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MEDICAL CLAIMS TO BE ALLOWED WITHOUT EVIDENCE

AN ASTONISHING new ruling allows makers of homoeopathic remedies to publish claims that they can cure specific illnesses. Since 1971 the legal right to make such claims has been reserved for products which hold a medical Product Licence, gained only after a long and costly process involving production of a vast body of evidence on safety and efficacy. But under the new ruling homoeopathic remedies are an exception: they can receive a licence without ever having to prove they work. David Bender, HealthWatch's chairman, reports. (Read how to object on page 2 of this issue; see HealthWatch's position on the new ruling on page 8)

From September 1st this year¹ homoeopathic remedies in the UK are allowed to describe the illnesses they claim to be able to treat, under the National Rules System introduced by the Medicines and Healthcare Products Regulatory Agency (MHRA). This is supposed to be to bring homoeopathic remedies into line with licensed medicines. However, in order to obtain a licence, medicines must have firm scientific evidence of efficacy, as well as safety. Homoeopathic remedies will not require evidence from clinical trials; they will simply "have to comply with recognised standards of quality, safety and patient information"² and the manufacturers need only show that the product has been used to treat those particular conditions within the homoeopathic industry.

Homoeopathic medicines on the market before the 1968 Medicines Act were given Product Licences of Right (PLR), which allowed them to make claims about health benefits. But under EU regulations new products were treated in the same way as medicines, requiring evidence of efficacy from clinical trials. Since 1992, homoeopathic medicines can be licensed, but until now the regulations have not permitted health claims. This has now changed, and claims can be made without evidence.

Professor John Garrow, past chairman of HealthWatch, told the

HealthWatch Newsletter, "I thought the MHRA existed to protect the public from fake medicines that do no good. It is disgusting that they should accept as evidence of efficacy the so-called 'provings' of homoeopathic products, for fear that otherwise it 'would inhibit the expansion of the homoeopathic industry'. It is not the job of the MHRA to support any industry. Their duty is to reassure the public that any medicine which has a licence has been shown by proper controlled trials to be effective. It seems that they have now failed in this duty. Unfortunately, clinicians will not trust them in the future."

Speaking to the *Guardian* newspaper Michael Baum, emeritus professor of surgery at University College London and a previous HealthWatch Award winner, said: "This is like licensing a witches' brew as a medicine so long as the bat wings are sterile."²

David Bender
HealthWatch Chairman

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1. See MHRA press release on http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON2024653&ssTargetNodeId=389
2. *The Guardian*, 1st September 2006. View online at www.guardian.co.uk/medicine/story/0,,1862554,00.html

Alarm over homoeopathic "malaria remedies" danger

HOLIDAYMAKERS have been advised against using homoeopathic remedies for malaria and other serious tropical diseases. In a BBC Newsnight investigation broadcast on 14th July, an undercover researcher from the organisation Sense About Science went to 10 alternative health clinics and asked for advice on protecting herself from malaria on a holiday to Africa. In every case she was recommended homoeopathic products instead of being directed to a GP or conventional travel clinic, advice which allegedly goes against government guidelines by recommending unproven remedies for malaria and tropical diseases such as typhoid, dengue fever and yellow fever.

Scientists interviewed by the *Guardian* said the homoeopaths' advice was "appalling" and likely to endanger lives. Malaria is a

major risk to people travelling in the tropics and can kill within days of the first symptoms. Almost 2,000 people returned to Britain with malaria last year and 12 died. The *Guardian* wrote that, according to the Department of Health, most cases resulted from people not taking the appropriate protective drugs.

In 2005 the Health Protection Agency issued a warning because of people falling seriously ill when using homoeopathic remedies. It said, "There is no scientific proof that homoeopathic remedies are effective in either preventing or treating malaria."

Guardian 14th July 2006

Read report and watch 14 July Newsnight programme on: <http://news.bbc.co.uk/2/hi/programmes/newsnight/5178122.stm>

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HEALTHWATCH OPEN MEETING AND AGM 2006

WRITER and broadcaster Ben Goldacre will receive the 2006 HealthWatch Award for his entertaining exposures of bad science through his regular newspaper columns.

The award will take place at this year's HealthWatch Annual Open Meeting and AGM. After the presentations Dr Goldacre will address the meeting on "Bad Science: from the classroom to the front page". The meeting is free and open to all and will take place on Wednesday 18th October 2006 at The Medical Society of London, 11 Chandos Street, Cavendish Square, London W1M 0EB (nearest Underground: Oxford Circus).

