

## Newsletter no 47: October 2002

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## Support for Europe's herb directive in face of celebrity protest

***HealthWatch has responded to the Department of Health in support of proposals for tighter laws on herbal remedies amidst protest from retailers, consumer groups and celebrities such as Sir Elton John and Sir Paul McCartney.***

The Traditional Herbal Medicinal Products Directive aims to standardise regulations across Europe. But the group Consumers for Health Choice (CHC) believes that the legislation would effectively ban any herbal medicinal product that has not been on the market for 30 years and would mean long established remedies being taken out of health food shops, until they have been subjected to a long, expensive testing process, as well as damaging the UK's £70m a year herbal medicine industry.

Professor John Garrow, Honorary Secretary of HealthWatch, argues that the proposals have been misinterpreted. In his response letter to Lord Hunt at the Department of Health he says, "As we read the draft directives 'long established remedies' would not be taken out of health food shops unless, in the two years before the regulations came into effect, the producers of these remedies could not show that they were of good quality. It is not a major infringement of consumers' choice if they are prevented from buying herbal remedies that are not produced in compliance with Good Manufacturing Practice if the same product, of good quality, is available elsewhere. Presumably the major manufacturers who say there is no problem are confident that their product is of good quality.

"Concerning herbal products that have not been used in EU countries for the required 30 years we do not think that the requirements under the proposed Directive are unreasonable. The evidence of purity, safety and efficacy are certainly less stringent than those required for new prescription drugs."

If approved by the UK Department of Health, the European Council of Ministers would have to vote on the directive before it could become law.

For background see the BBC's web site at [http://news.bbc.co.uk/hi/english/health/newsid\\_2141000/2141558.stm](http://news.bbc.co.uk/hi/english/health/newsid_2141000/2141558.stm)

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## Screening debate to continue at AGM

***An eminent and controversial voice will be heard at HealthWatch's Annual General Meeting later this month, when surgeon Michael Baum talks about the "deceptions" surrounding breast screening. He will be in good company. Professor John Garrow's recent article, "What is Screening Hiding" (HealthWatch Newsletter 45, April 2002)—which was commended by the Medical Journalists Association—roundly criticised the Department of Health's latest patient information leaflets on breast screening.***

Michael Baum, Professor Emeritus of Surgery at University College London, was even more outspoken against screening policies in a recent editorial in Practitioner, stating, "Clearly there are double standards of informed consent at work. One for those treating the disease and another for those screening for it."

All members, non-members, and press are welcome to the AGM at the Medical Society of London, Lettsom House, 11 Chandos Street, London W1. Reception begins at 6.30pm, followed by the meeting and talk by Professor Baum who, at 7.30pm, will receive the HealthWatch Award. Attendance is free, but anyone wishing to attend the buffet supper afterwards must inform John Garrow no later than the 23rd October and pay £25 per

person in advance. Cheques (made out to HealthWatch) to John Garrow, The Dial House, 93 Uxbridge Road, Rickmansworth, Herts WD3 2DQ.

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## COMMENT

### WHO'S AFRAID OF AMALGAM FILLINGS?

*Despite a lack of evidence, fearful warnings and rumours continue to circulate about the possible results of using mercury as an ingredient in the paste used to fill teeth. Why do people believe this madness? Neville Goodman explains, then invites readers to share his incredulity at some of the misinformation that he finds on the Internet.*

There are many diseases without known cause. There may be epidemiological evidence of factors that are associated with a disease, but this is not proof that the factors cause the disease. Sometimes, even when epidemiology identifies a factor for which there is a plausible biological mechanism for causing disease—such as leukaemia in the children of men working in the nuclear industry—the final proof can remain uncomfortably elusive.

We do know some of the factors that cause cancers, although usually not the precise reason why any particular patient develops a particular cancer. The honest answer to, "Why me?" is, "I'm sorry, but we just don't know." (I am ignoring here the largest known cause of cancer, which is smoking and lung cancer, as well as the other known chemical causes of industrial cancers, and the rare genetic cancers.) We know some of the factors that are important in the development of blocked arteries and coronary (ischaemic) heart disease. Again, these factors operate at the population not the individual level, which explains why some cigarette-smoking, alcohol-drinking, beefburger-eating people nevertheless live to receive the Queen's telegram. Cancer and heart disease are the two main causes of death in the UK, but if the government's health plans for the year 2010 succeed (to reduce deaths from heart disease by 40% and from cancer by 20% in people aged less than 75), we will be seeing a lot more of a group of diseases about which we know next to nothing of their causes, or even factors associated with their development.

