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# HealthWatch

for treatment that works

Newsletter 73 April 2009

## NEW COUNCIL CONTROVERSY

**T**HE UK'S FIRST regulator for complementary medicine has promised to get tough with the industry and drive out cowboy therapists. But there are doubts as to whether it will do much more than promote ineffective treatments to a trusting public. The new Complementary and Natural Healthcare Council (CNHC), launched on 19th January, invites voluntary registration from alternative health practitioners, with successful applicants being licensed to display the CNHC quality mark logo.

They hope to be regulating a dozen different types of therapy, including reflexology, cranial therapy and homeopathy, by the end of the year—currently registration is only being invited from massage and nutritional therapists. During 2009 the CNHC hopes to register 10,000 out of their estimate of 150,000 alternative therapists currently in the UK. However less than a month after the launch a press release from the CNHC said that they had been “overwhelmed” with the response, resulting in “some unavoidable delay in processing applications”.

According to the CNHC's new website [www.cnhc.org.uk](http://www.cnhc.org.uk) the council was founded with the help of the Prince's Foundation for Integrated Health, and of a range of complementary healthcare practitioners. For a practitioner to receive the quality mark, they must provide evidence that their training meets the National Occupational Standards for that discipline or achieved competency to the same level by means of relevant experience and assessment.

However, evidence that the treatments actually work is not required. There is also to be in place a complaints handling process that is, says the website, “not intended to be punitive”.

HealthWatch is concerned that the CNHC mark will engender false confidence among patients. In fact practitioners carrying the CNHC mark may be in breach of the 2008 consumer protection laws which specifically forbid false claims that a product can cure a disease. We pointed this out to health minister Ben Bradshaw who replied, “The CNHC does not promote the efficacy of the therapies it represents—whether they work or not is for those who choose to use the therapies to decide. The main aim of the CNHC is protection of the public.” That it might be counter-productive to launch a body to protect the public by issuing licenses to businesses that break consumer protection laws, seems not to have been appreciated by the Department of Health.

Within days of the launch David Colquhoun, professor of phar-  
...continued on page 2

## Ernst slates Duchy's “dodgy” remedy

PRINCE CHARLES' new range of herbal products has been slated publicly as “dodgy” and “outright quackery” in a critique that has been widely reported in national media. Edzard Ernst, professor of complementary medicine at the Peninsula Medical School, Exeter, accused the Prince of financially exploiting, “a gullible public in a time of economic hardship.”

Duchy Herbals' Detox Tincture, an artichoke and dandelion mix described as, “a food supplement to help eliminate toxins and aid digestion” costs £10 for a 50ml bottle. It is part of a range that was launched in January, when Duchy Originals' herbalist Michael McIntyre said that each mix had been meticulously researched and was, “manufactured to the highest standards after exhaustive lab testing”. But Ernst said the suggestion that such products remove toxins from the body was, “implausible, unproven and dangerous”. The word “detox” undermined the treatment of people with drug addiction, he was quoted in the *Scotsman* as saying, adding, “If people are led to believe they can overindulge on food and drink and

put that all right with a Duchy detox tincture, then that, to me, is endangering public health.”

In this issue of the *HealthWatch Newsletter* Edzard Ernst likens the NHS Alliance to a lobby group for complementary medicine (see page 5).

Mandy Payne

### Further reading

BBC News Online 10th March 2009. <http://news.bbc.co.uk/1/hi/health/7934568.stm>

The Guardian <http://www.guardian.co.uk/uk/2009/mar/11/prince-charles-detox-tincture>

The Telegraph <http://www.telegraph.co.uk/health/healthnews/4967749/Prince-Charles-is-exploiting-the-gullible-with-dodgy-detox-remedy-scientist-argues.html>

The Scotsman <http://thescotsman.scotsman.com/health/Prince-Charles-is-39dangerous-5058162.jp>

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## UPDATE ON CARDIOLOGIST LIBEL CASE

**WHILE BRITISH cardiologist Peter Wilmshurst waits to learn the date of the trial in which he risks bankruptcy as a result of being sued for slander and libel online in America, there has been coverage in the medical and consumer press in the UK and the USA, both in print and online, in support of his case. A support fund has been set up by HealthWatch<sup>1</sup> to help pay the mammoth legal bills and recent publicity is expected to boost the total still further.**

US company NMT Medical contends that Wilmshurst, of the Royal Shrewsbury Hospital, slandered and libelled it in an interview with the online publication *Heartwire* ([www.theheart.org](http://www.theheart.org)), although they have not sued *Heartwire*. Wilmshurst had been a lead researcher in the MIST trial, which aimed to discover a link between patent foramen ovale (a congenital condition in which a heart valve does not close properly) and migraine headaches. He reportedly speculated that the trial may have failed because NMT's Starflex device, which was used in the trial to close the valves, did not work well. Wilmshurst was also quoted as saying he believed the company had withheld trial data because it feared that it might undercut sales of the device for other uses, like stroke treatment<sup>2</sup>. NMT contend that his comments to the press breached a confidentiality agreement, and that the comments made were defamatory and untrue. It alleges that the comments were motivated by malice because the negative findings of the trial cast doubt on Wilmshurst's own personal theory on the link between PFO and migraine.