The evening will begin with a reception at 6.30pm, and will be

followed by a buffet dinner with wine at 8.45pm, open to all, at a cost of £28 a head. Those wishing to join for dinner must book in advance: please mail your cheque for £28.00 per diner (made out to HealthWatch) to Michael E Allen, 12 Balmoral Close, Putney, London SW15 6RP enclosing a stamped addressed envelope along with a separate note of your name, address, and the number of vegetarian meals required, to arrive no later than 3rd October.

Cancer fear from Chinese herb therapy

THE *DAILY MAIL* appears to be the only national newspaper to have reported that doctors have warned of the dangers of some herbal therapies after a patient developed bladder cancer from taking a traditional Chinese medicine, writes HealthWatch founder member Caroline Richmond.

The 30-year-old man had been taking a Chinese herb, Longdan Xieganwan, to "enhance" his liver for at least five years. The herb contained a plant ingredient called aristolochic acid, which is banned in Britain and has been linked to bladder cancer and kidney damage. Previous research has shown that cumulative doses exceeding 200 grams were "highly associated" with bladder cancer. A team from the Whittington Hospital in London,

where the patient was treated, had voiced their concerns in the *Lancet*, saying that aristolochic acid was now recognised as a "potent urological carcinogen".

Traditional Chinese medicine is one of the most popular alternative treatments in the UK, with at least 3,000 known practitioners. An editorial in the *Lancet* said that the case highlighted the dangers of aristolochic acid, but argued that it would be wrong to dismiss all herbal medicines. "All complementary medicines, like any medicine, have the potential for side-effects. They all need regulation as drugs".

Daily Mail, 21 July 2006
Lancet 2006; **368(9532)**: 338.

news in brief

NEW HOMOEOPATHY REGULATIONS are opposed by Sense About Science, who have published a section on their website which includes an online form by which you can add your voice to their Statement of Objection. Sign up before Parliament convenes on 9th October. Go to <http://newsite.senseaboutscience.org.uk/index.php/site/project/106>

MEDICAL journalist Oliver Gillie has called upon the government to formulate a new policy on sunlight and vitamin D. In a feature article in the *British Journal of Dermatology*, Gillie enlarges substantially on the case he made in the *HealthWatch Newsletter* last year (issue 57, April 2005). He argues that the majority of people in the UK receive insufficient vitamin D, resulting in a wide variety of chronic diseases and costing the nation perhaps billions of pounds a year. A new government policy to develop increased levels of vitamin D in the population would involve increased fortification of a wider variety of foods with vitamin D, revision of recommended supplements of vitamin D for people of all ages, and encouragement of safe sunbathing.

British Journal of Dermatology 2006; **154**: 1052-1061.

TWO CHILD health experts went head to head in the *British Medical Journal* recently over whether the dangers of childhood food allergy are exaggerated. Professor Allan Colver from the University of Newcastle upon Tyne believes that the dangers are overstated, and that the increasing prescription of adrenaline injector kits fuels anxiety rather than saving lives. In fact, the risk of death is very small. Eight children under 16 years died from food allergy between 1990 and 2000 in the UK. Yet childhood food allergy is being diagnosed more often and the number of prescribed adrenaline kits has greatly increased even though,

says Colver, they cause unnecessary anxiety, may not prevent death, and should be prescribed only when a diagnosis of food allergy has been confidently established. Professor Jonathan Hourihane from University College Cork, Ireland disagrees: food allergy is common: 2% of adults and up to 6% of preschool children are affected and, although deaths are rare, other reactions are almost inevitable over time. Delay in use of appropriate rescue drugs is associated with a worse outcome in severe reactions. Rather than advocate "more general use" of adrenaline, he urges increased availability of adrenaline kits for people who might need to use them.

BMJ 2006; **333**: 494-8.

View full paper: <http://press.psprings.co.uk/bmj/september/ac494.pdf>

DR MICHAEL BAUM, visiting professor of medical humanities at University College London and a founder member of HealthWatch, was the subject of a feature in the *Financial Times* recently. On the issue of whether complementary therapies might improve quality of life for cancer patients, the "outspoken academic" told interviewer Dr Margaret McCartney that, "This is where I get very sensitive. The idea that alternative medicine considers quality of life and we don't. I pioneered the measurement of quality of life in patients with cancer. That was provoked by my mother's experience. My mother was dying, her life seemed to be made worse by chemotherapy. I thought: 'Is there any way of measuring this?'" Dr McCartney suggested that some people think that subjective experiences aren't as valid or scientific. Baum replied: "If it exists, it can be measured."