I am referring to neurological diseases. These diseases—Parkinson's disease, multiple sclerosis, motor neurone disease, Alzheimer's disease, and one could include developmental conditions such as autism—are receiving more and more attention in the media, and are likely to affect more and more of us in the future. They are generally rather unpleasant and drawn-out diseases, for which doctors can offer little except support. It's easy for charlatans and the well-meaning misinformed to prey upon sufferers with easy explanations of why their disease developed and what they should do about it. Possibly even more susceptible—and there are certainly more of them—are the people who suffer within the spectrum of disease-to-unease that encompasses chronic fatigue to habitual shyness.

In this fertile ground, the idea that mercury amalgam fillings are harmful to health takes ready root. Mercury is toxic. The liquid metal is pretty harmless, and used to be drunk as a cure for constipation, but the vapour that it gives off is extremely harmful, as are many mercury compounds. In the United States, less so in the United Kingdom, a lucrative industry has sprung up of dentists willing, for a fee, to replace amalgam fillings with "non-toxic" materials.

"Non-toxic" is in inverted commas because there is no evidence that amalgam fillings are harmful. The mercury is bound in the amalgam much as hydrogen is bound in water. Worrying about being poisoned is on a par with worrying that free hydrogen might cause water to explode. The US FDA is unequivocal (1): "safety... has been reviewed extensively over the past ten years, both nationally and internationally. In 1994, an international conference... concluded there is no scientific evidence [of] a significant health hazard to the general population, although a small number of patients had mild, temporary allergic reactions. The World Health Organization (WHO), in March 1997, reached a similar conclusion." Their website was last updated 18 March, 2002. The American Dental Association has started a publicity campaign urging patients with neurological diseases not to have their fillings removed (2). A person would need 500 fillings and vigorous chewing to reach even the lowest limit of worry about free mercury. A National Institutes of Health seven-year study of children is now in its second year, with no indication of anything adverse.

You would not realize that from entering 'amalgam' into the Internet search engine "Google". First 'hit' was "Frequently asked questions about amalgam-related illness"(3). Careful reading of this extensive website shows that there is no actual evidence of harm, but the tone, and the implicit message of the title, would leave most people believing that on balance they should have their fillings removed.

There was no such equivocation on the second 'hit': "The dental amalgam issue" (4). Amalgam is "a terrible sin against humanity", and the site shows abstracts from "many on-going studies [that] have linked many aspects of amalgam mercury to brain tissue damage found in patients with Alzheimer's Disease". A site linked to a holistic organisation (5) listed 14 "facts", including a report of how rats exposed to mercury vapour "diluted to account for size differences between humans and rats" (which makes no sense, because size is irrelevant when breathing

vapours) developed the equivalent of Alzheimer's Disease. They may have done; but the site does not mention that amalgam fillings do not give off vapour. This site gave links to 14 other amalgam sites, but none to the FDA.

Further down the hit list was a site (6) that quoted a statement by the president of the American Dental Association, but I suspect the opening lines of this website would make a greater impression: "Maine Governor Angus King probably said it best when he compared the current use of mercury in dental fillings with the 1950's use in shoe stores of powerful x-ray machines called fluoroscopes, which exposed hundreds of thousands of adults and children to high doses of toxic x-rays."

The last hit on the first page was "150 years of Russian roulette" (7): "The story about what is going on behind the scenes and how information has been systematically kept from the public."

In the present climate of scientific mistrust, it is impossible to blame a scientifically naïve person coming away from their computer worried that dental mercury amalgam has made them ill. One thing is certain: there is a lot of money to be made from removing harmless fillings and, of course, from restoring the subsequent dental damage.

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7. <http://home.online.no/~reiersol/amalgam.htm>

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## MEDIA

### Damned lies, statistics and HRT

***Sensational reporting of clinical trial results caused alarm recently. Was it all really necessary? Oncologist Michael Henk reports***

On 10 July The Times carried the headline "HRT is linked to breast cancer: US study is halted after health fears rise: patients suffer 41% increase in stroke: 22% increase in risk of heart disease"! Equally sensational headlines appeared in other newspapers. Behind this propagation of alarm and despondency to millions of woman was the publication in JAMA of preliminary results from a large US randomised controlled trial of hormone replacement therapy (HRT) in post-menopausal women.

