

## Newsletter no 48: January 2003

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### More members, more awards

***The prestigious Medical Society of London was once more host to HealthWatch as the committee and members met for the charity's fourteenth Annual General Meeting. News of continued membership growth was welcomed and for the first time three HealthWatch prizes were awarded in one evening.***

The Annual General Meeting was opened by outgoing chairman Malcolm Brahams whose summary of the year's activities and thanks to all those who contributed appears below. He was followed by membership secretary Shirley Churchman who reported that once more our subscription list has grown, this year by 5%.

As Malcolm Brahams stepped down members re-elected Professor John Garrow, Emeritus Professor of Nutrition of University College London, as HealthWatch's new chairman.

With the committee business now over, the prize-giving began. HealthWatch's president, Nick Ross, awarded the first HealthWatch Prizes for Clinical Research Protocol Appraisal to James Hopkins, medical student from Guy's Hospital, and Elaine Sweet, nursing student from King's College. The competition, sponsored by a grant from the AJAHMA Charitable Trust, challenged the research and evaluation skills of students of medicine, nursing and complementary medicine. Entrants were invited to identify flaws in the design of clinical trials for a number of different complementary treatments. Mr Hopkins and Ms Sweet each won a cash prize of £500. The competition will be held again in 2003.

The highlight of the evening came after Nick Ross presented the 2002 HealthWatch Award for enhancing informed choice through reliable information to the leading surgeon Professor Michael Baum of University College London. Professor Baum's talk, "Screening for breast cancer: a cruel deception?" was extremely well received by the members and committee present and is reproduced [below](#) with his kind permission.

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### Complementary medicine research under threat

***Exeter University's department of complementary medicine is fighting for its future. The Independent reports that the world's leading research centre into complementary therapies is in difficulties. While department head Professor Edzard Ernst has raised millions of pounds for specific research projects, the department remains under threat from shortfalls in core funding to cover administration.***

Britain's only dedicated university department studying complementary medicines was founded in 1993 by an endowment from building magnate Sir Maurice Laing. But those who thought that the establishment of such a university department meant a stamp of approval for alternative treatments were disappointed. Professor Ernst and his team have rigorously applied scientific method to the testing of therapies such as acupuncture, herbalism and aromatherapy and have not been afraid to publicise negative results.

Discrediting popular therapies is not as lucrative as selling them, however. A number of potential benefactors have pulled out, says Ernst, on account of the department's reputation for being over-critical.

HealthWatch chairman Professor John Garrow supports the need for complementary medicine to subject itself to

scrutiny, and is quoted in the report as saying, "Ernst has done us a great service by making the evidence available to those who seek it."

The Independent, 6 October 2002

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## NEWS IN BRIEF

"A great leader" said the British Medical Journal's Minerva column (10th August) reporting on a fond farewell to Iain Chalmers at the Cochrane Collaboration's recent annual meeting in Stavanger.

The Cochrane Collaboration for Evidence-based Medicine, which Chalmers founded 10 years ago, now has 7000 members around the world. Commenting, "if anybody in medicine can match Gandhi, Churchill or Mandela it's Iain Chalmers", Minerva's tribute concluded, "The collaboration is just like Chalmers in that it celebrates reason but is driven by emotion."

British Medical Journal 2002; 325: 346.

**One in four hospital drug errors is "potentially serious", and likely to harm patients**, suggests a pilot study reported in Quality and Safety in Health Care. Pharmacists at a London teaching hospital recorded details of prescribing errors over a period of four weeks in 1999. Mistakes were made in 1.5%—equivalent to 135 drug errors a week. Of these, one in four could have resulted in significant harm to the patients. Paracetamol, morphine, diamorphine, metoclopramide and beclomethasone were the drugs most likely to be the subject of error, and more than half the errors were made by senior house officers. With one drug order made every 20 seconds it is impossible to eradicate all error, the authors acknowledge, but they point out that five potentially serious errors a day "is not acceptable." The Department of Health has recommended that serious errors in the use of prescribed drugs be cut by 40% by 2005.

Quality and Safety in Health Care 2002; 11: 340–4.

Joe Collier and Ike Iheanacho from Drug and Therapeutics Bulletin, writing in the Lancet recently, have suggested that multinational pharmaceutical companies manipulate information, contributing to a distortion of medical research. "Commercially determined goals", Collier writes, "represent genuine advances in health-care provision, but the huge scale of work involved, lack of openness, accompanying duplication, and distortion of the overall research effort and resulting messages make the business of information-generation inefficient and threatens patients' interests."

A Lancet commentary in the same issue cautions that, "Editors of medical journals should make decisions on content based on public-health needs, their journal's readership, and the medical community's needs, not on likely reprint revenues or advertising potential."

Lancet 2002; 360 (9343): 1346.

The belief that a person's mental attitude affects his or her chances of surviving cancer is not supported by the evidence, says a review in the British Medical Journal. Twenty-six studies on the effect of psychological coping styles—including fighting spirit, helplessness/hopelessness, denial, and avoidance—supplied little convincing evidence that coping styles play an important part in survival from or recurrence of cancer. Good evidence is also lacking to support the view that "acceptance", "fatalism", or "denial" have an important influence on outcome. People with cancer should not feel pressurised into adopting particular coping styles to improve survival or reduce the risk of recurrence, the authors from Glasgow's MRC Social and Public Health Sciences Unit conclude.

British Medical Journal 2002; 325: 1066–9.

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## CHAIRMAN'S REPORT to the Annual General Meeting on 30th October 2002

I thought I would give you a quick rundown on our activities, mention what I hope I have learned from my time as Chairman and of course thank all those who have put so much time and effort into maintaining and improving HealthWatch.

The way most people keep in touch is through the Newsletter. Although our editor Mandy Payne now lives in Naples, she has had no difficulty in producing it very effectively from there. In one of her more recent e-mails she thanked our members for providing her with such a wealth of excellent material and I can only echo that.

Over this past year many of the committee members have contributed thoughtful and well-researched articles for which, remember, they do not get paid. David Bender on [the Detox myth](#); Neville Goodman debunking the

[Barefoot Doctor's efforts in the Observer](#); John Garrow on whether [Practice Nurses](#) are qualified to advise on herbal remedies; Michael Allen on whether there is a connection between the [MMR vaccine and autism](#) and [Caroline Richmond](#) who in her very individual way has written about the dubious benefits of a daily gallon of coffee administered per rectum as a cure for myeloma.

From sources outside the committee we have [Paul Diamond's](#) article on local government funding for courses in questionable alternative treatments and a very illuminating piece from [Jan Willem Nienhuys](#) about the death of a Dutch actress who spurned conventional medicine and turned to complementary therapy for relief, alas in vain.