Financial Times Weekend, 22/23 July 2006

PHAKES

Michael Allen explores the reasons behind the current rash of counterfeit pharmaceuticals



THE SPAM arriving every time I switch on my computer contains a worrying range of offers of fakes of every kind and counterfeit pharmaceuticals are increasingly featured. From the profit point of view this is understandable: like many high class branded watches, pens and jewellery items, manufacturing costs of pharmaceuticals are very low when compared to the selling price.

Medicines are unusual in that the very high front end costs of research, development and marketing must be recouped by charging high prices during the period of patent protection. For some other products the pace of change is such that innovation obviates the need for this long pay back period; for others, branding and appeals to the label culture can maintain amazing price differentials. But I do find it hard to understand that anyone would be so stupid as to buy medicines in this way as, unlike the other items mentioned, it is not possible to determine quality at a glance and a great deal of careful regulatory control is bypassed.

At the time of first registration of a medicine three major criteria must be satisfied:

- it must be safe in relation to its intended use;
- it must be effective, which requires evidence from well-planned clinical research; and
- it must be of high quality.

When the innovator's product is legally substituted by another, only quality and comparability criteria are applied. However, a great deal of care needs to be taken to ensure this, as the following examples show.

Parallel imports

Within the European Union attempts to standardise the price of pharmaceuticals through the Transparency initiative proved a failure. All member states have some form of state-run health scheme and, as monopoly purchasers, were unwilling to lose control of price regulation processes. The UK system is unique in that it depends upon the overall profitability of the company, rather than upon price negotiation product by product; profit is hard to measure and consequently prices are usually higher than in other EU member states. Parallel importation, permitted in the EU for all products as a means of preventing market protectionism, is encouraged for pharmaceuticals by the UK government as a means of reducing the cost to the NHS. Medicines are imported and sold to the pharmacist, whose reimbursement is reduced according to the pricing bureau's estimate of the extent of the parallel trade. While you might think that a medicine made by the same manufacturer in different member states would be identical, this is not always the case and subtle changes in production of the dosage form can have surprisingly large effects on a product's bioavailability. Therefore, the MHRA (Medicines and Healthcare products Regulatory Agency) makes an evaluation of the documentation on the products before permitting their legal import in order to ensure quality and comparability is maintained.

Generic Products

At the end of a medicine's patent life, the generic industry at once produces a product to match that of the originator; again the MHRA is involved to verify from the documentation that the quality of the active ingredient and its bioavailability matches those of the original product. Strong competition between generic manufacturers used to favour the government's need for low prices, though prices of newer products tend to be relatively high. Manufacturers attribute this to the high quality standards they must maintain; the government believes there is some element of collusion between the small number of companies involved, which reduces competition.

For these products, maintaining quality standards requires:

- vanishingly low levels of impurities in the active ingredient;
- sometimes the manufacture of a chirally pure ingredient;
- dosage form manufacture that provides bioavailability to match that of the innovator's product; and
- protective packaging which maintains product integrity throughout the shelf-life.

For these legal products therefore, methods of control are applied that ensure quality and comparability; obviously, individual wholesalers or pharmacists may be tempted to cheat and illegally import parallel products which have not been registered or lower quality generics. But there is the Royal Pharmaceutical Society to keep this in check and powerful sanctions are applied when cases are detected. Therefore we can generally feel secure that products can be substituted without risk.

Fake Pharmaceuticals

Maybe the public is so unaware of the problems that low quality medicines can bring (some are detailed in the WHO Fact Sheet referenced below) that the inducement of low prices in internet offerings is the only thing they pay attention to. Our president Nick Ross has been sent a copy of an advertisement for "the original blue pill" that appeared in the *Telegraph* (*Telegraph Weekend*, 8th April) and was asked "what is HealthWatch doing about this?" This advert directs readers to the website www.originalbluepill.com where the only information about the product is its price. Incredibly, the active ingredient is not named, but the lubricious text suggests it has the action of Viagra. It is claimed there is 100 mg of this unnamed active ingredient per tablet; one can only hope this is lactose, which at least will do no harm! It is amazing that anyone would be so naïve nowadays and shows how little we have progressed since Victorian days, thought to be the heyday of the snake-oil salesman. Because of the uncontrolled nature of the Internet, attempts by regulatory agencies in the United States and Europe have had little impact on this market, but it does seem extraordinary that a respectable newspaper would accept such an advertisement.

If you look further in the spam or on the Internet, you will find numerous sources of prescription drugs on offer alongside the usual range of products that claim to expand your manhood. Buying in this way circumvents patient protection provided by prescription-only regulations: this is well illustrated by the recent case¹ of a woman who self-administered internet-purchased prednisolone over several years, resulting in steroid-induced glaucoma and cataract. But, back to the question: what can HealthWatch do about this?