**So what did this trial actually show?** The investigators allocated healthy post-menopausal women randomly to receive a combined oestrogen-progestin preparation or placebo. (This is only one of the many forms of HRT in current use: another trial of oestrogen-only therapy is still in progress). The primary outcomes were coronary heart disease, which would be expected to be reduced, and breast cancer, expected to be increased. In addition they devised a "global index" designed to summarise the balance of risks and benefits, for which they chose, in addition to the above, stroke, pulmonary embolism, endometrial cancer, colorectal cancer, hip fracture, and death due to other causes. By 31 May 2002 16,608 women were participating in the trial: 8506 in the HRT group and 8102 in the placebo group. The median follow-up was 5.2 years. On that date the trial data-monitoring board recommended stopping the study because the excess incidence of breast cancer had just hit the conventional 5% significance level, while the global index supposedly supported risks exceeding benefits.

Coronary artery disease and thrombo-embolic disease, in addition to breast cancer and strokes, were more frequent in the HRT group, while fractures attributable to osteoporosis and colorectal cancer were less frequent. The incidence of all these events was very low, and differences between them small, yet all were deemed to be statistically significant. There was no difference in deaths, or in the total number of cancers, between the two groups.

It is sad that despite the enormous amount of work the investigators put into this study, their paper, and especially the reaction of the media to it, tell us much about the pitfalls of statistics and little new about HRT. Focussing on relative risks when absolute risks are small can make a negligible effect appear huge. For example, only 212 of the 16,000 women in the study actually suffered a stroke, 127 (16 fatal) in the HRT group and 85 (13 fatal) in the placebo group. The percentages are 0.29 and 0.21 respectively. Therefore the "41% increase" in strokes actually represents a 0.08% absolute increase, or put another way, 8 more strokes per 10,000 person-years in those taking the HRT. Someone so minded could have extracted from the above data the

contrary claim that HRT confers a 22% improvement in the chance of surviving a stroke, but I must have missed that headline! The increased risk of breast cancer also works out to be 8 cases per 10,000 person-years.

The use of the 5% probability level, " $p < 0.05$ ", as the index of a "statistically significant" result has become a ritual in clinical research. All it means is that the probability that the observed result of a trial would occur by chance if there were no real difference is no more than 5%. In other words, one in twenty "significant" results are false positives. The 5% level was chosen arbitrarily by Sir Ronald Fisher many years ago, only because it was mathematically convenient, yet it has become the yardstick for publication of clinical trials. It is something of a quirk of mathematics that the smaller the absolute percentages the smaller the difference between them that will achieve statistical significance, hence the number of reportedly significant risks of HRT. Moreover, the  $p < 0.05$  figure for breast cancer is based on a calculation of "nominal confidence intervals", i.e. the variability that would arise from a simple trial with a single outcome. When the investigators applied a more complex adjusted method that takes into account multiple testing over time and outcome categories, only thrombo-embolic disease and fractures attained 5% significance. These were already known hazards and benefits respectively of HRT. Some of the other apparent effects that this trial purports to demonstrate could well have occurred by chance and may not be a genuine effect of the treatment.

It seems a pity that the trial is now ended, as it will probably now never give us any conclusive information. Most British medical statisticians would say that a probability of 0.01 is the maximum that gives grounds for stopping a clinical trial prematurely. However, the action of the trial group in this respect is understandable; breast cancer is such an emotive subject and " $p < 0.05$ " is so engrained in both the scientific and legal mind that the fear of litigation in USA would leave them with no alternative but to stop the trial.

In fact, litigation is already underway. The Sunday Telegraph on 11 August reported that lawyers in America have started a worldwide class action against Wyeth, the leading manufacturer of HRT. British women who have suffered strokes or other illness while on HRT are clamouring to join in, claiming they have been used as guinea pigs. The alternativists are also cashing in. In the weekly "What's the Alternative" page in the Sunday Times colour supplement on 11 August the writer Susan Clark pointed out the results of the trial, of course quoting relative risks. Instead of HRT she recommends treating menopausal symptoms with a cocktail of phytochemicals, one of which happens to be an oestrogen and another a progestin! Of course she omits to mention that there has been no objective assessment of the risks of the therapy she recommends. Presumably as it is derived from plants it must be, by definition, "natural" and therefore perfectly safe.

There is little in this American study that need cause alarm to women who take HRT and whose quality of life it enhances, but no doubt thousands will stop taking it. Such are the consequences of the misapplication of statistics in medicine and journalism.