Journalist Jerome Burne has taken the story out of the medical press and into the public domain with a feature in the *Daily Mail*<sup>3</sup> which reminds us that around 25,000 people have had NMT Medical's Starflex device inserted. Burne's article reports that Professor Sir John Lilleyman, head of the National Research Ethics service that oversaw the MIST trial, shares Wilmshurst's concern about the possibly conflicting results of echocardiogram reviews. He also reportedly told Burne that he was worried that some

patients in the trial may believe their foramen ovale had been closed when in fact it hadn't, and is quoted as saying, "I believe we may have a duty of care to those patients."

*Heartwire* has now also published an interview with Lilleyman<sup>4</sup>. Journalist Shelley Wood reported that he believes the legal dispute between NMT and Wilmshurst may be deflecting attention away from unresolved issues with the trial. "Ignoring the spat between Peter Wilmshurst and NMT, basically what I'm concerned about is that we don't know what the status of these patients is, and the only way to find out is to review their original scans with an independent, disinterested expert and possibly scan some of them again if the data are nonexistent or noninterpretable," Lilleyman was quoted as saying.

Mandy Payne

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1. Payne M. Libel suit against cardiologist. *HealthWatch Newsletter* 2009; 72: 1
2. Meier B. Device Maker Sues a Doctor Who Called Its Product Flawed. *New York Times* January 13 2009, see [http://www.nytimes.com/2009/01/14/health/research/14heartside.html?\\_r=1&scp=1&sq=&st=nyt](http://www.nytimes.com/2009/01/14/health/research/14heartside.html?_r=1&scp=1&sq=&st=nyt)
3. Burne J. Anger at bid to silence heart op whistleblower. *Daily Mail* February 3 2009. See <http://www.dailymail.co.uk/health/article-1156382/Anger-bid-silence-heart-op-whistleblower.html>
4. Wood S. Journal editors and UK research ethics group raise new questions about MIST migraine/PFO trial. *Heartwire* February 27 2009. See <http://www.theheart.org/article/944781.do>

## New council controversy ...continued from front page

macology at University College London and now a member of the CNHC, was quoted in the *Economist* calling for the National Institute for Health and Clinical Excellence, which rules on the cost-effectiveness of medical treatments, to examine the evidence for complementary medicine<sup>1</sup>. "The whole problem of regulating alternative medicine will remain impossibly chaotic until the government grasps the nettle of deciding what works and what doesn't," he said in the report, which was sub-headed, "Britain simultaneously licenses alternative medicine and outlaws it". Colquhoun again challenged the government to address the issue of efficacy in an open letter that he co-authored to *The Times*<sup>2</sup>. Whether his colleagues on the CNHC, who include some current or past practitioners of alternative therapies, will support his call

remains to be seen.

Meanwhile Sean Ellis of Farnham, commenting online on the *Times* letter, was so incensed that the CNHC does not require even basic evidence of efficacy and safety that he set up a petition on the Number 10 website which hundreds have now signed. Sign by 22nd April at <http://petitions.number10.gov.uk/CNHCSafety/>

Mandy Payne

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1. But does it work? *The Economist*, 22 January 2009. See [http://www.economist.com/world/britain/displaystory.cfm?story\\_id=12998201](http://www.economist.com/world/britain/displaystory.cfm?story_id=12998201)
2. *The Times*, January 30, 2009. See <http://www.timesonline.co.uk/tol/comment/letters/article5613750.ece>

## news in brief

NEGATIVE consequences of the NHS breast screening programme were highlighted in a letter to the *Times* in which 23 signatories, including HealthWatch members, called for more balanced patient information leaflets. Up to half of cancers detected by screening may not be harmful yet can trigger unnecessary traumatic treatment, and screening might save only one woman in 2,000 over a ten-year period, with reported falls in breast cancer deaths being due to improved treatment, not screening. The letter ran with an article by the *Times*' Health Editor.

*The Times*, 19 February 2009. See: <http://www.timesonline.co.uk/tol/comment/letters/article5761650.ece> and [http://www.timesonline.co.uk/tol/life\\_and\\_style/health/article5762516.ece](http://www.timesonline.co.uk/tol/life_and_style/health/article5762516.ece)

HEALTHWATCH'S GOOGLE group has taken off. There is a busy exchange of information, and interesting press reports

picked up can be quickly shared. Access is restricted to HealthWatch members only, if you haven't received your invitation please e-mail [david.bender@btinternet.com](mailto:david.bender@btinternet.com)

GOOGLE'S ADVERTISING, however, needs more control, say Italian doctors writing in *bmj.com*, to avoid linking to web pages that contain worrying medical claims. Google AdWords places ads automatically on web pages carrying key words. But Google's filters still allow inappropriate advertisements that could be harmful, say doctors at the University of Florence. HealthWatch flagged up the problem three years ago after a *Telegraph* online article on autism carried a Google Ad promoting homeopathic autism cures (*HealthWatch Newsletter* issue 61, April 2006).