It is probable that for our readers there is little need of warnings: many advertisements are so clearly doubtful that caveat emptor immediately comes into play. The excellent WHO Fact Sheet available from www.who.int/mediacentre/factsheets/fs275/en makes clear that the problem of fake pharmaceuticals presses far more upon the developing world, but also describes its increasing importance in the developed world. HealthWatch urges its members to read this Fact Sheet and show great caution; however, as with much else on the Internet doing something about it is not an option.

Michael Allen
Consultant in Drug Regulatory Affairs

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TO TAKE ANTIOXIDANT SUPPLEMENTS OR NOT? THAT IS THE QUESTION



THERE IS an impressive body of epidemiological evidence to support the view that people with high intakes of vitamin E and β -carotene are at considerably less risk of developing cardiovascular disease and some cancers. There are good theoretical reasons why these two nutrients should be protective, and supplements of both (sometimes together with other antioxidants) are widely consumed. However, the results of randomised controlled trials have been at best disappointing, and in many cases there was increased mortality among those taking the supposedly protective supplements.

A quarter of a century ago Peto and coworkers¹ reviewed a number of studies that showed benefits of high intakes of β -carotene. These included both case control studies, in which people with various cancers had lower plasma carotene than those free from cancer, and prospective studies, in which people were classified by their plasma carotene concentration at the beginning of the study, and followed for a number of years; there was a two-fold difference in the incidence of lung cancer in the group with the lowest plasma carotene compared with those with the highest level. A decade later, Gey and coworkers² reported an impressive negative association between plasma levels of vitamin E and ischaemic heart disease. They suggested that vitamin E status explained much of the difference in ischaemic heart disease between different populations in Europe, which could not be explained by differences in plasma cholesterol or blood pressure. Many other studies have similarly shown a negative association between blood levels of vitamin E and/or β -carotene and cardiovascular disease and various cancers.

These epidemiological studies only suggest that carotene and vitamin E may be protective. Apart from people taking supplements, a high blood concentration of β -carotene simply reflects a high intake of fruit and vegetables. Such a diet will provide a great many other potentially protective compounds; in addition, it will also, almost certainly, be lower in fat (and especially saturated fat) than a diet that provides less vegetable matter.

Associations are not evidence

Correlations only show that there is a relationship between the factors being studied. They do not, and cannot, demonstrate cause and effect. If you doubt this, look at the letter to the *Lancet* by St Leger and coworkers³ in which they reported a highly significant positive correlation between the number of doctors per head of population and unexplained infant mortality. Even in the light of the Shipman affair, we cannot take this correlation to mean that doctors routinely kill children!

A further problem with correlations is that they may be spurious. If you accept the conventional statistical 5% confidence level, then one correlation in 20 will be significant, whether or not there is any underlying relationship. Many years ago the late Professor John Yudkin produced a slide showing a highly significant association over many years between coronary heart disease in USA and a variable that he didn't immediately identify. When he had the audience on the edges of their seats with excitement he revealed the missing label for the graph. The significantly correlated factor was the number of radio receiving licences in the UK, a significant but meaningless association.

A plausible mechanism

The WHO report on diet, nutrition and the prevention of chronic diseases⁴ considers the evidence for associations between diet and disease to be convincing when the epidemiological evidence all points in the same direction, and there is a biologically plausible mechanism. This is the case for potentially protective effects of

β -carotene and vitamin E.

One underlying cause of many cancers, and of atherosclerosis and coronary heart disease, is oxidative damage to tissues and blood lipids by oxygen radicals that are formed in the body as a part of normal metabolism, in response to activation of the immune system and as a result of exposure to X-rays and ultra-violet radiation.

Free radicals are unstable molecules with an unpaired electron. Any individual radical survives for only a very brief time (of the order of 10^{-9} to 10^{-12} seconds or less), since collision with another molecule results in removal of an electron to pair the lone electron of the radical, or donation of the lone electron. In either case the radical achieves a stable electron configuration, but at the expense of creating a new radical. This chain reaction can be broken if two radicals react together, yielding a non-radical product. However, this is rare, because of the short life-time of individual radicals and because they are present in low concentrations. The most damaging radicals are reactive oxygen species, and antioxidants such as vitamin E and β -carotene are effective as radical trapping agents because they form relatively stable radicals, which survive long enough survival time to permit reaction to non-radical products.

Intervention studies

The epidemiological data, together with plausible mechanisms of action, have provided a rationale for a number of large-scale intervention trials of β -carotene and vitamin E to assess their effects in preventing cancer and cardiovascular disease. Typically, such trials involve several thousand people receiving the intervention, and a similar number receiving placebo, last for several years, and are extremely expensive.