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## POSITION PAPER

### MULTI-VITAMIN SUPPLEMENTS

***It is estimated that 40% of people in Britain take supplements, spending between £340 and £360 million a year, and the market is growing<sup>1</sup>. Healthy adults use supplements to promote "optimum health"; this may be defined as current well-being and maximum resistance to future infectious and degenerative diseases. Do they achieve these objectives? This review, an expanded version of David Bender's editorial published in the British Medical Journal in July 2002, will not discuss pharmacological use of vitamins to treat disease.***

Our estimates of vitamin requirements and tables of recommended or reference intakes are amounts that are calculated to ensure that no-one suffers from deficiency; reference intakes are derived on the basis of average requirement plus twice the standard deviation around that requirement, so are higher than the requirements of almost everyone in the population (3,4,5,6,7,8,9).

There are two difficulties. The first is the definition of the word requirement. The US usage<sup>5</sup> is that the requirement is the lowest intake that will "maintain a defined level of nutriture in an individual", i.e., the lowest amount that will meet a specified criterion of adequacy. The World Health Organization (10) defines both a basal requirement (the level of intake required to prevent pathologically relevant and clinically detectable signs of deficiency) and a normative requirement (the level of intake to maintain a desirable body reserve of the nutrient).

The second difficulty is that in most developed countries vitamin deficiency is no longer a problem. We have very good markers of deficiency, at three levels: clinical, sub-clinical and biochemical, so that it is easy to determine requirements to prevent deficiency. The 2001 FAO/WHO report (9) introduced the term "protective nutrient intake", an amount greater than the reference intake that may protect against specified health risks of public health importance. Since we have no reliable marker that an individual enjoys "optimum health" (as defined

above) it is not possible to set dietary requirements to achieve this state.

**The important questions are whether levels of intake higher than current reference intakes may provide health benefits, and whether higher intakes are safe.**

### Safety of high intakes

Vitamins A, D, B6 and niacin are all known to be toxic in excess. For vitamin A the intake at which toxic effects occur is about 10 to 12 times the reference intake for adults, and about three times the reference intake for infants. Some children develop hypercalcaemia and calcinosis as a result of vitamin D intakes as low as 45µg/day, compared with a reference intake of 5 to 10µg (11,12).

The UK report on Dietary Reference Intakes (3) gave "guidance on higher intakes"; the US/Canadian reports (5,6,7,8) give "tolerable upper levels of intake" derived from the highest level of intake at which there is no adverse effect, divided by an appropriate safety factor. The tolerable upper level is defined as the maximum level of habitual intake that is unlikely to pose any risk of adverse health effects to almost all individuals in the (stated) population group. It is a level of intake that can (with a high degree of probability) be tolerated biologically, but is not a recommended level, and "there is no established benefit for healthy individuals consuming more than the RDA" (5).

In the UK, the Foods Standards Agency set up the Expert Group on Vitamins and Minerals "to establish principles on which controls for ensuring the safety of vitamin and mineral supplements sold under food law can be based; to review the levels of individual vitamins and minerals associated with adverse effects; and to recommend maximum levels of intakes of vitamins and minerals from supplements if appropriate". The Expert Group has published a series of working documents evaluating the evidence of safety or hazard (13).

The European Federation of Health Food Manufacturers has published upper limits of vitamins and minerals for use in over-the-counter supplements (14); although these are voluntary, responsible manufacturers are likely to abide by them.

Are there benefits from higher levels of intake?

There are two ways of answering this question: to identify biomarkers of optimum nutritional status, rather than the absence of deficiency, or to identify nutrients associated with lower incidence of chronic diseases epidemiologically, followed by intervention trials. Neither has yet provided satisfactory answers, and a recent review finds little convincing evidence in favour of supplements (15).

There are a number of promising suggestions for biomarkers, including metabolic markers of free radical damage, immune responses and damage to DNA. The problem is that we do not yet know how far these biomarkers reflect the likelihood of developing chronic degenerative diseases such as heart disease, cancer, parkinsonism or Alzheimer's disease. None of the biomarkers is responsive to only a single nutrient, and all are affected by many non-nutritional factors (16,17). To date we have no markers that can be used to determine optimum or protective intakes.