Both through the medium of the Newsletter and also the website, which David Bender maintains, we have issued statements and comments reacting to government or European Union policy. In October (HealthWatch newsletter, [issue 47](#)) you saw John Garrow's article reacting to and largely supporting the Department of Health's proposals on the regulation of herbal remedies. In this issue my colleagues on the committee, led by Michael Allen, have prepared a position paper on [Direct to Consumer Advertising of Prescription Medicine](#). It is all on the website but the general policy line we are taking is that we would resist this if possible but accepting that if it is going to happen, then there is a need for safeguards. For instance, we are suggesting that a summary of the patient information leaflet should appear in any such advertising.

Another position paper published this year was David Bender's on [Multi-Vitamin Supplements](#). He has pointed out that doctors are not immune from recommending these although for most people on a balanced diet, to alter that balance markedly is not "to be on the safe side".

In addition to items we publish ourselves, throughout the year my colleagues on the committee and other members of HealthWatch have appeared on radio and TV programmes and have written to the press. Not everything gets published and not everything that gets published or broadcast gets noticed but we are doing our best in our small way to redress the myths and inaccuracies about medical treatment that frequently appear in the press and on radio and television.

For completeness I will mention briefly our major new activity this year which is the award of the AJAHMA Prize to students for Critical Appraisal of Clinical Trials Protocols. Without John Garrow's persistence and inventiveness this would never have got off the ground and we are also grateful to Joan Gandy who John recruited in order to help with the organisation of the prize.

Throughout HealthWatch's existence we have had a somewhat ambivalent attitude to complementary and alternative medicine. At one extreme some of our members and supporters wish to condemn all such treatments outright. At the other end of the spectrum there are members who feel we are being unduly critical and that complementary medicine must have its fair crack of the whip. I was impressed by the report of an address given by Professor Edzard Ernst at the European Society for Medical Oncology in Nice a couple of weeks ago. As you probably know he is the Professor of complementary medicine at the Peninsular Medical School in Exeter and is also a life member of HealthWatch. As reported by the Observer (I may say the article was written by their Health Editor not by the Barefoot Doctor) I thought he struck the right note. He pointed out that many cancer patients are desperate and it is natural to them to turn to whatever remedies they think might help them. It is better that doctors should offer guidance to patients on complementary and alternative remedies rather than dismiss them out of hand with the risk that the patient may choose treatment that might be positively harmful.

Of course he reported that some alternative remedies were of no proven value—for instance ground-up shark's cartilage or preparations using mistletoe. On the other hand, some alternative treatments could reduce stress or make a patient more comfortable. For example, he said acupuncture may reduce nausea suffered by a cancer patient following chemotherapy. He also reported a randomised trial of 1,500 patients taught by psychologists to think positively. Whilst their lives were not prolonged he says, "the trials did undoubtedly show that patients were happier with a better quality of life".

So there seems to be something to be said for an attitude which insists on rigorous scientific proof of procedures that claim to treat or cure but which adopt a more benign and tolerant approach to remedies that patients report subjectively make them feel better. Provided of course that they do not divert the patient from vital life saving treatment.

So this strange experiment of asking a lawyer to become Chairman of HealthWatch draws to a close. My scientific studies stopped at General Science "O" level. It was a paper designed for those not going on the science "A" levels—an early experiment at dumbing down.

It has therefore been a great privilege, as well as a useful further education, to have been Chairman of this small charity. You'd better believe it—and I think you will—when I say it would have been impossible for me, as a lawyer, to function without the energy and commitment I received from the officers and indeed all the committee members. My thanks also to other members who have written to the Newsletter and who have supported HealthWatch's activities in other ways and to Nick Ross who, despite his many interests and commitments, has always been supportive and attentive whenever we needed him.

One of my last tasks was to write to all members reminding them of this event and I received a shoal of letters in return. It was very gratifying to receive them, especially the ones addressed to "Dr Brahams". I shall miss those.

Many of them said how much they appreciated our activities, even if they lived too far away or had too many commitments to come to the AGM.

So I think we are on the right lines and in handing the Chairmanship back to its natural incumbent, John Garrow, I am sure that we are in safe hands. Thank you very much.

Malcolm Brahams  
HealthWatch Chairman 1999 to 2002

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## The Healthwatch lecture 2002 by Michael Baum

### Screening for Breast Cancer: A cruel deception

**“For every complex problem there’s a simple solution; and it’s wrong”**

H.L.Mencken, 1927

*Why do I have a problem with screening and why do I appear to be out of step with the agents of the State? This question really bothers me. I have devoted my professional life to women’s health, I come from a family with a bad history of breast cancer, I’ve studied the disease for the best part of 30 years and still I don’t get it! Perhaps it’s because I have an unusual perspective on the subject?*

For example unlike those who deliver the screening programme I am at the sharp end, picking up the pieces after a screen detected abnormality drives an innocent woman crazy with fear. I’m also fairly numerate having been the principal investigator of many multi-centre randomized trials of the treatment of breast cancer. Finally I was responsible for setting up one of the first screening centres in the UK following the Forrest Report in 1987. This centre at Butterfly Walk, Camberwell, South East London not only serves the local population but acted as the training centre for the whole of the SE of England. I know a bit about screening, so why my problem?

#### Public perception of risk

Each year we enjoy breast cancer awareness month or what I choose to call “Black October”. Each October women are advised to practice breast self examination (a thoroughly discredited practice ) and are reminded that their risk of developing the disease is 1 in 11. This number is true only if a woman outlives all competing risks to reach the age of 85 with 25 out of 26 women dying of other causes. It is essential therefore that both doctors and the lay public understand the risk of developing breast cancer in the age groups invited for screening and understand the expectation of life after the diagnosis of breast cancer in the absence of screening in order to appreciate the absolute value of submitting themselves to screening.

However before we get into that I wish to describe some of the biases inherent in mammographic screening which support my somewhat counter-intuitive view that screening ain’t all that it’s cracked up to be.

#### Biases in Screening

Lead Time Bias: Say you get on a train to Edinburgh that crashes at Newcastle, then the duration of your fatal journey depends on your departure point. If you leave from Milton Keynes the journey lasts two and a half hours whereas if you leave from Kings Cross it is three hours...but you still die at the same time. In other words merely shifting the period of observation of breast cancer to the left might extend survival from the point of diagnosis without necessarily extending the duration of your life.

Length bias: If you were to trawl the sea for fish with a slow boat you’d catch the slow fish but miss those who can outswim your trawler. In other words if you trawl the female population for breast cancer at intervals you will catch the slow growing cancers that might be cured if allowed to grow to a clinically detectable stage whilst missing the rapidly growing cancers that appear in the intervals between screening and are probably the ones that will kill you in any case.

Class bias: Not all women invited for screening are “compliant” and graciously accept your invitation. The affluent upper classes who are health conscious tend to accept, whilst the poorer-educated lower classes may ignore your invitation or never get it in the first place because they maybe of no fixed abode. Futhermore we know that the outcome of treatment, stage for stage, is better amongst the better off so the apparent benefit of screening might just be a surrogate for class.