*BMJ.com* 20 March 2008.

See: [www.bmj.com/cgi/doi/10.1136/bmj.b1083](http://www.bmj.com/cgi/doi/10.1136/bmj.b1083)

# LIBEL AND THE THREAT TO PUBLIC HEALTH

**I**N DEBATES about public health, are there things which really should be left unsaid? Are there statements so damaging and unwelcome that the law should be invoked to ban those statements from ever being published or communicated? And, if so, should someone be able anyway to express serious concerns without any fear of expensive and exhausting litigation?

Two recent legal cases have raised these fundamental questions. Both cases involve high-profile science writers and, interestingly, both concern articles published in *The Guardian*.

The first case is that of Dr Ben Goldacre, the NHS doctor best known for his weekly Bad Science column and bestselling book of the same name, and also on his [www.badsience.net](http://www.badsience.net) website. Goldacre was sued by Mathias Rath in respect of adverse statements about Rath's promotion of vitamin pills as better than anti-retroviral medications for AIDS sufferers in South Africa. However, Rath's case collapsed in September 2008 before trial.

The second case is still ongoing. The defendant is Simon Singh, the well-known author of Fermat's Last Theorem, The Code Book, and Big Bang. Singh has recently worked extensively with Professor Edzard Ernst, chair in Complementary Medicine at Exeter University, and has published *Trick or Treatment: Alternative Medicine On Trial*.

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**"statements which are critical of those who promote treatments which cause concern may not be published or broadcast, even if true or fair, because of the ease with which a case can be brought and the expense and effort which would be required in fighting the case"**

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Singh is now being sued by the British Chiropractic Association (BCA), an English registered company, over a statement in *The Guardian* (and not in the book itself) regarding the BCA's promotion of chiropractic for six children's ailments, including asthma and ear infections. Singh stated that these treatments were "bogus" and that there was "not a jot" of evidence to support their efficacy. The BCA consider such comments as libellous. Singh is reported to be mounting an extensive defence of justification and fair comment. The full trial, to be heard by a judge alone, is due to take place later this year.

In both cases the litigation route was chosen by the claimant as a means to deal with the adverse and unwelcome statements. Why this was done reveals a great deal about the current state of the English law of libel. The ability to sue for libel can potentially distort important debates about public health issues.

The law of libel and slander together constitute the law of defamation. In broad terms, a libel is a defamatory statement made in a non-transient form to a third party; and a slander is one made in a transient form. The distinction can be significant, as libel (like trespass but unlike most torts) is actionable *per se*, without proof of loss, whilst a slander is not actionable *per se* unless it relates to a small group of exclusions. This is one reason why an English libel case is so easy to bring.

Another reason is that the threshold for what constitutes defamation is very low. There is no statutory definition, as defamation exists at common law rather than because of statute. The courts generally treat as defamatory a statement which would damage reputation, making the standing of the claimant lower in the eyes of society. By this measure many critical comments are defamatory.

Once the claimant (which can be a company and not a natural person) can make out the defamatory meaning of the statement then the defendant will be liable for damages and both sides' legal costs if a case is brought, unless the defendant can prove that the state-

ment was made on a "privileged" occasion or that the usual defences of fair comment or justification are available.

That the defendant has to prove privilege or a defence means that, in effect, there is a reverse burden of proof in defamation. The defendant has to prove that the statement is either privileged or true or fair. When this reverse burden is added to the ease with which a libel case can be brought, and the terrifying cost implications of losing (due often to the "no win no fee" model for funding claims where the claimant's lawyers can charge an "uplift", that is, cover their losses on losing cases by charging as much as double their regular hourly fee on winning cases, at the unfortunate defendant's considerable expense), then it is clear that the threat of such cases can have a "chilling" effect, making publishers or journalists think twice about publishing critical statements for fear of litigation. In the Rath case, which did not even get to court, *The Guardian's* costs are reported to be about £500,000.

In most areas of public life, this chilling effect has been addressed by the expansion of "qualified privilege". This means that a claim can be defeated if the statement was made in circumstances where the defendant had a duty to make the statement to a third person. Qualified privilege covers, for example, reports to the police or communications about employees. The only way of displacing qualified privilege is by the claimant proving malice.

Defamation thereby now just deals with a residuum of cases, usually where the statements have been published or broadcast by a media organisation. There were hopes a few years ago that this would also generally cover "responsible journalists"—the so-called Reynolds defence—but the courts have construed this defence so narrowly that it has rarely been successful.

When applied to the field of public health, the effect of the current state of English libel law is that statements which are critical of those who promote treatments which cause concern may not be published or broadcast, even if true or fair, because of the ease with which a case can be brought and the expense and effort which would be required in fighting the case.

**T**HIS IS a counterintuitive situation. Public health is, of course, one area where a debate should be as uninhibited as possible. It also is potentially contrary to the Human Rights Act 1998. The right to free expression under Article 10 of the European Convention on Human Rights expressly refers to "the protection of health" and any restrictions to free expression in that area should only be those "necessary". It is understood that Singh is taking the Article 10 point as part of his wide-ranging defence to the BCA's claim.