**The epidemiological approach has prompted a number of intervention trials, most of which have been disappointing.**

### Vitamin E and beta-carotene

There is clear epidemiological evidence that people with a high plasma concentration of vitamin E are less at risk from cardiovascular disease (18). The Cambridge Heart Antioxidant Study (19) found a reduction in non-fatal, but not in fatal, myocardial infarctions. While there are obvious benefits from reducing non-fatal infarctions, this is hardly convincing evidence of the benefits of vitamin E supplements. Other large intervention trials have found no beneficial effect of vitamin E in coronary heart disease (20,21,22). In the alpha-tocopherol beta-carotene study (23), there was a lower incidence of, and mortality from, prostate cancer in those people taking the vitamin E supplements (24). There is no clear evidence from other intervention trials that vitamin E reduces cancer risk.

Similarly, there is evidence that high intakes of beta-carotene are associated with lower incidence of lung, prostate and other cancers, but beta-carotene may simply be a marker of fruit and vegetable consumption. In the Linxian study in China (25), supplements of beta-carotene, vitamin E and selenium to a marginally malnourished population led to a reduction in mortality from a variety of cancers, especially gastric cancer. The results of two major intervention studies with beta-carotene, one in Finland among smokers (23) and the other in the USA among people who had been exposed to asbestos (26), both yielded unexpected, and unwelcome, results—more people receiving the supposedly protective supplements died from lung (and other) cancer than those receiving placebo. The US Physicians' Health Study (27) was a 12-year trial of beta-carotene supplements which found no effect on the incidence of cardiovascular disease or cancer.

Both vitamin E and carotene are antioxidants and might be expected to reduce the free radical damage that underlies the development of both cancer and cardiovascular disease. However, most compounds that act as antioxidants do so by forming stable radicals that persist long enough to undergo metabolism to non-radical compounds. By definition they therefore form radicals that can penetrate deeper into tissues and plasma

lipoproteins, and potentially cause more damage than the oxygen radicals they have replaced.

In the absence of co-antioxidants such as vitamin C, vitamin E increases the oxidative damage to plasma lipoproteins (28,29). While beta-carotene is an antioxidant that traps radicals under conditions of low oxygen availability (30), under conditions of high oxygen availability, as in the lungs, high intakes may lead to the formation of oxidized metabolites that are pro-oxidants (31,32).

## Vitamin C

Vitamin C is an antioxidant, and also inhibits the formation of carcinogenic nitrosamines from dietary amines and nitrites. It might therefore be expected to give some protection against the development of cancer and cardiovascular disease. However, as well as being an antioxidant, vitamin C can be a source of radicals and hence a pro-oxidant. It seems likely that the pro-oxidant actions are not important in vivo. Except in cases of iron overload there are almost no metal ions in free solution to catalyse radical generation, and because the vitamin is excreted quantitatively at high intakes, tissue concentrations are unlikely to rise enough to lead to free radical formation (33,34).

The epidemiological evidence linking a high intake of vitamin C with reduced cancer incidence is confounded by the fact that the fruits and vegetables that are sources of vitamin C are also rich in a variety of other compounds that may be protective. Studies of 8-hydroxyguanine excretion as a marker of oxidative damage to DNA do not in themselves provide evidence of a protective effect of vitamin C except in people whose intake is low (35).

Vitamin C deficiency is associated with an increased risk of atherosclerosis, but there is little evidence of protective effects at intakes greater than needed to meet requirements (36). A systematic review (37) found limited evidence of benefits of high intakes of vitamin C in reducing the incidence of stroke, but inconsistent evidence with respect to coronary heart disease.

High doses of vitamin C are popularly recommended for preventing and treating of the common cold. The evidence from controlled trials is unconvincing. Chalmers (38) reviewed 15 reports and considered that only eight met the basic criteria of well-conducted scientific research. Assessment of these eight reports gave no evidence of any beneficial effects. Similarly, Dykes & Meier (39), reviewing only those reports that had been published in peer-reviewed journals, concluded that there was no evidence of any significant benefit. Hemila in 1992 (40) reviewed a number of studies, and again concluded that there was no evidence that they lowered the incidence of colds. He did, however, find consistent evidence of a beneficial effect in reducing the severity and duration of symptoms (a notoriously difficult subject to research). He suggested that this might be due to the antioxidant actions of ascorbate against the oxidizing agents produced by, and released from, activated phagocytes, and hence a decreased inflammatory response. A systematic review (41) similarly concluded that there was no beneficial effect in terms of preventing infection, but a modest benefit in terms of reducing the duration of symptoms.