To get round these biases in order to truly assess the value of screening it is necessary to carry out randomized trials in whole populations with the outcome measure being breast cancer mortality. At the same time for all we know the intervention and its consequences might indirectly impact unfavourably on other causes of death. Ideally therefore the trials should be sufficiently well powered to look at all causes of death.

## The trials of screening and relative risk reductions

There have been eight randomized or quasi-randomized trials of population mammographic screening for breast cancer and a number of observational studies which I will choose to ignore because of the biases described above. In addition there have been a number of attempts to conduct a meta-analysis of all these studies to improve the precision of the estimate. Finally there was the 2001 Cochrane review<sup>1</sup>, which attempted to weight the studies for quality before providing a summary statistic. Let us first dispose of the latter. This provoked the editor of the Lancet, Richard Horton to state, "At present there is no reliable evidence from large randomized trials to support mammography programmes". This then provoked the screening enthusiast to cry foul!

Whatever the merits or flaws in the Cochrane review there are a number of unassailable facts that emerge. The Canadian study, that produced a negative result, was the only one with individual randomization with informed consent. The HIP study New York, which produced the most favourable result, excluded 336 subjects in the control arm because of a past history of breast cancer compared with 853 in the screened population. The Edinburgh trial, which randomized according to postal district, ended up with huge imbalances in socio-economic factors favoring those invited for screening. Finally the largest effects were seen in the trials with the worst equipment and the longest screening intervals.

## We therefore start off with the concern that screening has no proven effect.

Let's leave that for a moment and consider the more optimistic estimates produced by two overview analyses, Kerlikowske et al in 1995 and the US preventive services task force 2002. Neither could show a significant advantage for women under the age of 50 (in fact the latest result from the Canadian trial for the <50 group actually showed a detriment for the first 10 years!) whereas their estimates for the >50 age group varied between a hazard ratio of 0.76 (i.e. a relative risk reduction of 24%) and a hazard ratio of 0.84 (i.e. relative risk reduction of 16%) for breast cancer specific mortality. It is worth noting that most promotional material for screening includes a statement to the effect that screening will reduce the woman's risk of dying of breast cancer by 25%.

Let us now compute what that means in absolute terms so that an individual woman can work out her chances of benefit following a decade of mammographic screening. I can promise you that the numbers I describe are not in dispute but simply not offered up to the lay public.

The risk of a woman aged 50-60 for developing breast cancer is 2/1,000 a year or 2% over a decade (20 out of 1,000). The anticipated 10 year survival for clinically detected breast cancer in the absence of screening today is about 75%. Therefore we can expect 5 deaths per thousand women from breast cancer over this period (75% of 20). The relative risk reduction for screening applies to these 5 women. From the above overviews a realistic estimate would be the saving of 1 life (a relative risk reduction of between 16 and 24%). Therefore one in a thousand women stand to benefit from a decade of screening whilst 999 have to share the cost and by this I don't mean financial cost but the price in terms of "side effects".

This is what is meant by, "framing the result". Each year I play a little game with the senior postgraduate students at a course for specialists in breast cancer run by the Royal College of Surgeons of England. I tell them that there are two potentially effective screening tools for prostate cancer—one which will reduce their chances of dying from the disease by 20-30% whilst the other will save one life after 10,000 years of person screening. As a consumer or as a public health official which would you buy into? They all vote for the first and none vote for the second; yet if applied to breast cancer, they are the same. To continue marketing screening in terms of relative risk reduction in breast cancer mortality is disingenuous in the extreme.

## The down side of screening

Of course if screening were as innocent an intervention as wearing seat belts or fluoridization of the water supply, then apart from opportunity costs, there wouldn't be a problem. However screening is by no means an innocent activity.

Like any other imperfect screening tool there has to be a balance between sensitivity and specificity. Sensitivity is a measure of the ability to detect those cancers present in the population whereas specificity is a measure of the accuracy of the screening tool. These two measures tend to pull in opposite directions. For 100% sensitivity i.e. not missing a single cancer, specificity will fall and many women with benign changes on mammography will be recalled for biopsy. There always has to be a delicate balance between these opposing needs, to catch all the cancers whilst protecting women without cancer from false alarms and unnecessary invasive procedures. Even at its best for every cancer detected another woman will have a false alarm. Whereas at its worst, fuelled by a fear of litigation, the cumulative risk of a false alarm over a decade of screening is around 40%.

All this unnecessary surgery has its morbidity but also tends to throw up pathology of borderline significance. The lay public can be forgiven in thinking that a pathologist can make a clear distinction between cancer and non-cancer, but sadly that is not the case. There is a whole spectrum of abnormalities ranging from epithelial hyperplasia with or without atypia, lobular carcinoma in situ, low grade duct carcinoma in situ (DCIS), high grade DCIS, micro invasive DCIS and tubular carcinoma of uncertain significance and unknown natural history. A conservative estimate would suggest that fewer than half of these would threaten a woman's life if left

undetected and yet they account for 20% of “cancers” detected at screening. Furthermore many of these cases have field changes that affect the whole breast leading to a mastectomy for what might be a non-progressive condition. As a result the screening programme cannot claim that there is a net reduction of the mastectomy rate in the population, the opposite might be the truth.

Next there is the issue of “lead time”. If the woman with the screen detected cancer is either doomed to die or at the other extreme diagnosed with a cancer that would have been curable even if left to develop to the point of clinical diagnosis, she will live as a “breast cancer patient” for one or two years longer than needs be.

Finally women invited for screening should be aware that the detection of DCIS with all the uncertainties described above might have an effect on the premiums for their health or life insurance. In fact I would go further and advise women intending to accept the summons for screening, at the same time they are buying a house, to postpone the event until after they’ve negotiated their mortgage.

### Where do we go from here?

I believe that to carry on complacently now that we know the full costs and benefits of screening is NOT an option, so what should be done? In an ideal world I would recommend that we shut down the service and divert the resources (opportunity costs) to other issues to preserve the health of women. This might include improving the clinical care of women with symptomatic breast cancer as for example getting rid of the 12 week waiting list in some parts of our country for postoperative radiotherapy. We could also fund first class breast cancer research with the £50,000,000 a year so released. The promise of improved treatments holds more than improved screening which has nowhere to go.

Prevention of heart disease and osteoporosis would save more lives than the prevention of breast cancer yet the strategies could well be the same with the use of selective oestrogen response modifiers (SERMS).

However I see this as politically inexpedient so the best I could hope for here might be a shift in the screening window, to the 55-69 age group where sensitivity and specificity might be improved.

