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HealthWatch

...*for* treatment that works

Newsletter 56 January 2005

WE DON'T usually publish "letters to the editor" on the front page. However, nurse Debbie Kings' protest against the growing acceptability of untested medicines—spurred on by recent news of Government moves to encourage greater use of complementary and alternative therapies on the NHS (see next page)—is the most apt reminder possible of the very reasons why HealthWatch was conceived. We hope that 2005 will see a redoubling of the efforts of HealthWatch, its members and supporters, and perhaps even the prevention of some tragic and unnecessary deaths.

CRAZY REMEDIES, POINTLESS DEATHS

MY FRIEND'S husband has been diagnosed with breast cancer. She is now embarking on a quest to "cure him" with the use of "alkaline water" and the Hay Diet. She is about to spend $400 importing a water ionizer from the US. My husband is a scientist, I am a qualified nurse, with years of experience in oncology, but we are unable to convince her otherwise.

I have written long letters disputing the claims of the website, which she has then forwarded to her contact. He still maintains she should buy one. The claims of this site are outrageous! Water that can lower blood pressure, cure osteoporosis, deprive cancer cells of oxygen, "thin" the blood, make it alkaline, and so on. Is there any way of bringing some sort of action against these people? Or is it simply a hazard of the world wide web?

I have nursed people with curable disease, who have died because they use therapies such as Gerson or crystal healing. It is heartbreaking. I am no fool, and know that doctors are not always right. But science and medicine has a far better track record than fads or quackery that have evolved down the centuries. I fear that this will be yet another death that could be avoided, and I suspect this is not the only story like it. Only last night, my friend told me of an Ayurvedic supplement she had ordered for her husband. It sounded innocent enough. However a quick Internet search revealed that at least one young man died of leukaemia in the US after using it—four months after the practitioner told him he was free of his disease. His widow could not afford to bring action against this fraudster.

These people are pariahs. A diagnosis of cancer is so frightening, and the promise of an "easy cure" must be irresistible to such vulnerable people. I'm afraid we have done ourselves a disservice over the years with our attitudes in conventional medicine. That, as well as not having the kind of advertising these sites employ! But how could we? We have an ethical standard to maintain.

Last year, I nursed a young boy with testicular cancer. The tumour was as big as his head. His mother had been treating him with some crazy remedy. He died on my shift, a week away from his 18th birthday. The death of anyone when it is unnecessary is difficult—but a youngster.

I hope that you and others like you will eventually enable common sense to prevail, amidst a climate of openness and co-operation between those who are sick and those of us who want so much to help them.

Yours faithfully,
DEBBIE KINGS

Dr David Bender has written a fascinating analysis of the web site promoting "alkaline water", which will appear in the next issue of the HealthWatch Newsletter.

HealthWatch rated among 10 best health web sites

A JOURNALIST writing in the *Guardian* has named the HealthWatch web site among ten of the best online health resources.

In the article, titled "Surf yourself better", Sophie Petit-Zeman commends HealthWatch for its efforts to explain "why clinical trials—often portrayed as dangerous games for human guinea pigs—are the fairest way of distinguishing bad treatments from good."

Elsewhere Dr Petit-Zeman recommends reports on some sites with which HealthWatch members will already be familiar, such as the Cochrane Collaboration's vast evidence archive (**www.cochrane.org**), Dipex's innovative database of patient experiences (**www.dipex.org**) and the US health myth debunkers Quackwatch (**www.quackwatch.org**). Browsing of the other sites mentioned is also highly recommended. Read all at **http://www.guardian.co.uk/g2/story/0,,1367825,00.html**

The Guardian G2, 7th December 2004

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HEALTHWATCH AGM 2004 A SUCCESS

FORTY-FIVE members and guests attended the 12th HealthWatch Annual General Meeting at the Medical Society of London. This year's HealthWatch Award went to Dr Richard Smith, who was until recently editor of the *British Medical Journal*, and whose controversial speech is reported on pages 4 and 5 of this issue. The third HealthWatch Student Prize for Clinical Research Protocol Appraisal went to Emma Court of Barts and The London Medical School, with runner-up prizes to Christopher Coyle, Elizabeth Fairfax, Thomas Nolan, Vinay Parmar and Hoong Wei Gan.

Winning smiles: Richard Smith (near left) collects HealthWatch Award 2004 from Nick Ross; and Student Prize runner-up Elizabeth Fairfax (above)

Government to encourage use of CAM

GREATER use of complementary and alternative therapies on the NHS is to be encouraged by the Government, according to a recent report in the *Daily Telegraph*. Booklets, funded by the Department of Health and produced by the Prince of Wales's Foundation for Integrated Health, are currently being distributed to every GP surgery, describing a list of free therapies including osteopathy, acupuncture, aromatherapy and homoeopathy.

