMA* 1989;262:1210-3. Hill J, Britton J. Effect of intravenous magnesium sulphate on airway calibre and airway reactivity to histamine in asthmatic subjects. *British Journal of Clinical Pharmacology* 1996; 42:629-31.)
- Selenium is essential for the antioxidant enzymes glutathion peroxidase. It is found in grains and fish. There are concerns about decreasing selenium intake in the average British diet. In a population study in London, **a significant risk reduction of the prevalence of asthma was found with increasing dietary selenium intake.** People with low levels of selenium have a high – up to fivefold - increased risk of asthma. Asthmatics have also lower serum-selenium levels than non-asthmatics and in a small study selenium supplementation (100 micrograms selenium/day over 14 weeks) led to clinical improvement in half of asthmatic patients. (Shaheen SS, et al. Dietary antioxidants and asthma in adults. Population based case-control study. *American Journal of Respiratory and Critical Care Medicine* 2001; 164: 1823-8. Stone J et al. Reduced selenium status of patients with asthma. *Clinical Science* 1989; 77: 495-500. Flatt A et al. Reduced selenium in asthmatic subjects in New Zealand. *Thorax* 1990;45:95-9. Misso NLA et al. Reduced platelet glutathion peroxidase activity and selenium concentrations in atopic asthmatic patients. *Clinical and experimental Allergy*. 1996; 26: 838-47. Hasselmark, L et al. Selenium supplementation in intrinsic asthma. *Allergy* 1993;48:30-6)
- A strong correlation was found between table salt purchase and asthma mortality in both men and children, but not in women. **A high intake of salt is associated with an increased airways reactivity.** Switching from a low-sodium to a high-sodium diet led to an increased use of asthma medication, increased asthma symptoms and reduction in lung function in men with asthma. In a study of 2593 children aged 9 to 16, a high table salt intake was strongly related to cough, wheeze and wheeze with shortness of breath in boys, but not in girls. A reduction in salt intake improves asthma symptoms and the need for medication. (Burney P. A diet rich in sodium may potentiate asthma. Epidemiologic evidence for a new hypothesis. *Chest* 1987; 91 (Suppl): 143S-148S. Burney et al. Response to inhaled histamine and 24 hour sodium excretion. *British Medical Journal* 1986; 292 : 1483-6. Carey OJ et al. Effect of alterations of dietary sodium on the severity of asthma in men. *Thorax* 1993;48:714-8. Pistelli R et al. Respiratory symptoms and bronchial responsiveness are related to dietary salt intake and urinary potassium excretion in male children. *European Respiratory Journal* 1993; 6: 517-22. Burney P et al. Effect of changing dietary sodium on the airway response to histamine. *Thorax* 1989; 44: 36-31.)
- Zinc acts as an anti-oxidant and anti-inflammatory in the airways and protects the airways. Asthmatics have lower blood Zinc levels than controls, however one study found only reduced hair zinc levels in atopic children, but normal blood zinc levels. (Truong-Tran AQ et al. New insights into the role of Zinc in the respiratory epithelium. *Immunology and Cell Biology* 2001; 79: 170-7. Di-Toro R et al. Zinc and copper status of allergic children. *Acta Paediatrica Scandinavica* 1987; 76: 612-7.)
- Asthmatics who were given dietary antioxidant combinations (Vitamin E 400 IU and vitamin C 500 mg) responded less severely to ozone air pollution. The combination of Vitamin C, Vitamin E and beta-carotene prevented bronchoconstriction in Mexicans exposed to high ozone concentrations and the same combination of antioxidants for three months prevented bronchoconstriction in cyclists after ozone exposure. (Trenka DA et al. Dietary antioxidants and ozone-induced bronchial hyperresponsiveness in adults with asthma. *Archives of Environmental Health* 2001; 56: 242-4. Romieu S et al. Antioxidant supplementation and respiratory functions among workers exposed to high levels of ozone. *American Journal of Respiratory and Critical Care Medicine* 1998; 158: 226-32. Grievink L et al. Acute effects of ozone on pulmonary function of cyclists receiving antioxidant supplements. *Occupational and Environmental Medicine*. 1998; 55: 13-7.)
- **We conclude that dietary together with environmental interventions should reduce the development of asthmatic symptoms and should prove a cost effective approach to asthma management in addition to current pharmacotherapy.** It is estimated, that with interventions based on current knowledge, **a 50% reduction in the prevalence of asthma in the next generation of children could be achieved.** However, the main focus still is on treatment – for example with inhalers – rather than on prevention. (Greene LS.

Appendix F

1. Trans Fatty Acids – background

The example of how changes in diet lead to an epidemic of heart disease can be shown with the example of trans fatty acids. These are 'artificial' fats used in processed foods such as ready-made meals and margarines. If the cause of ischaemic heart disease is indeed nutritional and lifestyle, why is the main treatment proposed today through drug treatment? We are convinced that this is another area, where the pharmaceutical industry has influenced medical treatment.