Finally if nothing else I believe there is an ethical imperative to offer women full informed consent with the risk and benefits spelled out in terms that don’t patronize or deceive them. If after that the women vote with their feet—so be it.

Michael Baum  
Professor Emeritus of Surgery at University College London

#### Reference

Olzen O, Gøtzsche PC. Cochrane review on screening for breast cancer with mammography. Lancet 2001; 358: 1340–2.

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## Opinion

### An unforgivable cut?

***Minor surgery or unjustifiable mutilation? An estimated 20,000 men and boys in the UK are circumcised every year, and in most cases the procedure is not only medically unnecessary but will change their lives for the worse in a most personal way, says Dr Peter Ball, a GP of 34 years’ experience who now campaigns for patients to be better informed about circumcision***

Most people know that circumcision means cutting off the foreskin. For many this means nothing more than losing a bit of skin off the end of the penis, often done in childhood for a variety of reasons. Some are aware that its origins are shrouded in antiquity. Hieroglyphics in Egyptian Tombs depict a man being held while another attends to his penis probably to circumcise him. Many equate circumcision with being a Jew or a Muslim. All too many regard the operation as minor, hygienically desirable and of little consequence to the victim.

Somehow in the furore that the debate on circumcision causes, the fact is forgotten that the foreskin, like all parts of the body, has a purpose.

The end of the penis or glans is an internal organ. It remains mostly internalised until puberty. At birth it protects the glans from contamination by faeces or decomposing urine in nappies. At this time it is actually fused with the glans and has to be physically torn off if the foreskin is being removed as a religious sacrifice. Later it serves as a protection from chafing by underclothing and bedclothes.

### Important role in sexual enjoyment

The foreskin is lined by specialised skin called mucosa which is similar to that lining the inside of the cheek. Keeping the glans moist and sensitive enhances sexual enjoyment. After circumcision the glans dries out and becomes thicker and less sensitive. Recent research has shown that the inner mucosal lining has numerous

sensory organs that are sensitive to movement, touch and stretching. These organs are concentrated in an area about 3mm within the mouth of the foreskin. This area was first described by Dr John Taylor in 1998 who named it the Ridged Band. It is this ridged band that is responsible for the erotic feelings experienced when the foreskin is retracted and as the foreskin rolls to and fro during intercourse. The foreskin also contributes to the female's comfort during intercourse—the penis moves in and out of its own skin sheath and as a result the female's natural moisture is not dried up by the thrusting of the circumcised penis.

### **The right of the infant to its bodily integrity**

In my opinion it is unforgivable to remove such an important part of a defenceless child's anatomy. Women are already protected by law from circumcision. It is sexual discrimination not to afford the same protection to boys.

If a sexually mature man wishes to be circumcised for religious, cultural or any other reason, after considering all the pros and cons, I have no problem with that. I acknowledge that if the foreskin is tight it severely restricts the enjoyment it should provide. However it can usually be loosened by a regime of stretching combined with steroid creams or by a variety of plastic surgeries called preputioplasties which preserve the foreskin, rather than circumcision.

### **Why circumcise?**

At the start of the last century circumcision was recommended as both a treatment and a cure for masturbation. In 1891, Jonathan Hutchinson, president of the Royal College of Surgeons of England, in his article "On Circumcision as a Preventative of Masturbation," wrote: "Measures more radical than circumcision would, if public opinion permitted their adoption, be a true kindness to many patients of both sexes." It was also cited as a cure for malnutrition, paralysis, bed-wetting, hip-joint disease, headache, alcoholism, criminality, club-foot and heart disease.

As the absurdity of these assertions became apparent, further reasons for recommending circumcision were produced. The most frequent one being that it is cleaner to be circumcised. However, during childhood the penis requires no more washing than any other part of the body, and once the foreskin is retractable it is no more difficult to wash than the armpits or behind the ears.

Circumcision has been recommended for the prevention of cancer of the penis. This extremely rare disease is associated with poverty, alcoholism, chronically neglected personal hygiene, frequent history of sexually transmitted disease and other unhealthy life style choices. Cancer of the penis has also been recorded in circumcised men. More recently the foreskin has been incriminated as a portal of entry for HIV infection. A \$6-million joint Canadian-American five-year research project in Kenya is attempting to determine whether circumcision can stem the spread of HIV/AIDS. It may indeed be prudent to suggest circumcision as an adjunct to the desperate attempt to quell the AIDS epidemic in central Africa. The regular use of the condom would be a cheaper and less drastic method of control.

Circumcision has again been suggested as a preventive for cancer of the cervix in women. The disease appears to be caused by infection by the human papillovirus type 1 which is found more frequently in uncircumcised men. It is also related to teenage unprotected sex and frequency of sexual partners.

The only medical reason for circumcision is in the treatment of Balanitis Xerotica Obliterans (BXO) otherwise known as Lichen Sclerosus Atrophicus. This is a rare skin disease that manifests itself in the foreskin as a white leathery change in the tip of the foreskin. This becomes non-elastic and the foreskin non-retractile. Untreated, in some cases the disease spreads to the glans and the urethra. There are studies that suggest that applying strong steroid creams can halt or even reverse the changes particularly in boys. So hopefully one day there will be no medical indications whatsoever for circumcision.

I hope I have made it clear that I believe circumcision is an operation that should only be inflicted on men who have been fully informed of the disadvantages and advantages of the operation and have given their consent.

Peter J Ball MB BChir  
Vice-chairman of the anti-circumcision charity NORM-UK  
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## **Informing patients**

### **BOLLYWOOD MEETS ONCOLOGY**

***Oncologist Robert Thomas found that tailoring an award-winning cancer video for use by ethnic minorities meant changing more than just the spoken word. After two years of exhaustive research his team have remade the film in the languages of four Asian communities***

As a profession oncologists are increasingly realising the importance of patient information and education as

major part of their daily practice. Very few patients are content to let the doctor make decisions for them yet, despite the global revolution in communications, patients still report difficulty obtaining enough reliable information and many remain dissatisfied.

Our multi-centre trial, for example, found that 69% of 300 patients felt the information they received could be improved upon. The National Cancer Alliance and The Audit Commission recorded a similar trend. Furthermore, the satisfaction rate was significantly worse among patients who indicated they were from ethnic minority groups. It was also these patients who recorded higher levels of anxiety and a stronger need to seek information outside the clinic.

Educational materials are clearly no substitute for good verbal discussions in conveying treatment-related information to patients. They do, however, allow patients to continue the learning process outside the sterile, and often alien environment of the hospital clinic in the comfort of their own home, in their own time, in the presence of friends and relatives who may not have attended the hospital consultation. A wide variety of information tools are required for a comprehensive service, but video seems to be a particularly attractive option—a well-made film communicates a large quantity of practical information in a short period of time.