The GP's committee at the British Medical Association has expressed concern at the move. Meanwhile Edzard Ernst, professor of complementary medicine at the Universities of Exeter and Plymouth, said alternative medicines should "definitely" be available on the NHS—provided they had been properly tested. "We should not be using therapies that are not demonstrably safe and efficient," he commented.

The following week Peter Hain, secretary of state for Wales, wrote in the *Independent* in support of CAM, although his evidence was limited to his own family's personal experiences. *See also letter from David Crosby, page 7 of this issue.*

Daily Telegraph, 9 October 2004 or see
http://www.telegraph.co.uk/news/main.jhtml?xml=/news/2004/10/09/nmed09.xml
Independent, 19 October 2004 or see
http://comment.independent.co.uk/commentators/story.jsp?story=573548

SENSE ABOUT SCIENCE

A new organisation, sharing many of HealthWatch's aims and concerns but with relation to the world of science in general, came into being three years ago. Ellen Raphael explains.

BACK in 2001, the newspaper front pages were ablaze with headlines about mobile phones 'frying your brain', genetically modified 'Frankenstein foods', the MMR vaccine, experiments using animals, and the dangers of cloning. Scientists seemed very much on the fringes of many of these debates, and their scientific evidence and data had even less of a presence.

Responding to this apparent challenge to reasoned debate, Dick Taverne, a member of the House of Lords' Animals in Scientific Procedures Committee and himself married to a scientist, wrote and published a series of articles. He was inundated with calls and letters from people, including leading figures from the worlds of science and medicine, telling him "you must do something".

He did do something. At the end of 2001, he convened a meeting which resolved that scientists need to take more responsibility, and do so more immediately, for putting evidence at the centre of debates about scientific issues. In 2002, after recruiting a director, the collaboration became Sense About Science, an organisation to promote an evidence-based response to matters of science and risk among institutions, government, the media, companies and NGOs.

In 2003, following a very busy first year and rapid growth of a network of people keen to contribute to a more reasoned discussion of scientific controversies, Sense About Science was formalised as a Charitable Trust. It is governed by a Board of Trustees, many of whom have led Sense About Science from that initial meeting. The charity is further supported by a 31-member Advisory Council of scientists and individuals with a passion for science, who are keen to promote the evidence-based approach.

Funding moves at a much slower pace than social debates, but with the pump-priming help of a few companies and societies in the beginning, Sense About Science has been able to reach a stage where its main donors are trusts and foundations.

Currently, Sense About Science is asking scientists to take part in initiatives including: peer review—building on our working party report, *Peer review and the acceptance of new scientific ideas*; chemicals—challenging popular assumptions that natural chemicals are safer than artificial ones; radiodiagnostic screening—considering the implications of advances; and Voice of Young Science—bringing more younger scientists into difficult areas of discussion about science.

The mood is beginning to change—scientists contact us for support and advice when they are concerned about an issue and are often willing to get involved in challenging meetings and discussions. The establishment of the Science Media Centre at the same time as Sense About Science has also been very helpful, with the centre being highly effective at providing scientific voices for national news journalists.

The challenge, however, remains, and extends beyond the daily headlines. We are often struck by the strange gap between everyone talking about communicating science and the struggle to find people to do exactly that on some difficult issues. Few people propel themselves into difficult meetings with campaign groups or uncomfortable phone calls to lifestyle commentators, for example, so it takes a bit of pressure to remind people of what's at stake, both for science and society.

We need to keep supporting scientists willing to communicate when it matters most, as well as working to ensure that evidence is at the forefront of debates about science.

Ellen Raphael
Programme Manager, Sense About Science
www.senseaboutscience.org

OUR IMPORTANT CONTRIBUTION

HealthWatch's Chairman John Garrow addressed one of HealthWatch's busiest ever Annual General Meetings at the Medical Society of London on 19th October 2004.

I AM MORE THAN EVER convinced that HealthWatch can make an important contribution to health services in this country. Our aim is to provide the public with *reliable* information about healthcare. There is no shortage of people who want to provide information on healthcare to the public, but in many cases this is better described as advertising than education.