There have been two large-scale intervention trials of β -carotene in people at risk of lung cancer. In the α -tocopherol β -carotene study⁵ in Finland, heavy smokers were given supplements of 20 mg/day β -carotene, 50 mg/day vitamin E, both or neither. The results were unexpected. Not only was there an increase in death from lung cancer among those receiving the supposedly protective β -carotene supplements, but there was also increased mortality from prostate and gastric cancers.

In the carotene and retinol efficacy trial (CARET) in USA, two groups of people at high risk of lung cancer were studied: smokers and those who had been occupationally exposed to asbestos. The intervention group received 30 mg β -carotene and 7500 μ g retinol (vitamin A) daily. The design of the trial was such that 18,000 participants were to be recruited, and to be followed for an average of 6 years, giving an 80% power to detect a 23% decrease in the incidence of lung cancer cases⁶. In fact, the trial was terminated early (in 1996) because of a 46% excess mortality from lung cancer in the intervention groups.

One of the early trials of vitamin E to prevent coronary heart disease was the Cambridge heart antioxidant study (CHAOS)⁷. There was a significant reduction in non-fatal myocardial infarctions, but there was an increase in fatal infarctions, and overall an increased mortality among those taking vitamin E supplements. Other trials of

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Hidden data, ghosted-science and betrayal of public trust in pharmaceutical research

Many commentators are suggesting that we need to strengthen the system that ensures the integrity of pharmaceutical scientific literature. The case of Aubrey Blumsohn at Sheffield University suggests that we need to pay greater heed to those questioning current practice. Blumsohn was Senior Lecturer in Metabolic Bone Medicine at Sheffield University between 2000 and March 2006. In September 2005 he was suspended from his university position for communicating with the media about scientific integrity. He can be contacted at ablumsohn-3@yahoo.co.uk

PHARMACEUTICAL companies sell products under the banner of science. Attempts to ensure that “patients do not receive misleading information about the effectiveness of alternative medicines”¹ will fail if we don’t also address urgent problems with the integrity of the scientific literature upon which patients should rely. We are heading, like the Titanic, towards an iceberg of enormous size.

The past year has seen many erudite commentaries about the integrity of pharmaceutical medicine^{2,3,4,5,6}. The suggested remedy is that pharmaceutical companies must be divorced from direct involvement in researching clinical aspects of their own drugs³. The industry has developed an extraordinary stranglehold over academic discourse, the safeguards of science and common sense. The stranglehold extends to the regulators including the MHRA⁷.

The most fundamental of these safeguards are the accountability of authors⁸ and the primary importance of raw data. International standards were adopted by scientific journal editors following embarrassing disclosures. These standards reassert that authors should state in writing that they have full control of all primary data and controlled the decision to publish. Despite this, when the scenario in Sheffield was exposed to the media, Procter and Gamble (P&G) declared it was “standard industry practice”⁹ to limit authors’ access to raw data, but that “occasionally” authors are given such access.

“The MHRA is itself accused of failing to examine or to secure raw data in drug licensing applications, simply accepting the word of industry with blind faith...”

In 2002 I signed a research agreement with P&G in collaboration with another academic, Professor Richard Eastell. The consequences of my disagreement with the company and with my collaborator have been widely discussed in the media⁸. I do not intend to discuss what happened in Sheffield in greater detail than is already in the public domain.

In spring 2006 *The Journal of Bone and Mineral Research*¹⁰ placed a “Statement of Concern” on its website. The statement relates to one of three intended Procter and Gamble publications¹¹ about change in bone turnover and fractures in patients taking P&G’s osteoporosis drug Actonel. The other two publications (one based on an extended set of the same data and another on new data) have only been published in abstract form because I declined, as first author, to sign journal declarations while being refused access by the company to randomisation and event codes⁹. The research involved an important secondary endpoint in the key randomised trials used to gain regulatory approval for Actonel.

Data were required by the academics to verify scientific reports, statistical analyses, meeting abstracts, and draft publications “ghost written” in their names. Various statements made by P&G officials in their defence are illuminating⁹. For example, they claimed⁹ that “we don’t need to ask an independent person to analyse the data just to make a few people happy” (the independent person being the intended first author). They also claimed⁹ that that refusal to supply data to authors was in accordance with “PhRMA guidelines” (PhRMA is the main US lobby group that

represents pharmaceutical manufacturers). On one occasion when asked for the data, the company stated that, “On the plus side it does add an extra layer of external credibility - with this however, industry loses the opportunity to demonstrate its ability to be a true partner in scientific endeavours”⁹.