## Vitamin D

An intake of vitamin D above what can be obtained from normal diets (possibly in combination with supplementary calcium) delays the loss of bone with increasing age, so supplements may be advisable to prevent osteoporosis and osteomalacia (42). Vieth (43) suggested that normal sunlight exposure may provide the equivalent of 20 to 50µg/day, with possible benefits with respect to the prevention of some cancers, hypertension and the progression of osteoarthritis. For most people increased sunlight exposure is probably more effective than supplements, although we may have to balance the beneficial effects on bone against increased risk of skin cancer.

## Folic acid

The benefits of folic acid supplements taken periconceptually in preventing neural tube defect have been demonstrated convincingly (44). High intakes of folic acid also reduce plasma homocysteine, a risk factor for cardiovascular disease independent of plasma lipids and other risk factors (45), and low intakes of folic acid are associated with increased risk of colo-rectal cancer (46). This has led to mandatory fortification of cereal products in USA and elsewhere. However, although folic acid lowers plasma homocysteine, there is no evidence yet from controlled trials as to whether or not this will reduce cardiovascular disease or cancer; until the results of intervention trials in progress are available, the benefits of folic acid supplements other than to prevent neural tube defects, remain unproven (47).

## Conclusion

***So, should healthy adults take a multivitamin tablet every day?***

***These supplements will probably do no good, apart from folic acid taken periconceptually, and possibly vitamin D for the elderly. For children, supplements of vitamins A and D are desirable.***

It is worrying that multivitamin tablets are promoted as an aid to "optimum nutrition", or to make good a diet that is inadequate. It is not possible to show that supplements promote optimum nutrition if the diet is already adequate by WHO standards. If the diet is not adequate, or if health risks are increased by other factors (e.g.

smoking or obesity) then taking a multivitamin tablet is unlikely to help. It is even more hazardous to take a cocktail containing many nutritional supplements "to be on the safe side". Overloading with one nutrient (e.g. a particular amino acid, vitamin or mineral) may cause disorders of metabolism of other amino acids vitamins or minerals. Human beings evolved on a diet of mixed animal and plant foods in which the balance of nutrients is about right; to alter that balance markedly is not "to be on the safe side".

There are lessons for physicians, and pharmacists, as well as the news media. There is a fad for vitamin supplements—and doctors are not immune to being swayed by fashion. Pharmacists tend to depend on vitamin supplements for a considerable proportion of their profit. Newspapers and magazines tend to abandon journalistic scepticism when it comes to articles on health. It is incumbent on all these groups to recognise that their actions in respect of vitamin supplements can be tantamount to the promotion of quackery.

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## TRADING STANDARDS

### Food fraud, and the law's delay

*John Garrow offered expert advice about "slimming tablets" in a case brought by the North Yorkshire Country Council. His remarkable story details how what seems like an open-and-shut case can turn into a lengthy and expensive process. Mr Richard Flinton, of North Yorkshire Trading Standards, has kindly explained for us why it all took so long.*

In May 1999 a Mrs Jarvis in North Yorkshire received a telephone call inviting her to buy slimming tablets from the Regional Health and Diet Centre (RHDC), for which the Head Office was at 12 Harley Street, London W1N 1AA. She was told that they were 100% safe and natural, she would lose 15 pounds in a fortnight even though she continued to eat all her favourite high calorie foods, and that when she stopped the tablets she would not put all the weight back on. She sent £93 for a 6 month supply (180 tablets).

Mrs Jarvis received by post a package with 90 tablets, and 14 pages of dietary advice. She took the tablets for six weeks but gained weight, and did not receive the remainder of the tablets she had paid for. On the 6th July 1999 she contacted the North Yorkshire Trading Standards Department, who started a prosecution of the management of the RHDC for conspiracy to defraud. On 12th July 2002 (three years after the initial complaint from a member of the public) in Teesside Crown Court the chief defendant was given a 12-month prison sentence after pleading guilty, and his assistant, who was given legal aid, also pleaded guilty and was given a six-month jail sentence. In brief, the Harley Street address served merely as a post box. The slimming formula was initially hydroxy-citric acid and chromium, but later repackaged capsules containing vitamins, zinc and iron were

substituted. The advertising claims had no scientific or experimental basis.

There was a three-year interval between the complaint and sentencing. We asked the prosecution team if it would have been possible to reduce the delay and cost. The reply from Richard Flinton of North Yorkshire Trading Standards Department follows. Readers' comments would be welcomed by the Editor.