Peer-reviewed medical journals are at the highest academic level of information providers. These publish the results of randomised controlled trials, which are the most respected form of clinical trial to establish the efficacy of treatments. I will say no more about this here, because our Award Winner this year is Dr Richard Smith, for 25 years editor of the *British Medical Journal*, and an outstanding champion of ethical medical journalism. The title of his Address implies that he has some concerns about the influence of pharmaceutical companies on the material that is published in the medical press. You can read a full report of his speech on pages 4 and 5 of this issue.

It would be invidious to identify the lowest academic level of information providers about healthcare, but a contender for this title would be "the world's most acclaimed nutritionist". This lady provides nutritional advice to a television audience of four million, her book has been high on the best seller list, and her patients (we are told) are high on the celebrity list. It is now being demonstrated that her academic qualifications are very much less impressive than they seem—indeed one of the diplomas that testify to her academic prowess has recently been acquired by a dead cat[1]. However, readers or television viewers (and consequently journalists) are not fastidious about academic credentials: as Geoff Watts has explained[2] they want exciting stories about exceptional individual people.

"Our aim to inform the public...is now less about exposing charlatan snake-oil salesmen, but more about the grey area in which commercial interests, often by subtle methods... overstate the efficacy of their product."

HealthWatch is keen on proper testing of treatments by well-designed clinical trials, rather than exciting stories about exceptional individuals, so we cannot look to the media to publish the evidence that we consider to be important. Royalty does not always see the need for proper clinical trials before claims of efficacy are made[3]. Sadly, *Health Which?* has now ceased publication. But new structures are being created to ensure that new research projects are transparent and fraud-proof, that published research is comprehensive and unbiased, and that attention is paid to the experience of the real "expert" on a particular disorder—that is, the patient.

All this is very encouraging, but there is a trade-off between productivity in research and rules to improve safety. Even more stringent regulations about permissions and documentation for clinical trials become counter-productive: eventually they make some important types of research virtually impossible[4]. Meta-analysis of publications by experts in the field may reach more authoritative conclusions than selective reviews by proponents of one particular therapy, but the inclusion criteria for studies to be analysed are crucial, and these inclusion criteria may reflect the interests of the meta-analysts[5]. The Expert Patient Programme[6] brings forward the experience of patients suffering from a particular disease, but generous sponsorship of patient support groups by commercial organisations that have an interest in the disease may, by this route, bypass the rules forbidding Direct to Consumer advertising[7].

Expenditure on healthcare is huge, and wherever huge sums of money are being spent commercial providers will quite properly seek to capture a good share of the market. Our aim to inform the public about "the treatment that works" is now less about exposing charlatan snake-oil salesmen, but more about the grey area in which commercial interests, often by subtle methods that are difficult to detect, overstate the efficacy of their product. This is a difficult and often thankless task.

I would like to thank most sincerely all the Committee that do this work, but in particular our President, Nick Ross; our vice-chairman, David Bender, who brilliantly manages our website and (for example) provided the audiovisual equipment for this meeting; our Secretary, Michael Allen, who has done even more than usual this year due to the illness of our Membership Secretary, and our Treasurer, John Hanford, who has for the past eight years looked after our finances, but who is sadly resigning at the end of the current financial year. The AJAHMA Charitable Trust has continued generously to support our Student Prize, which is administered by Dr Joan Gandy, and Caroline Addy seeks out potentially libellous items in our Newsletter. All of these put in many hours work for HealthWatch without any financial reward whatever. I am very proud and grateful to work with such a talented and dedicated group of people.

John Garrow
Emeritus Professor of Human Nutrition
University of London
and *Chairman of HealthWatch*

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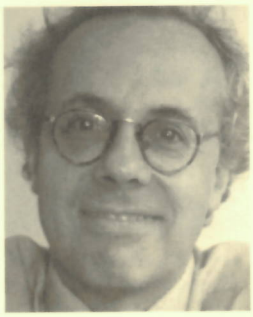
MEDICAL JOURNALS: AN EXTENSION OF THE MARKETING ARM OF DRUG COMPANIES?



EVERYONE KNOWS that medical journals and drug companies are economically interdependent. Drug companies need journals to publish the results of their clinical trials showing the efficacy and safety of new drugs in order to obtain product licences for these drugs. Journals obtain substantial income from drug advertisements, reprints and supplements. "So what?" you may say, "isn't this how it is with all products advertised through the print and broadcast media, so why make a fuss?"