In response to further media scrutiny P&G produced a new “Bill of Rights” governing its relationships with academics in February 2006⁹. The bill stated that “research authors will define and control the content and direction of any publication resulting from their work”, have “final authority” over all publication content, and will be “in no way restricted” from publishing findings. It says authors will have “full access to all relevant data to confirm the accuracy of statements and conclusions”. This “bill” stipulates the rights and obligations academics have always had, as well as the conditions for publication in any respectable journal. Nevertheless, it is a step forward.

In April 2006, after a three-year delay, P&G supplied the data codes underlying the three intended publications. A key conclusion of all three papers had been that there was plateau at a commercially convenient point in the response relationship for the drug - a matter of practical clinical relevance. These data, a statistical report⁹, as well as many documents and dozens of tape recordings confirm that the conclusion in all three publications did not appear to be supported by the data.

The Sheffield dispute was discussed in the UK parliament in December 2005 and was transmitted by the Health Minister to the UK drugs regulator, the MHRA for “investigation.” The MHRA is itself accused of failing to examine or to secure raw data in drug licensing applications, simply accepting the word of industry with blind faith^{5,7}. No investigation (or at least anything fitting that definition) took place. The MHRA has failed to produce any report as yet, declined to accept any documentary evidence⁹, stated that the matter was of “low priority”⁹, and that the agency does not have any procedure for investigating research misconduct (response to FOI request to MHRA #FOI 06/188). Further, it claimed that the drug regulator has no remit, nor any necessary obligation to be interested in the integrity of the scientific literature about drugs⁹ (response to FOI request to MHRA #FOI 06/188) unless related to licensing (and collected using documentation appropriate for licensing). It even argued that it is “illegal” for a scientist to have data pertaining to information written in his name without the consent of the company “owning” that data⁹. It refused to compare data it was sent from Sheffield with the original data it should have received and examined as part of the licensing process for Actonel. Initially, this refusal was on the basis that it would be “too much work”. Later, it admitted that that it had not in fact seen or retained raw data prior to approving the drug (response to FOI request to MHRA #FOI 05/404). With governments setting the standard for

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To take antioxidant supplements or not? That is the question

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vitamin E have shown similar results. Miller and coworkers⁸ published a meta-analysis of trials of vitamin E supplementation; while low dose supplements were generally protective (though two of these studies were in Linxian in China, among people whose general nutritional status, and especially antioxidant status, was low), most of the trials of high dose supplements showed increased mortality, which increased as the dose of vitamin E increased.

The antioxidant paradox

We have ample epidemiological evidence that high vitamin E and β -carotene status is associated with lower incidence of some cancers and ischaemic heart disease, and there are good plausible biological and chemical mechanisms to explain the protective effect. However, most of the intervention trials have shown increased mortality. The answer seems to lie in the way in which these antioxidants act. They quench radical chain reactions because they form

stable radicals, which persist long enough to undergo reaction to non-radical products, but this means that they also persist long enough, as radicals, to penetrate deeper into tissues, and deeper into plasma lipids, to cause more damage.

The Editor of *Nature* was remarkably prescient in 1981 when he printed a footnote to the Peto *et al* paper¹ stating that “unwary readers (if such there are) should not take the accompanying article as a sign that the consumption of large quantities of carrots (or other dietary sources of β -carotene) is necessarily protective against cancer.” The same caveat still applies, but now to the consumption of supplements of β -carotene and vitamin E, rather than to foods rich in these nutrients.

David A Bender

Department of Biochemistry and Molecular Biology
University College London

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Hidden data, ghosted-science and betrayal of public trust in pharmaceutical research

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scientific conduct, it is hardly surprising that independent science has encountered such difficulties.

The problems of medicine could not happen without the participation of medical journals, most of which receive substantial advertising and “reprint” income from industry.

The solution to these problems is not clear. However, the independent investigation of the MHRA suggested by the Health Select Committee⁷ must take place. Research participants and patients must also be involved. Data is derived from human participants who subject themselves to risk in the public interest. Participants have the right to know that the data derived from their assumption of risk are used properly. When data are closed to scrutiny even by the supposed authors of research this cannot constitute an appropriate

or ethical use of that data. As academics we need to reassert the importance of data, the meaning of authorship, our right to speak the truth as we see it, and to allow that truth to be subjected to open debate.

“...the integrity of a body of literature is itself our society's ultimate temporal forum for negotiating life and death, suffering and wellness...the medical well-being of the society it serves is dependent on the question of who stands behind the word.” Fr Mark Gruber, 1999, cited in reference⁸.

Aubrey Blumsohn

MB BCH, PhD, MRCPATH
Sheffield

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Is there a way to roll back the dark ages of clinical medicine?