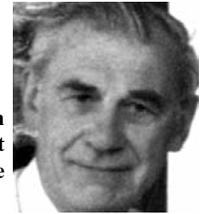
False or misleading statements do not help debate about public health, but one function of such a debate is to drive out or discredit these statements. It is not a function which can be performed instead by the English law of libel, especially in its current form.

It would, however, be interesting if the English High Court uses the case as an opportunity to provide general guidance on the relationship between libel and debates on public health, or even develop the law so to prevent the potential chilling effect of the law as it stands.

*Jack of Kent*

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# DANGEROUS DIETS



**T**HIS JANUARY, as is usual after the Christmas celebrations, the paperback best seller list was packed with books on dieting, about which there is little new to be said. Most of these are about how to lose the weight gained in the previous month, and claim to reveal “secrets” hitherto unknown about diets that will make you thinner and/or healthier. In truth there are very few secrets still to be revealed.

Since World War II we have learned a great deal about human nutritional requirements. There was an urgent need to know how to design rations for the civilian population, and to rehabilitate survivors from starvation in prison camps. Intravenous feeding saved the lives of severely wounded people who could not have been fed by mouth. A by-product of this was that we learnt far more precise information about the daily requirements of micronutrients than could be obtained by analysis of oral diets. In 1969 the Department of Health reported on daily requirements of 10 nutrients, by the time they reported in 1991 this had increased to 40 nutrients, but there has been little change since then.

## *Lethal diets*

If addition of a poison is excluded, the only way in which the diet of a normal adult could be altered so as to cause death in less than a week is to exclude all water. Someone deprived of any non-salty water because they are trapped under debris from an earthquake, or adrift in a lifeboat after a shipwreck, will soon die. How soon depends largely on the temperature and humidity, and hence the rate of evaporative loss of water.

Even if enough water is available total starvation will also inevitably cause death, but after a much longer period. The survival of victims of famine due to drought or warfare is usually threatened by disease as well as hunger, and they may be having small amounts of edible vegetation, so they do not provide reliable information about the lethal effects of starvation alone.

A healthy adult of normal build who takes no nutrients apart from water—such as a hunger striker—will probably die in about 10 weeks. Between 1964 and 1970 there were several reports of severely obese patients who were treated by total starvation for long periods. The longest period recorded is 249 days starvation, during which she lost 64.9 kg. However some people on starvation diets unexpectedly died and at autopsy were found to have severe damage to their heart muscle, so this treatment was abandoned.

The largest reported weight loss (227 kg) was on a low calorie diet (800 kcal/day) and took 2 years as a hospital inpatient<sup>1</sup>. The patient was admitted weighing 310 kg, but an unknown proportion of that was water, since he was initially massively oedematous. Since 1970 it has been accepted that prolonged total starvation is too dangerous, but 800 kcal/day will keep the patient alive and losing weight quite quickly. There is still controversy about how much lower than 800 kcal it is safe to go, since a few patients have died while using very low calorie diets, although there has been insufficient evidence to implicate the diet itself as a cause in these cases. Our research indicates that it is not the prescribed energy intake, but the actual rate of weight loss, that determined the danger. A desirable rate of weight loss in obese patients is 0.5 to 1.0 kg per week.<sup>2</sup>

## *Macronutrient imbalance*

The dangers of too great a reduction in total energy intake have been considered above, but many commercial diets emphasise alterations in the balance of protein, carbohydrate and fat, from which dietary energy comes. (Alcohol is also a source of dietary energy, but it will not be considered here since the dangers of a high intake of alcohol are well known).

Human beings tolerate very large differences in macronutrient

balance. For example vegetarians have a much lower intake of protein and fat than omnivores, but the amount of protein in vegetables is enough to maintain health in adults if total energy intake is adequate. However small children have a higher requirement of protein in relation to body weight because they need extra protein to support growth, and they cannot eat such large quantities of the bulky carbohydrate diet as adults. Hence in chronically undernourished populations the deficiencies show up first in stunted growth of children. Protein supplements are not very effective in improving the health of children who also have an inadequate energy intake: both deficiencies need to be remedied.

The other two macronutrients, carbohydrate and fat, are the main sources of energy. High fat diets (of which the popular “Atkins” plan is an example) have been advocated for weight loss, because if carbohydrate is restricted total energy is almost bound to be restricted also. Very severe reduction of carbohydrate causes ketosis (signalled by an unpleasant smell on the breath), since some carbohydrate is needed for the normal metabolism of fat. There is good evidence that a high fat diet causes a high concentration of lipids in the blood, so if a high-fat diet is used repeatedly or adopted as a long term strategy there is an increased danger of cardiovascular disease and coronary thrombosis.

On the other hand, extreme restriction of fat such as in the most stringent versions of the low-fat diets popular in the 1990’s causes reduction in the intake of fat-soluble vitamins A and D and possible deficiencies in these nutrients.