After accepting the 2004 HealthWatch Award Dr Richard Smith (pictured above) formerly editor of the *British Medical Journal*, explained to his audience why it is very necessary to make a fuss, *reports John Garrow.*

The relationship between medical journals and the pharmaceutical industry is far more intimate and sinister than that between advertisers and the general media. It is not only Smith that says so. He cited some important commentators in support of his case: *Lancet* editor Richard Horton[1] claims, "Journals have evolved into information laundering operations for the pharmaceutical industry". Marcia Angell, former editor of the *New England Journal of Medicine*, has commented[2], "[The pharmaceutical industry] has moved very far from its original high purpose of discovering and producing useful new drugs. Now primarily a new marketing machine to sell drugs of dubious benefit, this industry uses its wealth and power to co-opt every institution that might stand in its way, including the U.S. Congress, the Food and Drug Administration, academic medical centres, and the medical profession itself." The promotional blurb of a book by Jerry Kassirer[3], another previous editor of the *NEJM*, reads, "Dr Jerome Kassirer offers an unsettling look at the pervasive payoffs that physicians take from big drug companies and other medical suppliers, arguing that the billion-dollar onslaught of industry money has deflected many physicians' moral compasses and directly impacted the everyday care we receive from the doctors and institutions we trust most."

"Independent reviewers found about half of the advertisements for prescription drugs in medical journals are biased, giving too great prominence to claims of efficacy, too little to side effects, often recommending use of the drug in a patient group other than that in which it had been tested."

These are eminent medical editors whose warnings we should heed. If, as Kassirer states, the enormous economic power and influence of drug companies has "deflected many physicians' moral compasses" to the extent that the public is now fed misleading information about the efficacy of drugs, this is something HealthWatch should mind about very much indeed.

A few simple figures illustrate the great economic power and profitability of the drug industry. They are now producing relatively few new drugs, but concentrating their efforts more on marketing existing drugs. US companies spent $15.7 billion on drug promotion in the year 2000. That represents about $10,000 on each individual doctor. Since 1995 research staff numbers have been reduced by 2%, while marketing staff have increased by 59%. Researchers comprise just one in five of drug company staff—they are outnumbered two to one by marketing staff.

At present prescription drugs cannot be advertised in the general media (although this rule is being undermined by advertisements on the internet) so the industry needs to persuade doctors to promote and prescribe new drugs in place of older and less profitable ones. It has been shown that endorsement by doctors is more effective in altering prescribing practice than an equal expenditure on company representatives. Independent expert reviewers have found that about half of the advertisements for prescription drugs in medical journals are biased in favour of the drug, giving too great

No need to falsify data:

ways in which companies might use real trial results to get the results they want

- The new drug can be compared with placebo, or too low a dose of a competitor drug, so the new drug is shown to be "effective", when really it is no better than an alternative treatment.
- The new drug can be compared with too high a dose of a competitor drug, so it can be seen to have fewer side effects.
- The new drug can be compared with a better (but more expensive) drug in a small trial so the results show "no significant difference" and the new drug appears good value for money.
- The trial may have several different end-points, and the report cites those results in which the new drug performed well, but not those in which it performed badly.
- The drug may be tested on a heterogeneous group of patients, some of whom did well and others badly. Select a group (eg. men over age 50) who did well and publish those results and forget the rest.
- If there is no subgroup that does well do not publish that study at all.
- If you have a good study, publish it more than once.
- Sponsor multicentre trials, but publish only those centres that show favourable results.
- Publish separately different outcome measures from the same trial.
- Publish different follow-up periods, eg. results at 3 months, one year, two years…
- Publish positive results in major journals and negative or neutral results in minor journals.
- Combine results in ways that are favourable.

prominence to claims of efficacy, and too little to side effects, and that often the advertisement recommended the use of the drug in a patient group other than that in which it had been tested. It would be possible to peer review all advertisements in medical journals, but this would be very expensive and most editors would rather spend the money on maintaining as high a standard as possible in the research publications. It is not unknown for advertisers to strike a deal with editors, such as favourable editorial mention of a drug in return for placing an expensive advertisement. Some journals carry a section on "product news" which appears to be independent but is in fact "advertorials". And as we heard from the winner of the 2003 HealthWatch Award, Dr Peter Wilmshurst, it may be very difficult to publish reports of an adverse drug effect in major journals, because the makers of the drug will fight vigorously to suppress any such publication.

But perhaps the most important, and certainly the most subtle, way in which the drug industry can influence the opinion of doctors about the efficacy of a drug is by the publication of clinical trials in reputable journals. Systematic reviews of randomised controlled trial are the very best evidence on which Evidence Based Medicine is based. But the systematic reviews are only as reliable as the trials that the meta-analysts have analysed. Of course if trials are technically poor (bad randomisation, weak blinding, inappropriate statistical analysis, etc.) they are given little weight in good systematic reviews, but if the trial is technically perfect we must believe it, mustn't we?