An additional attitudinal survey found that 89% of cancer patients felt that information videocassettes, in addition to written material, would be helpful and that 87% had easy access to a video player. This format is also an attractive option for patients with reading difficulties, as high as 15% in some areas of the United Kingdom and often higher in ethnic minority-concentrated areas.

Four years ago a dedicated team of patients, relatives, doctors, nurses, radiographers and pharmacists made a 21-minute film designed to be given to patients to take home prior to chemotherapy or radiotherapy. The film was introduced by Sue Lawley and narrated by Anton Rodgers, both experienced and popular TV personalities in the UK. It gave an initial overview of therapies with clear indications of the associated risks. Separate sections on radiotherapy and chemotherapy (demarcated by a different coloured background and an "R" or a "C" in the corner of the screen) featured patients describing their own experiences, side effects and the methods used to alleviate them. A national multicentre, randomised trial amongst 220 patients found that those who received the film prior to therapy watched it on average 2.5 times and had a significantly lower treatment-associated psychological morbidity and higher satisfaction, than the control group. The film is generic and free from commercial bias (The £40,000 cost of the film was raised entirely from educational grants). This evaluation won the NHS 2000/1 communication prize, a BMA film prize and contributed toward the 2000/1 Hospital Doctor Magazine prize. In the UK Cancer BACUP has adopted it as their official cancer video and likewise in Australia the Victoria Cancer Confederation. It has been digitised and can be viewed free on the UICC patient information web site Geneva and in the UK on the [cancernet.co.uk](http://cancernet.co.uk) website.

In view of the large Italian speaking population in the Bedford area links were forged with the medical attaché at the Italian embassy and charitable information organisation in Rome called AIMaC. A cultural and literal translation was made with Italian patients both locally and from Italy. It is now offered free to all Italian-speaking patients in Bedford and Cambridge and has been very warmly received. In Italy and other Italian speaking communities internationally it is widely distributed by AIMaC.

This is where Bollywood steps in. Spurred on by the benefits patients gained from the first two films the editorial group managed to team up with Asian celebrities to make further films in four ethnic languages of the UK namely Urdu, Hindi, Gujarat & Bengali.

Making a film for different cultural groups requires a great deal of preparation if it is to be accepted and used by the target audience. The Italian film, for example, had several re-editing sessions and four complete re-shoots to get it right. The final version even dropped our homely distinguished guest presenter Antonio Carlusio for a young, attractive, glamorous popular TV presenter who was more acceptable to the Italian viewer, even on the sober topic of cancer therapies. Within Asian ethnic groups inappropriate clothing, the wrong gesture or comment can easily offend especially in the emotional milieu of newly diagnosed cancer. An insensitive religious remark can lead not only to poor acceptance but even hostility.

All these issues were considered in detail by the Editorial panel before rewriting the script. A year was spent visiting hospitals in high-concentration ethnic areas, religious groups, charitable and government organisations to seek their opinion and feed back. We also showed the film to more than twenty patients from each cultural group before starting production. The Bollywood actor and star of *A Passage to India*, Saeed Jaffery, and the Eastenders star, Rani Singh, gave invaluable enthusiastic support for the project. These actors, well known both to the Asian and non-Asian communities, not only boosted the project's professionalism but their familiar faces are likely to improve the patients' trust in the information.

In these times of global health care imbalance, at least on our own doorstep we can strive toward giving all patients equal opportunity to understand their treatment options. We are grateful to The National Lottery and NHS executive for providing the funding for this project and the Royal College of Radiologists for its support and help. We hope that these films, if used correctly, will help iron out the inequalities of provision of oncology information in the United Kingdom.

Dr Robert Thomas FRCP MD FRCR

Macmillan Consultant in Clinical Oncology  
Bedford Hospital

For further information and a supply of the films, oncology departments or information organisations involved with patients speaking Urdu, Hindi, Gujarati & Bengali are invited to contact Romeena Khanom, The Primrose Oncology Research Unit, Bedford Hospital, Bedford, MK42 9DJ, telephone 01234 795769 or e-mail [romeena.khanom@bedhos.anglox.nhs.uk](mailto:romeena.khanom@bedhos.anglox.nhs.uk)

For the English film write to Health Education Publications Ltd, c/o Alex Silver PR, 1 Heath Street, Hampstead, London NW3 6TP, or e-mail [hcp@clara.co.uk](mailto:hcp@clara.co.uk)

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## Position paper

### Direct-to-consumer advertising of prescription medicines: a bad idea, but if implemented it needs rigorous control

*A position paper drafted by Michael Allen (left) and Nick Ross and endorsed by the HealthWatch committee 27th November 2002. This position paper is also available in Adobe Acrobat format at [dtc.pdf](#)*

HealthWatch is a registered charity that promotes evidence-based assessment of all forms of treatment. Our objective is to provide the public with reliable information about healthcare. HealthWatch has no vested interest for or against direct to consumer advertising of prescription medicines (DtCA); our sole concern is the honesty, reliability and transparency of claims made to people who are ill or who may be persuaded they are ill.

Our members include scientists, clinicians, lawyers and journalists; recipients of the annual HealthWatch Award have included leading health journalists as well as academics and clinicians.

DtCA is an EU matter but some of the issues are especially acute in the UK because of chronic problems in the NHS. This position paper is written largely from a British perspective.

#### Reason for this Position Paper

The European Commission<sup>1</sup> has proposed a large number of changes to the conditions under which medicines are sold in the EU. These include a provision that DtCA be permitted for some prescription medicines, specifically those intended for treatment of:

- acquired immune deficiency syndrome
- asthma and chronic bronchopulmonary disorders
- diabetes

Advertising is to be controlled by self-regulatory procedures set up by the pharmaceutical industry at member state level.

Unlike consumer organisations, the medical profession or the pharmaceutical industry we have no particular commercial or other interests; nonetheless we share some of the reservations expressed by, among others, the UK Consumers' Association<sup>2</sup> and the European BEUC<sup>3</sup>. This is obviously of great significance in Europe, where state health schemes bear most of this burden. HealthWatch starts from the premise that freedom of expression is generally desirable, but nonetheless believes some of these concerns are valid.

#### The current position

DtCA has never been permitted for prescription medicines within the EU. The role of the physician has been that of learned intermediary—only he or she was thought to be qualified to make judgements about medicines that could be dangerous if misapplied. Over the last few decades, however, the relationship between doctor and patient has changed greatly. Decisions once accepted without question are now subject to consumer discussion; patients increasingly expect to be told about uncertainties and alternatives. Indeed some procedures (such as the MMR vaccine) are met with scepticism and even hostility.

#### The need for review

This democratisation has already been reflected in several important liberalisations about information on pharmaceutical products. In particular, prescribed medicines are no longer labelled the tablets and take as directed; the product is named and specific dosage instructions are given. In addition, a patient information leaflet (PIL) now accompanies products dispensed by a pharmacist on prescription. It explains the purpose of the drug, describes its constituents, warns about contra-indications and expected side effects and lists information that helps track down the cause of an allergic reaction.