## *Micronutrient deficiency or excess*

In affluent countries deficiency of vitamins or minerals is very rarely found among people who are having an adequate energy intake from a variety of foods. I have worked in some countries where dietary deficiency of vitamin A, iron, or iodine cause serious illnesses, but I have never seen such cases in the UK. The problems usually arise in adults who are deliberately restricting energy intake in order to lose weight, and are taking inappropriate supplements in order to correct the resulting deficiency of micronutrients. The exceptions to this general statement are old people who are not exposed to sunshine; pregnant women; and adults or children who have metabolic diseases or dietary intolerances.

There is a huge industry that promotes micronutrient supplements on the false premise that if a deficiency of Vitamin X causes ill health then a massive intake must bring extra good health. The reverse is nearer the truth. Especially when the supplement contains a dose of a single micronutrient that could never be encountered in a diet of normal food. For example health food shops offer capsules containing single amino-acids which can never be helpful except in rare metabolic diseases. Aminoacids are the building blocks from which protein is synthesised. A single amino-acid such as leucine or lysine are “essential” amino-acids, so without them protein cannot be synthesised. But a supplement of one of these does more harm than good, because an excess of one amino-acid cannot make protein unless the others are present in the appropriate proportions. The extra aminoacid therefore has to be used to make urea and excreted, resulting in a net loss of protein to the body.

Trace elements such as zinc and copper are required in very small quantities. Transport mechanisms in the gut wall normally absorb the right quantities, but a large supplement of one (for example

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## ALTERNATIVE MEDICINE AND THE NHS ALLIANCE

**T**HE WEBSITE of the NHS Alliance informs us that this body, apparently one of the largest GP organisations in the UK, has a “plays a major part in supporting and developing Primary Care Trusts and similar primary care organisations and in providing opportunities for them (and the individuals within them) to network and exchange best practice”<sup>1</sup>. There is no clear mission statement and the site might easily give one the impression that the NHS Alliance is a lobby group for “alternative” medicine.

Apart from the full text of several speeches its chairman, Dr Michael Dixon, gave promoting this type of healthcare, we find ten press releases on the subject of complementary or alternative medicine. Most of us know that this topic is controversial, so one might expect a degree of critical assessment. However, all the press releases seem to be promotional. Here are quotes from the short excerpts of each press release that appear on the website<sup>1</sup>:

“Complementary medicine is becoming increasingly popular with patients...[and] has the potential to improve health and reduce demands on conventional health services” (2/12/1999)

**“Complementary medicine...provides a holistic approach in line with primary care” (1/12/1999)**

“GP practices and primary care increasingly provide their patients with access to therapies such as these [acupuncture, osteopathy, chiropractic, herbal medicine, hypnotherapy or homeopathy]” (26/2/2001)

**“Conventional medicine and the modernised NHS risk becoming too mechanistic” (29/1/2001)**

“The NHS Alliance today backed Health Ministers’ support for alternative therapies to be made available to NHS patients” (4/1/2001)

**“...three quarters of the public believe complementary medicine should be available from the NHS” (26/2/2002)**

“...it is time for orthodox medicine to embrace complementary therapies...” (21/1/2004)

**“The NHS Alliance welcomes the government’s proposals for statutory regulation of acupuncture and herbal medicine...” (3/3/2004)**

“...HRH the Prince of Wales presented awards to the winners and runners-up of the NHS Alliance Acorn Awards” (22/5/2006)

Moreover, several statements are misleading or incorrect. For instance, there is no good evidence demonstrating that, in the UK, the popularity of alternative medicine is increasing. The notion that complementary medicine “provides a holistic approach” implies that primary care is no longer interested any longer in whole individuals. Finally, I would argue that alternative therapies should not be “embraced” and “made available to NHS patients”; it should be

scientifically tested, and those parts that are supported by sound evidence should be used. Sadly the vast majority of alternative therapies fail to fulfil this basic criterion<sup>2</sup>.

But the NHS Alliance seems to condone even more unproven practices: “A crusade against ignorance—enables patients to remove their straight jackets and take a new approach to improving health. Dr Michael Dixon, Chairman of the NHS Alliance”<sup>3</sup>. This endorsement appears on the front cover of a recent book entitled “Food is Better Medicine than Drugs. Your Prescription for Drug-Free Health”<sup>3</sup>. In it, patients are advised, for example, not to take the drugs prescribed for heart disease: “If you are on one or more of these drugs [warfarin, heparin, aspirin], it’s highly likely they are going to unbalance various complex systems in your body, possibly putting you at risk for a number of other problems in the future. The same applies if you are reasonably healthy but have been given statins...”<sup>3</sup>. As an alternative, the book recommends taking “several foods, nutrients and spices...[which] together...are likely to be far more effective...”<sup>3</sup>. There is, of course, no sound evidence for this disturbing claim<sup>2</sup>.

What strikes me most with the NHS Alliance’s promotion of “alternative” medicine is the absence of the term “evidence” in relation to it. The GMC demands of its members: “You must provide effective treatments based on the best available evidence”<sup>4</sup>. This begs the question whether the NHS Alliance’s uncritical promotion of alternative medicine does not put them into conflict with the currently accepted ethical standards of the UK medical profession.