It is unthinkable that reputable pharmaceutical companies and reputable medical journals would collude to publish fraudulent results about a drug trial, but we should bear in mind the pressures that operate when a major drug trial is submitted to a journal for publication. From the journal's viewpoint the financial benefits of publishing the trial are very large (see below). From the drug companies' viewpoint the stakes are even higher. They have already spent many £m in developing the drug, but if a major multicentre trial shows that the drug is relatively ineffective, or has serious side effects, that is a commercial disaster that must be avoided if that is at all possible. Initial drug trials are usually designed and funded by the manufacturer of the drug, the design of the trial is beyond reproach, and almost always the results are favourable to the sponsor. However, when independent researchers study the same drug the results are usually less favourable, and in some cases the drug is withdrawn because it is shown to be ineffective or unsafe. How can this occur?

"Setting the record straight about the efficacy of drugs is not a task for the faint-hearted: those with an interest in selling, say, Cox-2 inhibitors or HRT will fight fiercely to discredit any evidence that their value has been overstated"

Dr Smith led us through the methods that can enable companies to get the results they want without falsifying the data—see the table on the previous page. As an illustration he cited one particular drug about which there were publications describing 84 trials on 11,980 patients. In fact there were only 70 trials involving 8,645 patients, but 17% of the trials had been published more than once, though this was impossible to tell from the published studies. Smith used a Cochrane-type diagram to illustrate the way in which duplicated trials could increase apparent effectiveness. Initially 16 trials (group A) showed that the Number Needed to Treat (NNT) to obtain one favourable result was 9 patients (confidence interval 7-16). Three of the most favourable trials were duplicated (group B): now analysis showed only 4 NNT.

Next group B was duplicated again to give group C, so combining B+C gave 9 trials with 4 NNT, and finally combining all the trials and their selected duplicates there were (apparently) 25 trials giving 5 NNT (CI 4-6), which is a considerable improvement on the initial 9 (CI 7-16). Further examples were given of drugs that had apparently favourable clinical trial evidence (for example Cox-2 inhibitors *vs* NSAIDs, or HRT to protect against coronary heart disease) but scrutiny by independent experts showed the evidence was flawed. Setting the record straight about the efficacy of drugs is not a task for the faint-hearted: those with an interest in selling, say, Cox-2 inhibitors or HRT will fight fiercely to discredit any evidence that their value has been overstated.

AT THIS stage of the address Dr Smith had convinced us that his title proposition was true: to a very great extent medical journals are an extension of the marketing arm of the drug companies, and someone should do something to correct the situation. But what about those pillars of society—physicians sworn to serve only the interests of their patients? Or the medical press—are they not part of the Fourth Estate, champions of the people, said by Edmund Burke to be more powerful than parliament itself? Why do they condone this scandalous abuse of public trust? As I looked around the audience, many of whom were, or had been (like myself) physicians and medical editors, there were no confident smiles to be seen. A lone representative of the pharmaceutical industry was not looking very happy. How had we got into this mess, and how could we get out?

The first question was easily answered. Reprints of important drug trials, or supplements sponsored by drug firms, are major sources of revenue for journals. Two-thirds of trials in major journals (*Archives of Internal Medicine*, *JAMA*, *Lancet*, *New England Journal of Medicine*) are funded by the drug industry—for the *British Medical Journal* it is only one third[4]. Editors of journals (or their publishers) cannot afford to reject everything that is commercially sponsored. In many fields of medical research (such as obesity, in which I have experience) industry is virtually the only source of funding to employ research registrars, or buy expensive equipment. Unless (like me) they are fortunate to have departments funded by a charity, the great majority of physicians depend upon industry for their research bread and butter, never mind the champagne and canapés that may also be on offer. Politicians call it "partnership with industry" but it is a partnership in which power lies with the commercial sponsor.

What is the solution? Dr Smith offered some answers: A register of trials, so unfavourable trials do not "disappear". Publication of online journals not beholden to commercial sponsorship, such as PLOS Medicine (**http://medicine.plosjournals.org**); critical review of trial protocols by independent experts; and of course much more public funding of clinically-important trials. Whether his call will be heeded remains to be seen, but it will be certainly receive support from members of HealthWatch.

At the end Dr Smith received a standing ovation, and coped with another 30 minutes of well-informed and pertinent questions. Truly he is a worthy recipient of the 2004 HealthWatch Award.