From retired surgeon David L Crosby OBE LLM FRCS, of Cardiff

Sirs,

I AGREE with Dr Goodman, in his article "There's none so deaf" (*HealthWatch Newsletter*, issue 62 July 2006), that critics of complementary and alternative medicine (CAM) are commonly accused of having closed minds, which is of course entirely untrue. Nevertheless this is a turf war which we who like to think of ourselves as medical scientists are steadily losing. Medical scientists therefore need to review the situation if they are to evolve successful strategies which vindicate their fundamental belief in EBM. The motivation of the main players and stake-holders seems a reasonable place to start.

Patients are by definition a vulnerable population. Few have much understanding of medical science, and the differences between opinion, anecdote and statistical evidence. On the other hand, they do have considerable experience of the failures and inadequacies of orthodox treatment, particularly when told that only symptomatic treatment is available to them, correct though this often is. It is unsurprising that many look for solace and relief elsewhere, and want to believe that it will be successful, above and beyond the placebo effect.

For the purveyors of CAM, there is plainly a commercial interest. As far as I am aware there are no charitable outlets. Also, despite a large income, the industry does not fund research, or audit its many alleged therapies, though its advocates often suggest that others should do so.

General practitioners are also a vulnerable population, insofar that they are constantly harried by the "worried well". Mild hypochondriasis is common, which is also unsurprising in the light of the media attention given to medical disorders and their treatment. Referral for CAM, once serious organic disorder has been excluded, is a convenient way to sideline the pressures which such patients exert on busy clinics. Complementary therapists are willing to help, and usually have more time available to listen and provide sympathy.

DESPITE its cost, the provision of CAM under the auspices of the NHS is now widespread. In addition, several politicians have advocated publicly an extension of the NHS provision of CAM, and a cynic might suspect that votes must therefore be involved. They appear to be undeterred by the transfer of private expenditure on CAM to the already embarrassed NHS budget.

August bodies such as the BMA and GMC do their best to appear

as "honest brokers", and are adept at mixed and indecisive messages. The steady expansion of CAM in the NHS has occurred largely by default. The one body which has been set up *ex officio* to deal with issues of this kind is NICE, from which thus far there has been silence. Why do they not make a start on homoeopathy, reflexology, and aromatherapy? And finally, do we know what our medical students and other health workers are now being taught in relation to these alleged therapies, not to mention their basic instruction in the assessment of clinical evidence and the effects of bias?

Right-minded medical scientists are mainly NHS devotees who wish to see it run as effectively and efficiently as possible. Any form of resource wastage is detrimental to these aims. The late Archie Cochrane's plea as a student activist was that, "All effective treatment should be free". He clearly recognised a respectable niche for placebos, but he must be turning in his grave at the current state of affairs. The good guys are losing.

"this is a turf war which we who like to think of ourselves as medical scientists are steadily losing"

If I were a general pursuing a campaign aimed at rolling back the dark ages of clinical medicine, there are a number of points of attack that I would consider. Firstly I would work to separate the NHS from the day-to-day interference which now emanates from the DoH and its political affiliations. Secondly, I would scrutinise what medical students and other health professionals are being taught, and in particular what education they are given in regard to the evaluation of clinical evidence. Relevant examination questions should help. It would also be good to know that they are being taught to treat patients with tender loving care in addition to the application of medical science. One suspects that patients who do not receive this are more likely to be attracted to CAM and fake if not hazardous remedies.

And, thirdly, I would stimulate NICE to get on with what they are supposed to be doing. There is already a reservoir of information gathered by Professor Ernst's excellent department in Exeter. Failure to respond suggests that political brakes are being applied. More publicity along the lines recently initiated by Professor Michael Baum should also help, including brisk rebukes to the royals and others who pontificate on clinical care yet have no medical training.

Yours,

DAVID CROSBY

A medical student replies

From *HealthWatch* Committee member Elizabeth Fairfax, currently a final year student at St Bartholomew's and the Royal London Medical School:

Sirs,

HERE, the curriculum incorporates teaching of both 'complementary' and 'alternative' medicine (CAM) and there are also further optional modules in this area.

Our teaching has covered the basic types of CAM, current regulations and the training of practitioners. Lectures provide an insight into both the positive and negative aspects of CAM. There are many reasons why the general public are turning to alternative methods of healthcare, not all of which are evidence based. It has been argued that the use of CAM reflects dissatisfaction with conventional healthcare and also permits individuals to feel they have more control over their treatment.

However, if scientific evidence does not exist to support such treatment, then I believe it should not be paid for with public money.

It would be wrong to dismiss CAM as being worthless in medicine.