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*Adapted from an article first published in Pulse 24 Feb 2009, with the author’s kind permission. See [www.pulsetoday.co.uk](http://www.pulsetoday.co.uk)*

zinc) may overload the transport system and block the absorption of copper. This can create clinical problems that are very difficult to diagnose. If you do not know about the zinc supplements you have to be quite astute to recognise copper deficiency in a patient who has a normal amount of copper in his diet, but an inadequate absorption of copper caused by an excess intake of zinc.

### Importance of kidney function

This brief review has implied that so long as you eat a reasonable amount of ordinary food you will avoid major problems. However this depends on having kidneys working well so that if you take an excessive amount of fluid, or water-soluble vitamins, the kidneys will excrete the excess in urine. The situation is very different in people with impaired kidney function.

The commonest supplement-related life-threatening situation is when someone with damaged kidneys and legs swollen with fluid is

advised to take supplements containing potassium. The concentration of potassium in the blood may then rise to a level at which regulation of the heartbeat is disturbed, and this may cause death.

**Attempts to achieve rapid and marked weight loss, or consume inappropriate amounts of dietary supplements, should be discouraged. A safer and more useful approach would be to aim for a smaller but sustained rate of weight loss, and to modify eating habits so as to maintain the desired level of weight achieved.**

*Position paper prepared by John Garrow and approved by the HealthWatch committee on January 2009*

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# PLACEBOS AND DISEASE-MONGERING

**L**ITTLE PROGRESS seems to have been made since the description of the placebo effect at the end of the 18th century, when Benjamin Franklin and Antoine Lavoisier investigated Franz Mesmer's magnetic healing techniques. Recently, Tilburt and his colleagues showed that most specialists in the US are still prescribing placebos.<sup>1</sup>

In fact many, respecting at least the informed consent principle, fall from magic into insanity—by prescribing a placebo and saying so.

By doing so, they reduce the second component of the placebo effect. Scientific analysis separates the placebo effect into the response to three components: assessment and observation of subjective outcome, therapeutic ritual, and a supportive patient-practitioner relationship<sup>2</sup>. New methods highlight neurobiological evidence showing the activation of specific brain regions after administration of a placebo<sup>3</sup>. This is not surprising: it is the result of a psychosocial effect based upon the subject's expectation. Even so, this effect is observed in only one third of the subjects and only under certain conditions.

Pragmatically, the placebo effect is simply a belief. Placebos do nothing. If you slip a placebo into a person's tea, it doesn't work. Placebos do not affect health outcomes such as mortality and morbidity. The placebo effect does not have powerful objective clinical effects: the subjective patient-reported alleviation of pain is small and cannot be distinguished from reporting bias<sup>4</sup>. The effect, if any, rapidly wears off.

Sadly, in too many cases, we would like to do more for the patient but we cannot. But the numerous successes of medical science have not changed our duty since the 16th century when Ambroise Paré claimed that the physician's duty was to "occasionally cure, often relieve, and always console". There is no need for placebos to provide reassurance, comfort and hope. *Placebo* is Latin for "I will please"; the doctor's duty is not to please but to help.

A placebo is a dangerous tool. Resorting to a placebo to get rid of a troubling patient can delay the proper diagnosis of a serious medical condition. It also jeopardises the doctor-patient relationship, which is based on trust. Lying to the patient is a serious breach of confidence and it risks a backlash.

Moreover placebos strengthen medical arrogance and infantilise people. The consequence is disease-mongering. By defining vague symptoms as an entity requiring a drug treatment people are converted into patients. They need explanation and reassurance that promote autonomy, not to be given faith in a non-existent disease and crackpot medicine. "Be strong and of good courage, there is nothing wrong with you." Why do so many doctors avoid telling people the truth? Oncologists have learnt how to do it for more serious conditions.

In 1923, Jules Romains wrote a comedy: *Knock or the Triumph of Medical Science* in which, thanks to frightening graphs, an inventive village doctor succeeds in turning the robust inhabitants into confirmed hypochondriacs<sup>5</sup>. Today in the real world, despite continuous progress in health and longevity more and more people are worried about their health with unreasonable fear and irrational expectations.

Across Europe the situation differs from country to country. In the UK the vast majority of primary care trusts have cut funding for homeopathic preparations and the number of prescriptions for these remedies dropped from 83,000 in 2005 to 49,300 in 2007, despite an increase in the number of prescriptions for medical treatments overall. In contrast, in France much of the cost of homeopathic remedies is reimbursed under the mandatory National Health Service scheme and everything is done to increase the faith in the remedy. The high price increases the subjective effect<sup>6</sup>. For example, treatment with a homeopathic preparation of *Ginkgo biloba* costs 0.53€ a day (Captopril for hypertension is only 0.33 €, diuretics are even cheaper). Readers will be amused to learn that the French Medicine Agency (AFSSAPS) issued an official warning after a mix-up in the labelling of two homeopathic preparations:

"Vials labelled *Ginkgo biloba* mother tincture contain *Equisetum arvense* mother tincture and vice-versa...AFSSAPS has said that this mix-up does not pose any particular risk...Pharmacists will have to report this information to the doctors in their neighbourhood likely to have prescribed these products...and to the patients known to have used one of these two products between May and October, 2007."<sup>7</sup> And yet, modern science indicates that the vials' contents are identical in every way and that the only means of distinguishing one from the other is the label. Not surprisingly, no-one seems to have noticed the difference over the five months of this inadvertent double-blind trial.<sup>8</sup>

In my view placebos must be restricted to clinical trials and then only to measure the "nuisance" effects in the experimental setting. Even here their use is very limited: the Helsinki Declaration stressed that new therapies must be tested against the current standard of care, not against placebos. Nevertheless, *Gastroenterology* recently published a trial of Etanercept for the treatment of alcoholic hepatitis against a placebo rather than the standard care. The American Society of Gastroenterology states that "corticosteroids should be used in patients with severe alcoholic hepatitis in whom the diagnosis is certain"<sup>9,10</sup>. Corticosteroids have a proven efficacy against mortality in this condition—pooling data from all published studies shows that corticosteroids allow a relative risk reduction in mortality of 0.32 (number needed to treat 9.2)<sup>11</sup>. However patients in the placebo arm of the Etanercept trial were untreated and at least one out of nine died. In such a case, placebo use is not scientifically justified.

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# Defeating autism: a damaging delusion

by Michael Fitzpatrick

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**A**UTISM IS a form of mental handicap. Some children with learning difficulties can be recognised at birth as they look abnormal, but autistic children look like any other children, and their handicap doesn't start to show until after the first year of life, and not long after children have had their routine vaccinations.

Few people had heard of it twenty years ago. Now, thanks to the pressure of outraged, vaccine-refusenik parents, everyone has. The condition was depicted by Dustin Hoffman in the film *The Rain Man*, and the writer Mark Haddon gets wonderfully inside an autistic boy's mind in his book *The Curious Incident of the Dog in the Night-time*.

Many HealthWatch members will be familiar with Michael Fitzpatrick's work. He is the author of *The Tyranny of Health*, a critique of the new health orthodoxy, and *MMR and Autism*, a title that speaks for itself. He is a London GP and father of an autistic son. His son had two years of analytic psychotherapy in an unnamed "centre of excellence", where the ghosts of Freud and Melanie Klein lingered. Not surprisingly, it was not helpful. This was the era in which Bruno Bettelheim coined the idea that the 'refrigerator mother' was responsible for autism, until parents got justifiably angry about being blamed for their child's condition. In this book Fitzpatrick has gently and systematically teased apart the folk wisdom about what causes autism and what, if anything, can be done about it.

Once upon a time, parents of handicapped children regarded themselves as having drawn the short straw of fate. Now, many want to feel that there is someone or something to blame. In Britain, many parents believed—thanks, mainly, to some now discredited work by Dr Andrew Wakefield—that the measles mumps and rubella vaccine (MMR), when given as a single shot, causes autism. In America, parent groups blamed the condition on the mercury-based preservative once used in the vaccine. Removal of the preservative has not reduced the incidence of autism, but knowing this has done little to calm some parents' fervour.

In this new book Dr Fitzpatrick gently but thoroughly examines—as befits a good doctor—the idea of toxic childhood, the idea that we live in an age of autism, the phenomenon of angry parents, and the ideas of toxic triple vaccine or mercury. There is also the issue of unorthodox biomedics, among them Paul Shattock, director of the Autism Research Unit at Sunderland university. He was a pharmacy lecturer, has an autistic son, and was impressed by some Scandinavian research that appeared to show a relationship between dietary wheat and milk products and various mental health problems including schizophrenia and autism. Bernard Rimland, who died in 2006, was a psychologist and founder of the Autism research Institute in San Diego, California, which he set up nine years after his son was diagnosed. He advocated the no-dairy, no-gluten diet and high doses of vitamins and minerals, "a retreat into the byways and cul-de-sacs of the biological psychiatry of the 1960s and 1970s".

This book is an essential exercise, though not one that will bring much comfort to parents. The people who will find this useful are GPs and their nurses. General practice nurses probably bear the brunt of dealing with fearful or angry anti-vaccination parents.

Lastly, to declare my interest—I once had a friend, the boyfriend of a chum, who died of measles. He was 33. It shouldn't have happened. We are a long way short of preventing or treating autism, but we can and should prevent people from dying of of ignorance.

*Caroline Richmond  
Medical Journalist*

# Body Shopping: the economy fuelled by flesh and blood

By Donna Dickenson

Published by Oneworld Publications, paperback edition available 240 pages out 1st April 2009, £9.99.

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**T**HE FIRST shock comes on page eight when we learn that, in law, we cannot own our own bodies or body parts. Once that bombshell has exploded, the stage is set for the issue which is the focus of Donna Dickenson's book. If we don't own our own organs, cells, genes, can anyone else? The answer, of course, is yes.