Knowledgeable consumers can also ask their doctors for an SPC, or Summary of Product Characteristics. This

provides detailed information on the product and is intended to assure EU-wide consistency in indications, dosage and use of medicines. In the UK, it is not legal for a pharmaceutical company representative to promote a product without first giving a copy of the SPC to the doctor, so that factual information can put the promotion into perspective.

Consumers can now access information about medicines in several other ways, including:

- newspapers and magazines (most of which now carry extensive copy about health issues)
- broadcasting
- popular books
- telephone advice lines
- the Internet
- voluntary organisations and support groups

Unlike PILs or SPCs, which are closely regulated by the regulatory authority (in UK, the MCA; in the EU, the EMEA), these other sources of information vary greatly in quality.

Newspapers and general magazines often carry a doctor's advice column as well as news and features on medicines. While these often contain good advice and balanced coverage, they sometimes show scant scientific literacy. Few journalists are specialists on medicines. Newspapers in particular, because of a journalistic imperative to create strong headlines, are prone to promoting health scares. Moreover, for commercial reasons they are loathe to confront misapprehensions among their readers and tend to massage preconceptions, sometimes devoting much uncritical space to complementary medicine.

Broadcasters tend to paint health issues in broad brush strokes because of the need to maximise audience interest and, with notable exceptions, rarely tackle complexities about medicines. News stories and documentaries tend to have a driving narrative, which means that they may promote a particular perspective; but they have been generally more cautious than the print media, and probably of relatively little influence on medicine use. In the future, however, with the advent of multi-channel broadcasting, which can cater to niche audiences and is regulated with a light touch, broadcasting may follow the path of newspapers and magazines.

Books on health and medicine range from authoritative guides such as those published by the BMA, through thoughtful, well-researched and critical appraisals, to wild and misleading nonsense.

Helplines include (in the UK) NHS Direct and advice lines from some pharmaceutical companies and insurance companies; but manufacturers of food supplements and other unregulated products are free to promote these by phone unfettered by constraints imposed on the pharmaceutical industry.

Another way in which patients can now access information about medicines is through various health charities and support organisations. Many of these are supported by pharmaceutical companies and 'health supplement' companies, sometimes with few strings attached but often as a cloak for public relations activities. There is little control over what can be said in the casual atmosphere of a meeting. Moreover some voluntary organisations may appear to be neutral while substantially relying upon financial support from these companies.

The Internet has seen a proliferation of sites advising on drugs, and there is a good deal of authoritative information available to diligent researchers. However, as with all publications on the Internet, quality varies considerably. There is often a direct or hidden bias. Many articles are written by well meaning but misguided people with information poorly supported by research findings, and countless sites contain claims that are frankly wacky.

The global nature of the Internet makes it hard to regulate; now that DtCA is permitted in the US, pharmaceutical companies are effectively free to promote prescription drugs worldwide. If the European Commission wanted to ban DtCA via the Internet it would be unable to invoke sanctions on pharmaceutical companies which market in North America without a politically damaging battle with the US authorities and enthusiasts for the freedom of the world wide web; battles they would not be likely to win.

**The present situation thus already allows largely uncontrolled collateral promotion of prescription products to the general public.**

Now that in the US the rules on DtCA have been greatly liberalised, it is inevitable and right that rules should be reviewed in Europe.

### **The need for caution**

As a general principle, HealthWatch takes it as self-evident that free expression is preferable to censorship and that reliable information is more likely to emanate from openness than from over-regulation. However strong the evidence appears to be in favour of a single view, however diligent and honourable the regulator, there must be room for challenge.

But medicines have several features that distinguish them from other goods and services. Their misuse can cause great harm, both to an individual and (as with abuse of antibiotics) to the wider community. Even proper use can

sometimes be dangerous and medical supervision is often necessary or desirable—the same medicine can have subtle, and sometimes not so subtle, effects on different patients and at different times. Equally it can be dangerous if the proper medicine is not taken, or is not taken according to the proper recommendations.

Medicines are obviously intended for people who are ill and their illness may make them especially susceptible to misinformation. Half-truths may be damaging in any advertisement, but can be especially cruel when aimed at people desperate for a cure.

There are special economic issues with medicines. It is generally held in Europe that healthcare should be available to all on an equitable basis. Most medicines in the UK are provided through the state-funded NHS, with almost all the rest through private insurance companies. Few prescribed medicines are bought by individuals out of their own pockets. Moreover, healthcare is a scarce and expensive resource. The NHS is severely stretched so that treatments are rationed through queuing or non-availability; and prescribing is specifically restrained by budgets and guidelines from bodies such as NICE (the National Institute for Clinical Excellence). Insurance-based schemes are also highly sensitive to costs; premiums are already so high that most of the population is priced out of the market.

There is therefore a strong case for ensuring that medicines are not just effective and safe, but cost-effective too. Big companies promoting expensive products can substantially outspend small companies whose drugs may be just as good and perhaps a lot cheaper.

By definition, prescription medicines are controlled by doctors and pharmacists and it may be said that clinicians are quite capable of acting as proper guardians, regardless of consumer pressure. On this view, DtCA would make very little difference to the nature of prescribing since it is the doctors, not the patients, who make all the key decisions. HealthWatch regards this as naïve. Doctors are profoundly influenced by patients, and rightly so. Sometimes the views of patients are of paramount importance, but even when a clinician believes a patient is wrong, pressures of time and the desire to avoid a confrontation can lead to inappropriate prescribing. The hardheaded pharmaceutical industry does not spend hundreds of millions of dollars each year in the US for no return; they invest heavily in DtCA because they know consumers exert huge and effective pressure on prescribers. Indeed prescribers themselves are not immune to the persuasive influence of advertising. An obvious example of the power of DtCA is the explosive growth in prescriptions of the expensive COX-2 specific anti-inflammatory drugs Celebrex (celecoxib) and Vioxx (rofecoxib) despite complaints by American pharmacy managers and consumer groups<sup>4</sup>. In the UK, NICE has cautioned that for most patients cheaper compounds are just as safe and effective, but it is an open question how such recommendations would fare in the face of widespread demand for the more expensive drugs.

**Indeed, we regard it as inevitable that DtCA will increase health costs. Pharmaceutical companies naturally tend to advertise costly blockbusters much more than marginally profitable generics, so that—assuming the advertising is successful—the pattern of spending will shift from cheaper generics to premium-priced proprietary medicines. HealthWatch strongly advises that any change in the rules on DtCA must be designed carefully so that they do not destabilise national health systems such as the NHS.**

### HealthWatch recommendations

For the reasons advanced above, HealthWatch strongly opposes DtCA of prescription medicines. However, if it is to be allowed in Europe, it should be started very cautiously. The proposals for DtCA for the limited number of conditions suggested by the Commission could be accepted if self-regulation can be made fully effective.