"This case, as many do, started with a single consumer complaint with a member of the public feeling that they had been misled by a so-called slimming product. However, what at first may have appeared to be a simple complaint, was in fact the tip of an iceberg of a complex fraud. Regional Health and Diet Centre was in fact an amalgamation of four separate companies. Three of these were set up for the primary purpose of selling a bogus diet pill to members of the public with the fourth company being an associated debt collecting company.

"The fraud took in some 6,000 consumers and netted at least £300,000. The selling operation by Regional Health had been undertaken across the country. The fraud was run from premises in London. North Yorkshire as a county was far from being the worst affected region, therefore you may ask the question why did we lead the investigation? The simple answer is that no other authority or agency had taken the matter up and we were concerned if we didn't act this fraud may slip through the net. Consequently, a number of search warrants were executed on premises across London relating to Regional Health & Diet Centre and the two individuals responsible for establishing the companies. A number of computers and a large quantity of paperwork were seized from these premises.

"The investigation had to resolve a number of issues, not least the fact that a range of alias's had been used within the Regional Health & Diet Centre companies. These had to be broken down to show who was actually culpable for the fraud. This involved detailed handwriting analysis and a number of identity parades.

"The case therefore was far from a simple investigation into a one off complaint but a complex fraud which took time to unravel. The investigation was concluded in less than a year and this led to the start of long drawn out and expensive legal proceedings.

"There were a number of reasons for the protracted length of the legal proceedings. Firstly, the main perpetrator who established the fraud, Madjide Khalik, had been a disqualified director of a previous fraudulent operation. We felt that it was important to bring this fact to the attention of the court and to bring charges for the fact that Khalik had established the Regional Health & Diet Centre companies in breach of his Director's disqualification order. The usual agency who would bring such offences is the Department of Trade and Industry, however, they refused to bring proceedings in this case. This led to a heated legal debate as to whether these offences could be brought by North Yorkshire County Council. The second and most significant factor which explains the delay in these proceedings was that after Madjide Khalik had entered guilty pleas to the substantive charges of fraud against him, his co-accused Marcella Hynes, maintained not guilty pleas. Space had to be found at Teesside Crown Court to accommodate a six-week trial with some 50 prosecution witnesses. Witnesses had been contacted and scheduled to appear with the case fully prepared and some witnesses even attended on the first day, only to find that Hynes changed her plea at this stage to guilty.

"Now that the matter has been successfully concluded we can ask ourselves what lessons have been learned? In response I would make the following points.

"Trading standards services need to be adequately resourced to enable them to investigate major consumer frauds of this type.

"Central Government departments such as the DTI should work more constructively with local authorities to investigate and jointly prosecute consumer frauds.

"The criminal justice system needs to be more robust in dealing with defendants and their legal representatives who maintain not guilty pleas only to subsequently change them on the first day of a trial after large amounts of public money have been expended in preparing for the trial."

We sent a copy of this article to the Legal Services Directorate of the Department of Trade and Industry with the invitation to respond. Their reply is as follows:

"This Department recognises the importance of prosecuting consumer frauds and does prosecute such in appropriate cases. However after very careful consideration we decided not to join the RHDC investigation/prosecution. We concluded that it would not best serve the interest of justice in this case for us to duplicate and unnecessarily complicate the investigation and prosecution already initiated by North Yorkshire Trading Standards Office. This may also have resulted in even further delays.

"On the question of reducing delay and the costs in these cases, you will note the White Paper recently published outlining proposals to further improve the efficiency and effectiveness of the Criminal Justice System."

John Garrow  
Emeritus Professor of Human Nutrition  
University of London

## PERSONAL VIEW

### **“This herbal remedy could save my father’s life. Why won’t someone give us some?”**

A cry for help appeared in The Guardian on 13th June this year. Emily Fielden’s father, desperately ill with prostate cancer, found apparent relief in a herbal remedy that was subsequently withdrawn. It is clear that some herbal medicines are useful in the treatment of disease, but while safety and efficacy remain unproven how can personal tragedies such as this be avoided? Here follows a shortened version of the article reproduced with kind permission of the author and The Guardian. What advice or solutions might HealthWatch offer?

There’s a certain irony in this story: a rationalist sceptic finding a cure for his cancer in a mysterious hotchpotch of Chinese herbs, only to have it taken away by an apparently obdurate bureaucratic organisation. This has triggered an imminent personal tragedy in my life, and the purpose of writing this is to share what I believe to be the quite extraordinarily callous way in which people who rely on any “unconventional” medicine are treated by those who control and regulate the industry.