Many herbal medicines have been shown to be effective treatments. For example, *Tripterygium Wilfordii* Hook F has been shown through double-blind, placebo-controlled studies to be therapeutic against Rheumatoid arthritis¹. If CAM is to be used, however, then the medical profession needs enough information about any treatment offered to ensure that a patient receives the most appropriate treatment for their condition.

Due to the toxicities associated with many herbal medicines, it would be unethical and dangerous to advise the use of such drugs without the evidence of any therapeutic effect.

Yours,

ELIZABETH FAIRFAX

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The Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006

HEALTHWATCH IS a small independent charity (No 1003392) set up in 1990 to promote the proper testing of all forms of treatments, whether “Orthodox” or “Alternative”. Patients are entitled to have reliable information about the treatment they are offered: has it been shown to work or not? The Medicines Act 1968, which followed a review of the thalidomide tragedy, required controlled clinical trials to provide scientific evidence of the safety and efficacy of medicines, and applied strict controls on the marketing of medicines and the medical claims made on them.

To protect the public the UK’s licensing body, the MHRA was set up to “enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe.”

Tragically, the MHRA has now failed to do what it was set up to do.

From 1st September 2006, new regulations have come into force for marketing authorisation of homeopathic products, with the specified aim of removing barriers to the expansion of the homeopathic industry. In recognition of homeopathic products being unable to meet standards of clinical efficacy required under the Medicines Act, these separate rules set out safety requirements (in accordance with Directive 2001/83/EC) but reduce requirements for efficacy, accepting homeopathic ‘proving’ as sole evidence of efficacy.

“The MHRA has accepted homeopathic ‘proving’ as evidence of efficacy in order to protect the commercial interests of the homeopathic industry, and with disregard for the truth, or the health interests of the public.”

Homeopathic “proving” are not in any way a proof of efficacy or safety. They are based on the observation that quinine (for example) when taken in normal dosage may cure malaria, but it can also cause symptoms similar to those caused by malaria. In the 1790s Dr Samuel Hahnemann applied the Hippocratic theory that “like cures like” and reasoned that quinine could cure malaria, but if sufficiently diluted should be free of side effects. Not surprisingly, controlled clinical trials in the 20th century have shown that the almost infinitely diluted homeopathic remedies are free from side effects, but unfortunately do not cure malaria, or any other disease.

The new regulations also permit new homeopathic products to indicate on the label their intended use for relief of minor conditions

or symptoms, as was the case prior to the Medicines Act 1968. For over thirty years it had not been possible to make medicinal claims for new homeopathic products other than those still around from before the Medicines Act (i.e. products known as PLRs). Such claims, however worded, imply that efficacy has been proven, which is simply untrue.

In the past HealthWatch has often criticised alternative treatments (as well as orthodox ones) when they made health claims that were untrue or misleading. The response from alternative practitioners has always been that we are mere puppets defending the commercial interests of the pharmaceutical industry. This is untrue, and in the case of the new regulations about homeopathic treatments it is the exact opposite of the truth. The MHRA has accepted homeopathic ‘proving’ as evidence of efficacy in order to protect the commercial interests of the homeopathic industry, and with disregard for the truth, or the health interests of the public. It was under no obligation to do so. Under Directive 2001/83/EC, national governments are permitted to make their own regulations stipulating efficacy requirements and labelling authorisations of homeopathic products.

HealthWatch has no vested interests for or against homeopathy, but a duty to tell the public the truth about treatments. The MHRA has a similar duty, but their shameful betrayal has been achieved furtively, while Parliament was in recess. The new regulations should be rescinded when parliament reconvenes, and all homeopathic products, including those with PLRs, should be required to submit to the requirements of the Medicines Act 1968 in order to seek authorisation to be marketed as a medicine with indications.

John Garrow

*Emeritus Professor of Human Nutrition
University College London*

Published by HealthWatch
Box BM HealthWatch, London WC1N 3XX
Press Office: 0208 789 7813
www.healthwatch-uk.org

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**The Editor, HealthWatch Newsletter, HealthWatch,
Box BM HealthWatch, London WC1N 3XX**

Letters and articles may also be sent to the Editor by e-mail to:
newsletter@healthwatch-uk.org

HealthWatch promotes:

1. The assessment and testing of treatments, whether “orthodox” or “alternative”;
2. Consumer protection of all forms of health care, both by thorough testing of all products and procedures, and better regulation of all practitioners;
3. Better understanding by the public and the media that valid clinical trials are the best way of ensuring protection.

HealthWatch welcomes membership enquiries from those who share its aims. Membership costs £16.00 per year (£10.00 for students; £20.00 for those outside Europe). Questions about membership can be sent to Michael Allen at michael.e.allen@btinternet.com

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