We are aware that once any DtCA is permitted pressure will grow for further liberalisation. Thus proper precautions should be built in from the start, mindful of the likelihood that advertising may become much more pervasive and emotive. We note the experience in the United States where drugs have been marketed with “splashy, expensive TV ad campaigns”<sup>4</sup>. We believe that in the European model some of the marketing money devoted to DtCA should be spent on providing balanced information which allows consumers to make reasoned judgements.

The Commission proposes that all advertisements should be submitted to the EMEA (the pan-EU regulatory agency) and can proceed if no objection is made within 30 days. HealthWatch believes this negative vetting process will not be effective and urges the Commission to incorporate an additional set of precautions, using systems similar to those already in place, which should therefore be easy for pharmaceutical companies to adopt. These would ensure:

- consistency between terms set by the regulatory agency and DtCA;
- quality of product description;
- honest disclosure of adverse events;
- candid reporting of relative efficacy and price evaluations where they are available

The methods proposed have the additional advantage of being largely self-policed, cutting the burden of regulation without reducing its potency.

## HealthWatch proposes the following principles:

- **At least 50% of DtCA spend must be on substantive advertising, defined as explanatory text, as opposed to marketing which relies mostly on slogans.**
- **A summary of the PIL must accompany all substantive DtCA, as is now the case with the SPC for professional advertisements. The complete PIL must be linked prominently to Internet advertisements.**
- **A summary of the other relevant information must be included in any substantive advertisement such that consumers can determine the class of drug, the context of rival products, and any authoritative judgement of cost-effectiveness. Because of differences in regulatory framework and language between EU Member States each Member State should determine the most appropriate frame of reference to ensure compliance with these rules. For example, in the UK reliance would most sensibly be placed on the BNF (the British National Formulary) and NICE (the National Institute for Clinical Excellence). Relevant texts from BNF and NICE would be reproduced in the same format and type size as the rest of the advertisement.**

The BNF is recognised as the main source of unbiased information on medicines in the UK and inclusion of BNF entries in advertisements has the merit of positioning each company's product in relation to others available for the same condition. A synopsis of the relevant monograph should be carried prominently in any substantive advertisements, and all Internet advertisements should also show links to the appropriate BNF web pages. Summaries in substantive advertisements may be brief but must be agreed in advance with the BNF. This is an important remedy for smaller pharmaceutical companies which lack the marketing muscle of larger rivals.

Similarly, and for similar reasons, all substantive advertisements must carry a summary agreed with NICE of any recommendations about the product and others for the same condition, with specific comparisons of cost-effectiveness where available, again with a link to the NICE site for Internet advertisements.

Companies would be liable to the regulatory authorities (the EMEA or, for example, the MCA in the UK) for all statements made in DtCA and for compliance with the above terms. In addition to corporate accountability, each company placing DtCA must appoint a suitably qualified pharmaceutical physician to take personal responsibility that all advertisements are consistent with the marketing authorisation and to agree texts with the appropriate agencies. The qualified person would accept liability similar to, and parallel with, responsibilities already demanded for quality and pharmacovigilance functions, and could be disciplined or even disbarred if the regulatory authority found incorrect information had gone into advertisements.

Where a company gives financial support to a patient group or other organisation working in a field in which its products may be used, it must ensure that the link is transparent. This is analogous to the present situation when companies support professional meetings, where they must make their vested interest overt. Where more than 20% of the finance or other resource for such an organisation, or for one of its projects, comes from a pharmaceutical company, newsletters and other documentation from the organisation must acknowledge prominently the obligation to the company and its relevant product(s). The company will be obliged to set out details of its links with such organisations in its annual report.

We believe these proposals strike a fair and proper balance between the needs of pharmaceutical companies, clinicians and consumers. They ensure that a reasonable proportion of the marketing power is committed to balanced information as opposed to simplistic or largely emotional appeals. By placing the emphasis on self-policing they minimise the administrative and financial burdens on companies and on the regulatory authorities.

We believe the mix of substantive advertising with the freedom to place strap-line commercials will allow companies to stress the scientific merits of their products and also to deliver more traditional persuasive messages. It may be necessary to monitor that the substantive and emotive advertisements are not aimed at different audiences, but we believe the 50% spend rule could help to ensure that substantive advertisements are aimed at the popular media in reasonable proportion. Additional measures will be needed if the rule does not achieve this.

We believe this mix will produce a flow of information which will inform the intelligent consumer without misleading the stressed or gullible and, through its attractiveness and authority, will rival less reliable information available elsewhere.

## Postscript

HealthWatch is concerned about honest dealing in all healthcare: orthodox and complementary. The European Commission proposals on DtCA rightly enshrine careful controls of direct advertising for prescription medicines, to which we have added our own suggestions; but we point out that other medicines will be subject to much less stringent constraints. In some respects this is justified. If consumers are persuaded to buy for themselves expensive OTC brands, as opposed to generics, there are no repercussions on the NHS and no added health risks to patients.

However, it is a different matter with complementary medicines. A few are harmful, most make vague but enticing claims which may mislead sometimes vulnerable consumers, and in general their marketing creates pressure to provide such alternative treatments on the NHS and through insurance schemes. HealthWatch

believes complementary medicines should be treated in the same way as orthodox pharmaceutical products not simply to create a level playing field, though that is an important part of competition policy, but to safeguard public health.

Michael Allen,  
Regulatory Consultant and Honorary Secretary, HealthWatch

Acronyms used:

- BEUC Bureau Européen des Unions de Consommateurs—the European Consumers' Organisation, which represents 32 independent national organisations from 20 European countries
- BNF British National Formulary—a publication of the BMA and Royal Pharmaceutical Society, a primary source of unbiased information on medicines in the UK
- CA Consumers' Association of the UK
- DtCA Direct to Consumer Advertising (of prescription medicines, in this context)
- EMEA European Medicines Evaluation Agency—the EU RA, which acts on the advice of the EU Committee for Proprietary Medicinal Products
- EU European Union
- MA Marketing Authorisation—RA approval for the marketing of a medicine
- MCA Medicines Control Agency—the UK RA, which acts on the advice of the Committee on Safety of Medicines
- NICE National Institute for Clinical Excellence—an NHS Health Authority charged with evaluating the cost-effectiveness and fair availability of medicines and medical procedures
- PIL Patient Information Leaflet—information on a prescription medicine addressed to the patient. All products receiving an MA must have a PIL approved by the RA
- RA Regulatory Authority: in UK the MCA, for the EU the EMEA
- SPC Summary of Product Characteristics—information on a prescription medicine addressed to the doctor. All products receiving an MA must have a SPC approved by the RA

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4. Asia Intelligence Wire via NewsEdge Corporation, Suz Redfearn, 06 April 2002.