Professor John Garrow
Chairman of HealthWatch

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REGULATION OF UNLICENSED MEDICINES: A CASE STUDY

Les Rose, a freelance consultant with 30 years' experience in the health care industry, mostly in clinical research, writes in despair of his failed efforts to draw the authorities' attention to illegal promotion of unlicensed health products.

THIS STORY typifies one of the reasons that unproven remedies are able to be so widely used. A local high street shop advertises in its window "effective treatments" for a long list of medical conditions, some potentially serious. I asked the proprietor for a treatment for psoriasis, a very difficult to treat skin disease. He showed me a white plastic bottle labelled "psoriasis tablets". There was nothing else on the bottle.

I asked for some evidence that it was effective. He said that these were all Chinese medicines. As this was not an answer, I asked whether he had any clinical trial data. He said he did not. I asked whether he had any evidence of effectiveness from clinical trials for any of the many products in the shop. He said he did not. I asked what was in the psoriasis tablets. He said that all these medicines might contain as many as 30 different herbs, so he could not say. I asked whether he could tell me what any of the medicines contained. He said he could not.

I complained to the Advertising Standards Authority, but they said that their remit excludes shop front advertising. I complained to the Trading Standards department. They said that it is clear that an offence has been committed, but that enforcement is the remit of the Medicines and Health Care Products Regulatory Authority (MHRA). I spoke to the MHRA Herbal Remedies Policy Unit. They admitted that they do not provide any enforcement. They only send out threatening letters. They agree that these products commonly poison people but they are unable to do anything to stop them.

I then sent in a report to the MHRA Enforcement Unit. Nearly three weeks later they sent me a press release about MHRA concerns as to the quality of traditional Chinese medicines. There was no mention in the press release about unsupported claims of efficacy. I telephoned and e-mailed the writer several times to clarify that I was at least as concerned about efficacy, but received no reply. Finally—four weeks after I sent my original report—my telephone rang. A very charming and helpful lady explained that there are only 20 people in the Enforcement Group to cover the entire UK. By act of Parliament they are not able to elicit support from the police. From this revealing conversation the following key points emerged.

1. There is ongoing discussion between the MHRA and the Department of Trade and Industry regarding unsupported trading claims. It appears that these may breach the Enterprise Act. However there has been no decision as to who will enforce whatever Act is being breached. Meanwhile retailers in their tens of thousands have pretty much an open season to claim whatever they like.
2. It is impossible to say how long it might take to investigate a complaint. Regulation is reactive rather than pro-active—for example if someone dies from poisoning then action is taken.
3. Complaints about herbal medicine are typically referred to the Borderline Substances unit, who will decide whether it is an unlicensed medicine. I pointed out that a medical claim surely makes it a medicine, licensed or not!
4. The MHRA is funded not from taxation, but from licence fees. Thus manufacturers applying for genuine products to be approved are paying for their own regulation. Clearly there is almost nothing left over for regulating those suppliers who choose not to apply for licences.

Why can the MHRA not work in the same way as the Advertising Standards Authority (ASA)? You can complain to the ASA via its web site, with copies of the ad, and within days the advertiser is notified and asked to defend the complaint. In a month or so the matter can be adjudicated and action taken. The MHRA, in contrast, is mired in bureaucracy and grossly under-resourced. There are 49,000 registered 'alternative' practitioners in the UK, and only about 30,000 qualified physicians. In addition there is a huge army of organisations and individuals peddling every imaginable remedy to a gullible public (and many unimaginable ones). The spokesperson agreed that both politicians and the public think that anything which can be described as 'natural' must be good, and never mind the evidence. Well aristolochia* is natural and they have banned it.

After many weeks I reached a senior investigator in the MHRA Criminal Investigation Unit. I learned that this unit has only 12 investigators to cover the whole UK, which means they can only deal with cases of actual harm to consumers. That is, they have to wait for someone to be poisoned first. Disturbingly, he told me that when they try to investigate or regulate CAM products, they have received phone calls—apparently from a government minister—telling them to "leave these people alone".

I conclude that there is absolutely no chance of my complaint being followed up. What will happen when the EU Directive on herbal medicines comes in? Will the UK government provide any means of enforcing it? No prizes are offered for your answers.