In 1997 my father was diagnosed with prostate cancer. For a while it was controlled by a series of conventional hormone treatments, but these eventually failed. He then turned to chemo- and radiotherapy, with their associated side effects. The prognosis wasn’t good and his quality of life went into freefall. Then, early last year, I suggested he try a herbal remedy called PC Spes (PC for prostate cancer, and spes—Latin for “hope”).

I had read on the Internet—during long trawls to find something, anything, that might help my father—that this carefully prepared mixture of eight herbs, including ginseng and liquorice, had been successfully used by people with prostate cancer in the US, despite there being very little known about how it worked. By chance—quite independently—my father’s oncologist also suggested a course of PC Spes. But I was still surprised when my father, a scientist and a raging rationalist, placed his first order with a US-based company.

He never looked back. My father’s PSA (prostate-specific antigen, a “blood marker” that allows you to track the progress of the cancer) plummeted from 380 to 40 in just one month: in other words, from a terminal level to a safe one. And from then onward, apart from on the occasions when he was unable to take PC Spes, my father’s PSA remained below 10, which is to say, thoroughly under control. In the one month when he couldn’t take PC Spes, because of a minor operation, his PSA shot up to 108. It returned to its controlled level again only once the normal dose was resumed.

So, no scientific trials here. All I can say is that this herbal supplement worked for him: it worked beyond all doubt. Family, friends, nurses, surgeons, oncologists, and not least my father himself, were amazed. It gradually became clear to us that my father’s life depended on PC Spes, and he became happily resigned to taking it for the rest of his life. Or so he hoped.

On February 7 this year the California Department of Health Services, working with the US Food and Drug Administration, announced a nationwide recall of PC Spes because of “possible contamination”, requiring distributors to alert customers and return bottles to the manufacturers (although very few were returned). Since PC Spes was only marketed and sold in America, the decision had international impact: it was nowhere else to be found.

For my father, this was catastrophic. When his supply ran out, we calmly tried to find a new source, or an alternative to PC Spes, but five months later, he has still not found a supply. And all the while, he has been growing steadily sicker.

It turned out that PC Spes was recalled from the market because it contained a small and effectively harmless trace of warfarin, a commonly prescribed blood-thinning agent. How it ended up in the product no one knows, although the finger of suspicion has, inevitably, been pointed at the pharmaceutical industry. America’s rapidly expanding herbal medicine industry is now worth an estimated £4.2bn—and that has direct financial impact on the conventional medicine market. The two are not friends: can foul play be absolutely ruled out? But it sounds paranoid even to talk about sabotage.

According to the Wall Street Journal, BotanicLab, the manufacturer of PC Spes, says that it does not believe that warfarin was present. It suspects that the authorities might have detected a chemical that occurs naturally in the plants used to make the remedy. The company has ordered new tests at an independent lab; the authorities say they will consider them. Meanwhile, reports on the Internet talk about PC Spes being tainted with “conventional drugs”, or being dangerous. They talk about the fact that no one knows about the “long-term” effects.

All this is meaningless to my family, and families like ours. We know that whatever is in it, or was in it, it worked. If the firm that was making it was making an error, or was less than honourable about what was going into it, frankly: who cares? Whatever they were doing, they were doing it right.

In our experience, PC Spes has a fairly wide acceptance in the medical community in the US and the UK, though it is less widely known in the latter. Many oncologists with long experience of prostate cancer recommend it. However, its validation is tempered by two complications; first, no one knows why or how it works; and second, it appears to work for only 70% of cases. Some patients show no improvement at all. Studies have shown that PC Spes lowers PSA, but crucially, no formal scientific research has proved how it works and why it only works on a proportion of cases.

But for thousands of men it is, they believe, the sole reason they are alive. It is not scientific studies that drive these men to shell out £300 for a month's supply. It is the stories of men like my father whose lives have been transformed.

For the time being, however, it seems there is nothing to be done, and that no one will help while the bureaucratic wheels grind. Seeing my father's condition deteriorate each day is difficult to bear, and it is hard not to hold the FDA responsible. While they have a responsibility to make sure that people know what they are taking, surely they don't have the right to prevent someone taking what they believe to be a cure, particularly in life-or-death situations such as this? I think my father might be willing to risk the odd glass of warfarin at this point.

Perhaps there is nothing to be done now. But it is with a heavy heart that I imagine all those other men in my father's situation who might have some good time left, but for the want of a simple herbal remedy.

Emily Fielden

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