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## Trading Standards

### Slimming science over-stretched

***John Garrow scores another success in his campaign against ineffective slimming products sold with over-enthusiastic advertising claims. In this case the salesman's enthusiasm was genuine enough, he believes, though misplaced.***

A bench of magistrates in Harrogate appeared unfazed when called upon to adjudicate on a case involving some subtle points of lipid metabolism in man. The North Yorkshire Trading Standards Department brought a case against Power Health Products for claiming that if you take three "Slim-Nite" capsules before going to sleep, "Instead of converting calories into layers of fat, cells are encouraged to burn them as energy and convert them into lean body tissue. The result is loss of ugly bulges, a leaner, trimmer shape."

The case started in November 2000, and eventually came to court on 2nd July 2002. The defendants denied that the claim was false or misleading, and submitted a 17-page report from an expert witness with a PhD in Sports Science Research. She cited 22 references to the scientific literature that supported this view. One of the textbooks that she cited was edited by Professor John Garrow, Honorary Secretary of HealthWatch, who was invited to comment on her document.

Each Slim-Nite capsule contained 250mg arginine, 250mg ornithine, and 25mg of carnitine. The first two ingredients are amino-acids involved in the synthesis of growth hormone, and carnitine is important in the transport of fatty acids for oxidation. The justification for the claim was that after taking these capsules at night, at least 3 hours after food, there would be a surge of growth hormone that would mobilise body fat as fatty acids, and the carnitine would then activate pathways by which this fat would be selectively burned. Crucially, a paper was cited to show that this effect was produced in man by the oral intake of 500 mg acetyl-L-carnitine and 25–100 mg L-ornithine<sup>1</sup>. However, no evidence was submitted of clinical trials of the Slim-Nite formula.

In such a trial, the onus is on the prosecution to show that the published claim is false. The defence do not need to prove it is true, but they must show that they looked with "due diligence" and were not convinced that there

was evidence against it. The case for the prosecution was principally that Parr1 also showed that a dose of carnitine less than 500 mg (as in Slim-Nite) did not cause a growth hormone surge.

However, magistrates are not invariably receptive to the idea that the dose is an important determinant of drug action. Several other weaknesses were identified. Even if there was a release of fat from depots it did not mean the fat disappeared: it had to be burned instead of other fuel, and, since there was no long-term change in metabolic rate, it was probable that the total fat lost overnight would not be increased by a temporary blip at the onset of sleep. There was no evidence to support the claim that the fat would be converted into lean body tissue: indeed this is biochemically impossible. Nor is there evidence that the fat loss (if any) would be from the “ugly bulges” any more than from innocent fat elsewhere.

We do not know which (if any) of these arguments would have swayed the bench, because, after much legal consultation, the defendants changed their plea to guilty, and were fined £2000 and ordered to pay £3294.50 costs. Had they fought on for the two days allocated for the trial, and lost, their costs would have been much higher. It seems that this was a case in which the defendants sincerely believed that their advertising claims were true. It was only when they came to court, and had seriously to consider the contrary evidence, that the seeds of doubt were sown in their minds.

John Garrow  
Emeritus Professor of Human Nutrition  
University of London

Reference: Parr TB. A new technique to elevate night time growth hormone release and a potential growth hormone feedback control loop. *Medical Hypotheses* 2001; 56: 610–613.

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## Letter to the Editor

### In defence of detox

***Dr Paula Baillie-Hamilton MBBS D Phil (Oxon) responds to John Garrow's criticism of her book, "The Detox Diet" in July's issue ([HealthWatch Newsletter issue 46](#)). Dr Baillie-Hamilton is Visiting Fellow in Occupational and Environmental Health at Stirling University.***

Dear Professor Garrow,

I have just read your review of my book “The Detox Diet” on the [HealthWatch website](#). I was disappointed to read it as it is pretty obvious from what you have said, that you haven't actually fully read my book.

Firstly, I would be interested to know exactly what evidence you think is against the proposition that agrochemicals are one of the factors behind the obesity epidemic? Indeed all the scientists on the board of the journal who published my recently published academic paper<sup>1</sup> on this subject were really excited by it. I think it was because they understood that toxins are far from being “hypothetical” and are real and very dangerous. Their academic background of toxicology and environmental medicine enabled them to understand what my hypothesis was all about.

Secondly, you accused me of making people want to avoid some nutritious valuable foods, such as fatty fish and fruit and vegetables. You may be interested to hear that the UK Government's own Food Standard Agency's advice to pregnant women and children is that they should not eat certain types of fish at all due to the levels of toxins they are likely to contain<sup>2</sup>. In addition several manufacturers have had to take certain fish oils off the shelves (such as Holland and Barratt) because the levels of contaminants they contained were considered unsafe<sup>3</sup>. Even the Consumers Association now recommends that people should not eat more than one portion of salmon or other oily fish a week due to the high levels of chemical toxins present<sup>4</sup>. If you had read my book you will realize that I had actually strongly suggested that people eat less contaminated foods to obtain all the vital omega 3 and 6 oils we all very much need to include in our diet. These include organically produced linseed oils, other vegetable oils and fish oils which have had the pesticides and heavy metals actively removed. The same goes for fruit and vegetables.

With approximately one third of all food containing chemical pesticides, these contaminants are far from “hypothetical”. And far from telling people to avoid these foods, I suggested they should eat the less contaminated versions by either buying organically or preparing the food in such a way that it becomes less contaminated. Again, my advice is echoed by the UK Government organizations. The Pesticides Safety Directorate suggest that fruit and vegetables—in particular potatoes—should be peeled before giving them to young children. Their 12 November monitoring report<sup>5</sup> recorded pesticide residues in about 30 per cent of 1,000 samples of food tested. In addition, scientists found pesticides on more than half of potatoes tested, including a banned fungicide and chlorpropham, a herbicide known to be toxic to laboratory animals. Eight of the 75 pears tested exceeded the minimum safety limit for humans for the fungicide folpet, a possible carcinogen for which no Maximum Residue Level, a legally permitted standard accepted in agriculture, has been set in Britain.

I would be delighted to send you a copy of my academic paper if you like as I am keen to get a debate started which actually looks for the truth about the current obesity epidemic—which examines all aspects of the way in which our environment has changed and not just the traditional calorie based ideas. I am currently receiving loads of mail from people who have not even cut their intake of food down at all, but who have now lost a very significant amount of weight. So cutting out toxins found in food and taking additional supplements appears to have a positive weight loss effect in many people.

Yours sincerely

PAULA BAILLIE-HAMILTON

email: [paulabh@slimmingsystems.com](mailto:paulabh@slimmingsystems.com)

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5. <http://www.pesticides.gov.uk/committees/PRC/2002.htm#Q2>

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