- A recent review by the Departments of Nutrition and Epidemiology, Harvard School of Public Health, analyses the **dangers of trans fatty acids, in particular their association with coronary heart disease**: (Asherio, A; Stampfer MJ and Willett WC. Trans fatty acids and coronary heart disease. Background and scientific review. Harvard College. November 15, 1999.)
- Trans unsaturated fatty acids, or trans fats, sometimes called hydrogenated vegetable oils are solid fats produced artificially by heating liquid vegetable oils. This process, partial hydrogenation, causes carbon atoms to bond in a straight configuration ('trans') and remain in a solid state at room temperature. Naturally-occurring unsaturated fatty acids have carbon atoms that line up in a bent shape ('cis'), resulting in a liquid state at room temperature.
- Trans fats are produced commercially in large quantities to harden vegetable oils into shortening and margarine. Food manufacturers also use partial hydrogenation of vegetable oil to destroy some fatty acids which tend to oxidize, causing fat to become rancid with time. The oils used to cook french fries and other fast foods are usually partially hydrogenated oils, containing trans fats. Commercial baked goods frequently include trans fats to protect against spoilage.
- Commercial production of partially hydrogenated fats began in the early 20th century and increased steadily until about the 1960s as processed vegetable fats displaced animal fats in the diets of the U.S. and other Western countries. Lower cost was the initial motivation, but health benefits were later claimed for margarine as a replacement for butter. Although the average level of trans fat in margarines has declined with the advent of softer versions, per capita consumption of trans fatty acids has not changed greatly since the 1960s because of the increased use in commercially-baked products and fast foods.

2. Adverse health effects of trans fats

- **Concerns have been raised for several decades that consumption of trans fatty acids might have contributed to the 20th century epidemic of coronary heart disease.** (Booyens J, et al. The role of unnatural dietary trans and cis unsaturated fatty acids in the epidemiology of coronary artery disease. Med Hypotheses 1988; 25:175-182)
- **Metabolic studies** have shown that trans fats have adverse effects on blood lipid levels -increasing LDL cholesterol (low-density lipoprotein, the 'bad' cholesterol) while decreasing HDL cholesterol (high-density lipoprotein cholesterol, the 'good' cholesterol). This combined effect on the ratio of LDL to HDL cholesterol is double that of saturated fatty acids. Thus individuals who are replacing butter with margarine high in trans fat to reduce their risks of coronary disease may obtain no benefit or - if trans fat has deleterious effects beyond those on LDL and HDL - may even increase their risk. Trans fatty acids increase Lipoprotein A [Lp(a)] when substituted for saturated fat. High blood levels of Lp(a) have been associated in some studies with increased risk of coronary heart disease, independently of LDL or HDL cholesterol concentrations
- **Epidemiological studies** The relation between trans fatty acids intake and risk of coronary disease has now been reported from three large prospective studies, the Health Professionals Follow-up Study, the Alpha-Tocopherol Beta-Carotene study and the Nurses Health Study. A pooled estimate of the results of these three studies gives a on average 31% increase for developing heart disease for an increase in trans consumption of 2% of energy The studies provide strong evidence that trans fatty acids consumption increases substantially the risk of CHD. (Ascherio A, et al. Dietary fat and risk of coronary heart disease in men: cohort follow up study in the United States. BMJ 1996; 313:84-90. Pietinen P, et al. Intake of fatty acids and risk of coronary heart disease in a cohort of Finnish men: The ATBC Study. Am J Epidemiol 1997; 145:876-887. Hu FB, et al. Dietary fat intake and the risk of coronary heart disease in women. N Engl J Med 1997; 337:1491-1499.)
- The Harvard review calculates the following figures for the number of deaths that may be due to consumption of trans fatty acids from partially hydrogenated fat in the amount of 2% energy (approximately the U.S. average). In the US, approximately 30,000 premature coronary heart disease deaths annually could be attributable to consumption of trans fatty acids. By a conservative estimate, **replacement of partially hydrogenated fat in the U.S. diet with natural unhydrogenated vegetable oils would prevent approximately 30,000 premature coronary deaths per year.** Epidemiologic evidence suggests this number is closer to 100,000 premature coronary deaths avoided annually. This is nearly a quarter of all coronary deaths. These reductions are higher than what could be achieved with realistic reductions in saturated fat intake. (Willett WC, Ascherio A. Trans fatty acids: Are the effects only marginal? Am J Public Health 1994; 84:722-724.)