If human body parts can be owned, they can be sold, and as with many areas of health in which the stakes may be so high as to be almost beyond value (what price a baby?) the potential for exploitation exists. Human eggs, for example, are in demand for fertility treatments and, increasingly, for research. Donating eggs involves risky ovarian stimulation and extraction under anaesthetic. "Expenses" seem in order, but financial rewards attract vulnerable women who donate repeatedly at risk of their lives. And how can use of eggs for research be controlled? In Korea over 100 women, many of them research assistants, donated 2,000 eggs for a single piece of research. It was later shown to be fraudulent.

Welcome to an underworld in which a pair of stolen thigh bones can change hands (so to speak) for \$7,000. And, on the subject of hands, now an injured person can get a new hand, even a new face, how long before hands and faces are sold off-the-peg? Whose and for how much?

Then there is the extraordinary story of a US patient who was hoodwinked into signing over his excised diseased spleen, only to see it turned into a factory producing a cell line valued at \$3billion, in whose profits a Supreme Court then ruled that he was *not* entitled to share.

*Body Shopping* is not, however, simply a romp through the grotesque, though it is as compulsively readable. The depth of Donna Dickenson's analysis befits her status as a heavyweight academic—she is emeritus professor of medical ethics and humanities at the University of London. Her case histories are meticulously researched, and her discussion informed. This important book is as essential to lawyers and philosophers as it is to healthcare-givers (and reading it should be made a condition of entry to medical school). I do hope that, with its publication in paperback format, it will get the audience it deserves.

*Mandy Payne*

## Changing practice in light of evidence

**I**N RESPONSE to John Garrow's challenge in the October 2008 newsletter, I offer a brief account of my own salutary and frustrating experience of attempting to change my clinical practice in the light of evidence from clinical trials.

Throughout my career I had a major interest in radiotherapy of head and neck cancer. It has long been known that hypoxic cells are more resistant to killing by ionising radiation than are well-oxygenated cells, and that squamous carcinomas contain viable but hypoxic cells whose presence militates against cure by radiotherapy. From the 1950's onwards attempts were made to overcome the problem of hypoxic radioresistance. One approach was to irradiate patients in a hyperbaric chamber: a definite effect was seen, confirming that hypoxia really was contributing to radiotherapy failure, but the method proved too hazardous and cumbersome for routine use.

The next approach was to administer drugs that mimicked the radio-chemical action of oxygen, so-called "sensitizers". A number of compounds were tried, but mostly proved to be too toxic to be given in an effective dose. There was however one exception: nimorazole, a not particularly useful antibiotic, was demonstrated in experiments at St Thomas' Hospital to be a hypoxic-cell sensitizer, and potentially clinically superior to other agents tried because of its free diffusibility and relatively low toxicity<sup>1</sup>. A placebo-controlled trial of nimorazole with radiotherapy in advanced squamous carcinoma of the pharynx and supraglottis was opened in Denmark in 1986 ("DAHANCA 5"). This trial fulfilled all the strict criteria of a prospective randomised clinical trial. The final results were published in 1998, with a ten-year follow-up on all patients<sup>2</sup>. The result was strongly positive: compared with controls, the nimorazole group showed a significantly higher disease-free survival ( $p=0.002$ , a value very rarely seen in cancer trials). Importantly nimorazole did not enhance radiation effects on normal tissues. The only side-effect of the drug was nausea, which made some patients reluctant to take it.

To me, the results of DAHANCA5 were more convincing than those of the many trials of concomitant chemotherapy and radiotherapy conducted at the same time worldwide. The latter, although showing a benefit from chemotherapy, were mostly published prematurely with short follow-up, and either did not report normal tissue effects or showed an increased

morbidity. Nimorazole became an integral part of standard treatment in Denmark, but few radiation oncologists worldwide believed the Danish results, perhaps because other radiosensitising drugs had failed. I remained convinced, and I wished to use nimorazole in my own practice, but could not obtain it. It was not licensed in UK, and in those countries where it was licensed it was a relatively cheap antibiotic, so no pharmaceutical company was interested in supplying it. Eventually one did reluctantly agree to give me some for a small phase 2 trial. Meanwhile, a second trial from Denmark was reported, showing improved results from a mildly accelerated radiotherapy regime with nimorazole (DAHANCA7)<sup>3</sup>.

The DAHANCA 7 regimen gave results that were comparable to any of the many chemo-radiation regimens in use in head and neck cancer, but with lower morbidity, so I decided that it should be standard treatment for locally advanced squamous carcinoma of the head and neck in my own practice. It was only in my final year before retirement that I was able to implement this, by importing nimorazole from Germany and giving it on a "named patient" basis. No other oncologist outside Scandinavia did likewise, while the pharmaceutical industry continued to show what can only be described as active disinterest.

The current trend in head and neck cancer is investigation of the very expensive signal transduction inhibitors, viruses and gene therapy as adjuvants to chemoradiation, mostly commercially sponsored. Hypoxia, despite being a proven and potentially reversible cause of radiotherapy failure, is now largely neglected, and nimorazole forgotten.

I changed my practice in response to what appeared to me to be strong evidence, while ten thousand other oncologists and the pharmaceutical industry did not. Was I wrong?

MICHAEL HENK

Consultant clinical oncologist (retired)

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