Les Rose
Pharmavision Consulting Ltd
http://www.crfx.co.uk/03_1065.htm

HealthWatch Chairman John Garrow comments: "What should have happened is that the local Trading Standards Officer should have issued a warning that the shop was in breach of the Trade Descriptions Act for applying a misleading description to the medicines if it was not "effective" as claimed. In practice only a few TSOs will do this, and then only to mail order sales that have a turnover of £10K or more. It involves too much time, trouble and expense to prosecute private herbal stores, because the TSO would have to import expert witnesses (very expensive, and paid for by the local authority) to convince the magistrate that the claims were false. Les Rose is right: retailers have (in practice) open season to claim whatever they like."

*Aristolochia is a plant species whose inclusion in herbal medicines has been banned by the Medicines Control Agency as they contain aristolochic acids, which are mutagenic, carcinogenic and cause kidney damage. See *Pharmaceutical Journal* 2000; **264 (7081):** 171.

MHRA 'not up to vetting job', says *Which?*

WHICH? MAGAZINE has told the government's Health Select Committee that the Medicines and Healthcare products Regulatory Agency (MHRA) is failing in key aspects of its job, particularly the vetting of advertisements for both prescription and over-the-counter (OTC) medicines, and asked that such areas of its remit should be removed.

Which?, published by the Consumers' Association, spoke out in October with examples of both over-the-counter and prescription-only adverts which potentially mislead the public and healthcare professionals. During the last two years, *Which?* and its sister publication *Drug and Therapeutics Bulletin* have resorted to initiating action through other agencies, bypassing the MHRA altogether.

For more news on *Which?* campaigns on health issues, see **http://www.which.net/campaigns/health/index.html**

Are we all wasting our time?

David Crosby, a consultant surgeon based in Cardiff, wrote after learning the news (see page 2, this issue) that more complementary medicine is to be made available on the NHS:

Dear Sirs,

IT IS ALL so depressing. Organisations such as HealthWatch do their best and work hard to steer healthcare in a sensible direction and to make it rationally based, and what do we get? Answer: complementary and alternative medicine (CAM) is to be "integrated" with the foregoing, and by government dictate made freely available by the NHS. Our efforts have been futile and we should not be surprised. The writing has been on the wall for some time.

We must all have seen shelves in high street pharmacies weighed down with all manner of disease curing remedies, and natural treatment centres in most shopping malls, all of which illustrate a major public demand. On top of that, the NHS itself has been making a significant provision of CAM for some years, particularly from physiotherapy departments and GP surgeries. The last estimate I saw reckoned that at least one billion pounds of NHS money was already being spent in this way. Protests that might have come from major health care bodies such as the General Medical Council, Royal Colleges, the British Medical Association, Department of Health, and even NICE, have been muted. It is difficult not to believe that royal patronage must have something to do with it.

A recent important straw in the wind was Michael Baum's brilliant open letter to the Prince of Wales on the subject. Yet, despite the fact that it attracted more than ten thousand hits on the BMA Internet it failed, according to the *British Medical Journal*'s editor, to gain the majority of support from their subsequent correspondence.

"Only health economists of the calibre of Prince Charles and Peter Hain could possibly believe the suggestion that this will actually save money"

So why does most of the world not think as we do? Perhaps the first reason is that the majority of our fellow citizens have not enjoyed the privilege of a basic scientific education. Those familiar with Archie Cochrane's classic monograph on "Effectiveness and Efficiency" in the delivery of healthcare, will recollect his observation that "opinion" had become so much more important than "evidence". He also pointed out that the majority of the population strongly wish to believe that a particular treatment will work, especially when confronted by practitioners who wish to provide the solution to their problems. The result is a kind of willing conspiracy. To be fair, in relation to CAM, some of these practitioners genuinely believe they are right, but the majority are part of a provider led industry, which is now of mega proportions.

TELLING people what they want to believe, and already half believe, is one of the oldest tricks in the book, particularly when deployed by politicians. The damage that can be done in this sphere can make medical deception a sideshow. Take for example blaming unemployment on immigrants, and even worse, Hitler blaming Germany's problems on the Jews. It really is important to insist on having sound evidence. The general population seems quite ill equipped to do this, presumably due to educational failure, but it seems unfair to blame the general population when medical students and doctors appear to have similar shortcomings in their own field.

But to be fair to our colleagues in general practice who already provide a great deal of CAM, I suspect that most of them do not believe it to be effective, but justify their stance on two grounds. Firstly as they may fairly observe, much "orthodox" medicine has not been soundly proved, which is true. Secondly, CAM allows them to cope with many of the "worried well" hypochondriacs and heart sink patients who would otherwise weigh them down. The CAM option provides them with some escape from the remorseless demands that such patients make.