- Similar figures have been calculated for the **Netherlands, where the reduction in trans fat consumption from 4.3% to 1.9% of energy intake in between 1985 and 1995 is thought to have prevented about 23% of coronary deaths.** On this basis, further reductions in the trans fat content of fast food and confectionary are likely to be required. (Oomen CM, et al. Association between trans fatty acid intake and 10-year risk of coronary heart disease in the Zutphen Elderly Study: a prospective population-based study. *Lancet* 2001; 357: 746-51. Aro A. Complexity of the issue of dietary trans fatty acids. *Lancet* 2001; 357: 732-33.)
- A recent analysis for the UK estimates the dietary intake of trans fatty acids at around 1.3% of total energy intake. The consumption estimate was based on a seven day survey of 8000 households carried out by in 1994. The mean total fat intake was 77g/day, equivalent to 35.7% of energy intake. Mean trans fatty acid consumption was 2.8g/day (= 1.3% of energy) and 28.5g/day (= 13.2% of energy) was as saturated fatty acids. (Hulshof KFM et al. Intake of fatty acids in Western Europe with emphasis on trans fatty acids: the TRANSFAIR study. *European Journal of Clinical Nutrition* 1999; 53: 143-57)
- **What alternatives exist to trans fats?** In Europe, producers have responded to the evidence on effects of trans fats by developing trans-free margarines that are also low in saturated fats. It is thus evident that trans-free products are feasible, and that the technical constraints often invoked by the food industry can be overcome. However, out of the trans fatty acids provided by hydrogenated vegetable oil in the U.S., only 25% to 37% comes from margarines, the remainder comes from baked goods, fast foods and other prepared foods. Replacement of trans in such products by healthier fats may be more difficult than in margarines, but can be achieved. In spite of this, many products including most baked goods and fried fast foods still are made with partially hydrogenated fat both in Europe and in the U.S. and are high in trans fatty acids.

Appendix G

Comparison of diet treatment versus statins in secondary prevention of ischaemic heart disease show that nutritional interventions appear to have twice the beneficial impact on total mortality than drug treatment with statins. At a fraction of the cost of statin treatment, diet changes are far more cost-effective than statin treatment. Nutritional interventions – together with stopping smoking, regular exercise and maintaining a healthy body weight can prevent the majority of heart disease.

- In a prospective, randomised secondary prevention trial the effect of a **Mediterranean alpha-linolenic acid-rich diet** was compared to the usual post-infarct prudent diet. After a first myocardial infarction, patients were randomly assigned to the experimental (n = 302) or control group (n = 303). Serum lipids, blood pressure, and body mass index remained similar in the 2 groups. After a mean follow up of 27 months, there were 16 cardiac deaths in the control and 3 in the experimental group; 17 non-fatal myocardial infarction in the control and 5 in the experimental groups. **Overall mortality was 20 in the control, 8 in the experimental group, an adjusted risk ratio of 0.30** (95% CI 0.11-0.82, p = 0.02). (de Lorgeril M et al. Mediterranean alpha-linolenic acid-rich diet in secondary prevention of coronary heart disease. *Lancet*. 1994; 343: 1454-9.)
- In the Scandinavian Simvastatin Survival Study, 4444 patients with ischaemic heart disease including angina pectoris or previous myocardial infarction and serum cholesterol 5.5-8.0 mmol/L on a lipid-lowering diet were randomised to double-blind treatment with simvastatin or placebo. Over the 5.4 years median follow-up period, simvastatin produced mean changes in total cholesterol, low-density-lipoprotein cholesterol, and high-density-lipoprotein cholesterol of -25%, -35%, and +8%, respectively. 256 patients (12%) in the placebo group died, compared with 182 (8%) in the simvastatin group. **The relative risk of death in the simvastatin group was 0.70** (95% CI 0.58-0.85, p = 0.0003). (Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study. *Lancet*. 1994; 344:1383-9.)
- Comparing these early studies on the secondary prevention of ischaemic heart disease it becomes obvious that the dietary intervention using a Mediterranean- type diet (essentially replacing all fats with olive oil or olive-oil based fats) led to a 70% reduction in overall mortality after less than 3 years treatment. In a study using cholesterol-lowering statin treatment (4S study), after over 5 years, there was a mortality reduction of 30%. While it is not possible to immediately compare both studies it is noteworthy that the dietary intervention led to a significantly greater total mortality reduction after a much shorter period than the expensive statin treatment.
- In a secondary prevention trial in 2033 Men who suffered an MI several interventions were chosen among three subgroups. Two subgroups who reduced their fat intake or increased their fibre intake had no significant difference in mortality. However the subgroup where patients were advised to eat fatty fish (two or three portions per week) **The subjects advised to eat fatty fish had a 29% reduction in 2 year all-cause mortality** compared with those not so advised. (Burr ML et al. Effects of changes in fat, fish, and fibre intakes on death and myocardial reinfarction: diet and reinfarction trial; DART. *Lancet*. 1989 Sep 30 :757-61.)

