



Registered Charity no. 1003392

# HealthWatch

for treatment that works

Newsletter 75 October 2009

## WHO CARES ABOUT THE DANGERS OF HOMEOPATHY?

*The recent decision by the World Health Organisation to advise against the use of homeopathy for serious diseases followed a campaign by young doctors and scientists who alerted the world to its tragic effects in developing countries. HealthWatch's president Nick Ross reports on this triumph of reason.*



**O**NE OF THE CRITICISMS of conventional, allopathic medicine is that it is dangerous. Indeed it is. It has been claimed that about 200,000 people die each year in the US as a result of preventable medical mistakes and infections which, if true, would be a higher toll than through road accidents<sup>1</sup>. Even more conservative estimates, of 44–88,000 deaths a year, puts healthcare risks on a par with bungee jumping and mountain climbing<sup>2</sup> (they all result in more than 1 death for every 1,000 encounters).

The UK figures are comparable, and three years ago the then chief medical officer, Sir Liam Donaldson, reckoned: “The evidence...from scheduled airlines is the risk of death is one in 10m. If you go into a hospital in the developed world, the risk of death from a medical error is one in 300.”<sup>3</sup>

These mishaps happen for many reasons, not least that patients often bring infections into hospitals and ill people tend to be especially vulnerable to hospital-acquired diseases, but there are also failings in diagnosis, prescription errors, unforeseen drug interactions and surgical mistakes. Clinicians are acutely aware of this and, particularly in the last decade, a great deal of emphasis has gone into improving systems to make things safer.

Alternative practitioners claim that what they do is less invasive and more “natural” and so carries fewer risks; and to some extent, at least in theory, they are right. It is the very potency of allopathic medicine that makes it dangerous while, conversely, it is the impotence of most complementary therapies that can make them relatively safe. But folk medicine is not just antiscientific, or at best

pseudoscientific, with rarely any better outcomes than placebo. It too can be positively dangerous. Ray Tallis, the geriatrician and health ethicist, points out that the Mbeki government’s “traditional” approach to AIDs in South Africa has led to over a third of a million unnecessary deaths. It is hard to compare numbers because, while proper healthcare systems have invested heavily in improving their audit of medical errors, the CAM community keeps few such records.

But some of the dangers are obvious, most notably misdiagnosis, which is far more likely with lay practitioners than with those who are medically qualified, and even more so at the hands of people who believe in pre-Enlightenment ideas about disease. Some of the treatments are also hazardous including many herbal remedies (some of which have had to be outlawed), spinal manipulation, and even misplaced acupuncture needles. One of the most common generic traditional treatments, bloodletting, certainly killed far more people than it cured before it fell out of grace. Then there is

*...continued on page 7*

## IAIN CHALMERS TO ADDRESS AGM

ON 29TH OCTOBER Nick Ross will present the eighteenth HealthWatch Award to Sir Iain Chalmers at the Annual General Meeting. Chalmers is editor of the James Lind Library, and was a founder of the Cochrane Collaboration. He will speak on: “The James Lind Library: explaining and illustrating the development of fair tests of treatments in health care”. The open meeting and AGM will be held as usual at The Medical Society of London, 11 Chandos

Street, Cavendish Square, London W1M 0EB (nearest Underground is Bond Street) starting with reception at 6.30pm. The meeting is free and open to all and will be followed by a buffet dinner with wine at 8.45pm, also open to all, at a cost of £35. Booking forms being sent to members should be returned by 17th October. Any late applicants for the dinner should contact membership secretary Kenneth Bodman on [Kenneth.bodman@btinternet.com](mailto:Kenneth.bodman@btinternet.com)

### Contents

<b>NEWS</b>	<i>WHO withdraws support for homeopathy; Iain Chalmers for AGM award; latest news in brief</i>	1, 2, 7
<b>REPORTING RESEARCH</b>	<i>New development in the Wilmshurst case, reported by John Garrow</i>	3
<b>INTERNATIONAL VIEW</b>	<i>Aussie sceptic Loretta Marron on consumer protection down under</i>	4, 5
<b>MEDIA</b>	<i>When reasoned debate gives way to libel suits and threats, science suffers, says Edzard Ernst</i>	6
<b>BOOK REVIEW</b>	<i>Gillian Robinson enjoys fifty new ideas from the world of genetics</i>	7
<b>LAST WORD</b>	<i>David Bender on the mysteries of swine flu; and some light relief on YouTube</i>	8

## news

# IS EUROPE'S CLINICAL RESEARCH BEING SUFFOCATED BY PAPERWORK?

**FIVE YEARS** ago a special edition of the *HealthWatch Newsletter* was devoted to the implications of the forthcoming European Clinical Trials Directive (ECTD). Now that the directive is in place and established, many academics are confirming that bureaucratic overload is stifling their ability to undertake clinical research, compromising research's very future, and ultimately doing patients a disservice. However there is disagreement as to whether the ECTD is entirely to blame.