But why should the government volunteer to fund the additional costs to the NHS of "free" CAM? Only health economists of the calibre of Prince Charles and Peter Hain could possibly believe the suggestion that this will actually save money by taking the pressure off orthodox medicine. According to the *Daily Telegraph* there are about 56,000 CAM practitioners in the UK, making them far more numerous than GPs. Since many of them will now be paid fees by the State for services that have hitherto been funded privately, this money could only come from savings elsewhere in the NHS. This in turn would be inevitably reflected in a reduction in NHS staff.

No matter who else can believe this is likely to happen, I cannot believe that the hardheaded officers of the Treasury would do so, and yet this initiative must have passed their scrutiny. When I put this recently to a retired senior civil servant he agreed, but pointed out that such mandarins are not confined to the exclusive consideration of fiscal implications, but are also required to consider the political benefits to the government. With a general election forecast for the middle of next year, all becomes much clearer.

So what should well-motivated organisations like HeathWatch do? At the very least, new strategies are needed, and I wish I could think of some.

Yours faithfully
DAVID CROSBY

Letters to the editor...continued overleaf

Publish at your peril

MISGUIDED celebrity health advice has always amused and enraged supporters of evidence-based medicine. If a recent report in the *Weekly Telegraph* is to be believed Heather Mills, wife of Sir Paul McCartney, shows some confusion in her understanding of the aetiology of cancer. Following the recent death of the newspaper columnist Lynda Lee-Potter, who had in recent years been rather harsh in her criticism of the ex-model's abilities, Lady McCartney apparently commented to the *Telegraph's* Diary writer, "Why did she end up with a brain tumour? You have to look inside your karma and think about what you truly believe in and not just write what your editor tells you." Journalists everywhere beware.

Weekly Telegraph 10 to 16th November 2004

Letters to the editor

Evidence-based medicine and guidelines

The following letter originally appeared in the Journal of Family Planning and Reproductive Health Care *and is reproduced with the kind permission of the author Barbara Hollingworth, Consultant and Lead Clinician at Redbridge and Havering PCT; and of the journal's Editor-in-Chief:*

Dear Sirs,

I FEEL IT necessary to join the discussion about evidence-based medicine (EBM) and guidelines. I am dismayed at the constant negative attitude towards new contraceptives that are badly needed.

I do not believe (serious safety issues aside) that contraceptives should be viewed in entirely the same light as drugs used for a medicinal purpose; in the latter some minor adverse side effects are tolerated provided the overall risk benefit balance is acceptable for the condition being treated. With contraception, both efficacy and minor side effects are equally important. Indeed, for some women, the balance is reversed with a poorer efficacy being tolerated in favour of lesser or more acceptable side effects.

"if it will improve her compliance then it may be less expensive than paying for her termination of pregnancy"

The proponents of EBM have lost sight of the fact that most of what we do in family planning is not based on what would now be considered good evidence, and that it is reasonable to make certain assumptions. Last year the Clinical Effectiveness Unit's Product Review of Cerazette®[1] stated: "... an evidence-based recommendation cannot be made that the desogestrel pill is different from other POPs in terms of efficacy...", while the Drug and Therapeutics Bulletin[2] went further: "...there is insufficient evidence on whether it is a more effective contraceptive than other POPs..." and "... we believe the company's claim that Cerazette has the 'efficacy of a combined pill' is unsubstantiated and should be withdrawn". Less than a year later, the product licence for Cerazette has been officially altered to allow a 12-hour pilltaking leeway[3]—the same as for the combined pill. To most of us, this had been obvious from the start: while acknowledging a lack of good evidence, why could those writing the product reviews not have been less scathing, more willing to use a little common sense? Similar attacks have been made on both Evra® and Yasmin®, which should be welcomed as providing alternatives for women who may not have found a method that suits them.

Choice is extremely important: a woman may wish to use a product simply because her friend is happy with it. This may not be evidence based, but if it will improve her compliance then it may be less expensive than paying for her termination of pregnancy. Most modern contraceptives are very good: should we only have the one and tell women there is so little difference between them that it will do? Perhaps the *Drug and Therapeutics Bulletin* should learn from how people use its sister publication *Which?*: when I want to buy a washing machine, I might not chose their evidence-based top product if it doesn't match my kitchen, however well it washes my clothes.

Yours faithfully
BARBARA HOLLINGWORTH

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First appeared in *J Fam Plann Reprod Health Care* 2004; **30(4):** 276. The web site of the Faculty of Family Planning and Reproductive Health Care of the Royal College of Obstetricians and Gynaecologists is **www.ffprhc.org.uk**

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