- In a Health technology assessment the **cost-effectiveness of statins in saving lives was compared to the cost-effectiveness of other interventions, including Mediterranean diet. Statins were the least cost-effective intervention.** In primary prevention, based on IHD risk at levels of risk expected in primary prevention, the cost per life-year gained ranged from £5400 to £13,300 per life-year gained. This figure is lower in a **range from £3800 to £9300 for secondary prevention of IHD.** We are aware that this review was carried out before Simvastatin came off patent, the cost of statins therefore can be somewhat lower than using the data of those assessments. Use of low cost statins had the potential to reduce gross costs by 60%. The cost-effectiveness of other treatments was much better than for statins. **Cost per life-year saved** of aspirin (£53), bendrofluazide treatment for elderly people with hypertension (£45), low cost mixed drug antihypertensive regimens for middle-aged people (£1509), beta-blockers following myocardial infarction (£227) **and Mediterranean diet following myocardial infarction (£293) were all lower than for statins.** (Ebrahim S, et al. What role for statins? A review and economic model. Health Technol Assessment 1999)
- A recent analysis of data correlating primary care prescription of lipid lowering drugs to admissions for acute Myocardial infarction found only a small benefit from widespread statin prescribing. **Prescriptions of lipid regulating drugs (largely statins) increased from 3.1m to 17.6m items during 1996-2002, a total cost to the NHS of £571m in 2002 compared with £93m in 1996.** The standardised admission ratio for acute myocardial infarction fell from the baseline of 100.0 in 1996-7 to 95.8 in 2002-3. The authors conclude: **"Our results indicate that a large increase in the cost and volume of the prescribing of lipid regulating drugs has been associated with only a modest reduction in admission rates for myocardial infarction. During the study period, statins were recommended for high risk patients, but many myocardial infarctions occur in people at low risk who would not have been recommended for treatment with statins. This would limit the population impact of the increase in the prescribing of statins."** (Azeem Majeed et al. Prescribing of lipid regulating drugs and admissions for myocardial infarction in England. BMJ 329; 645. 18 September 2004)
- In an electronic response to this paper, the Director of Nutrition and dietetics at King's College states: **"I find it quite appalling that the statin bill for 2002 has risen to some £571M. Total NHS spending on dietetics of any kind is at most £90M. Perhaps if £571M were spent we might have some chance of helping patients to make informed choices about food and health rather than dosing them up with one medication after another."** (Richard C Wilson, Director of Nutrition and Dietetics, King's College Hospital, London; *British Medical Journal electronic response 20 September 2004*)
- Reviewing 147 studies that examine the relationship between diet and Heart disease, the Department of Nutrition, Harvard School of Public Health, finds strong evidence supporting the role of prevention of heart disease through diet. The authors state: 'Compelling evidence from metabolic studies, prospective cohort studies, and clinical trials in the past several decades indicates that at least 3 dietary strategies are effective in preventing CHD: substitute nonhydrogenated unsaturated fats for saturated and trans-fats; increase consumption of omega-3 fatty acids from fish, fish oil supplements, or plant sources; and consume a diet high in fruits, vegetables, nuts, and whole grains and low in refined grain products. However, simply lowering the percentage of energy from total fat in the diet is unlikely to improve lipid profile or reduce CHD incidence.' They conclude: **'Substantial evidence indicates that diets using nonhydrogenated unsaturated fats as the predominant form of dietary fat, whole grains as the main form of carbohydrates, an abundance of fruits and vegetables, and adequate omega-3 fatty acids can offer significant protection against CHD. Such diets, together with regular physical activity, avoidance of smoking, and maintenance of a healthy body weight, may prevent the majority of cardiovascular disease in Western populations.'** (Hu FB, Willett WC. Optimal diets for prevention of coronary heart disease JAMA. 2002 Nov 27;288 (20):2569-78.)
- The Finnish North Karelia Project was launched in **1972 as a community-based, and later as a national, programme to influence diet and other lifestyles** that are crucial in the prevention of cardiovascular disease. The intervention had a strong theory base and it employed comprehensive strategies. Broad community organisation and the strong participation of people were the key elements. Evaluation has shown how the diet (particularly fat consumption) has changed and how these changes have led to a major reduction in population serum cholesterol and blood pressure levels. It has also shown how **ischaemic heart disease mortality in a working-age population has declined by 73% in North Karelia** and by 65% in the whole country from 1971 to 1995. Although Finland is an industrialised country, North Karelia was rural, of rather low socio-economic level and with many social problems in the 1970s and 1980s. The project was based on low-cost intervention activities, where people's participation and community organisations played a key role. (Pekka P. et al. Influencing public nutrition for non-communicable disease prevention: from community intervention to national programme--experiences from Finland. Public Health Nutr. 2002 Feb;5(1A):245-51.)