In the August edition of *The Lancet Oncology*, freelance journalist Adrian Burton reported researchers complaining that UK interpretation of the ECTD has led to the requirement of a detailed protocol (which might reach 100 pages in length) and the answering of over 40 questions on a form spanning 28 pages<sup>1</sup>.

But not all agreed on the cause of the delays. The chief executive of the UK Medicines and Healthcare Products Regulatory Agency (MHRA) Ken Woods says that the UK did not 'add' to the ECTD in interpreting it; and adds that UK researchers already faced an increasing administrative burden due to the NHS research governance framework launched in 2001. The Director of the National Research Ethics Service, Janet Wisely, adds that the use of one form which can be sent to all appropriate regulatory bodies has streamlined research administration.

Burton concluded: "Clearly, approval authorities and researchers are only trying to do their jobs—some on a volunteer basis. But if clinical research is being delayed and there is a real danger of its future being compromised, then researchers, approval bodies, and policymakers need to foster better partnerships to develop more effective and efficient integrated solutions as soon as possible."

## A European view

Useful further reading on this subject is an editorial which was published last year in the *British Medical Journal* and which documents the negative effects the directive has had on research into cancer treatments in Europe. Finnish researchers Akseli Hemminki and Pirkko-Liisa Kellokumpu-Lehtinen echoed the views that some *HealthWatch Newsletter* contributors had expressed in 2004 that it is counter to the public interest if only commercial corporations

have the resources to plan and carry out clinical trials<sup>2</sup>. The development of unconventional approaches such as cancer vaccines and cell and gene therapy have come largely from academic clinicians, they write, but the directive has moved European research further into the hands of pharmaceutical companies who are better resourced to overcome the bureaucratic hurdles. They cited the results of an analysis by the European Organization for Research and Treatment of Cancer (EORTC), who found that in the first year of implementation of the ECTD the number of new trials fell from 19 in 2004 to seven in 2005 while trial costs increased by 85% and insurance costs doubled. The fact that the directives and rules for European clinical research are designed by the Enterprise and Industry Directorate General and not by branches responsible for health care or research may, they suggested, explain why rapid development of new strategies for severely ill patients seems to have received little priority.

For the *HealthWatch Newsletter's* original discussion on the wideranging possible effects of the directive, both positive and negative, read the text of HealthWatch's special European Clinical Trials Directive issue on [www.healthwatch-uk.org](http://www.healthwatch-uk.org) by clicking on Newsletter Archive and selecting Newsletter no. 53 April 2004.

Mandy Payne

## References

1. Burton A. Is paperwork suffocating British clinical research? *The Lancet Oncology* 2009; **10** (8): 749–50. doi:10.1016/S1470-2045(09)70212-8
2. Hemminki A, Kellokumpu-Lehtinen P. Harmful impact of EU clinical trials directive *British Medical Journal* 2006; **332**: 501–502 (4 March), doi:10.1136/bmj.332.7540.501

## NEWS IN BRIEF

THE LIBERAL DEMOCRATS voted overwhelmingly in favour of libel law reform at their party conference on Sunday 20th September. Sile Lane of Sense About Science, who are co-ordinating the "Keep Libel Laws Out Of Science" campaign, said, "This is a great step forward in recognising that the chilling, stultifying effect of the English libel laws—on scientific debates and other important public discussions—has become dangerous and intolerable." Dr Lane wrote recently in a *British Medical Journal* blog that the cost of defending a libel case in England is 140 times the European average. At the time of writing almost 17,000 people had signed the SAS petition in favour of reform.

[www.senseaboutscience.org.uk/index.php/site/project/403](http://www.senseaboutscience.org.uk/index.php/site/project/403)  
<http://blogs.bmj.com/bmj/2009/09/10/sile-lane-on-keeping-libel-laws-out-of-science/>

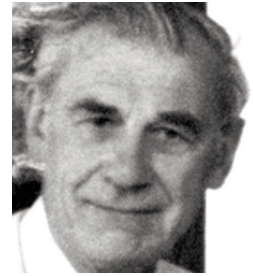
MEANWHILE the libel action that triggered the campaign, brought by the British Chiropractic Association against the science writer Simon Singh, continues. On 14th October Singh will make an oral application to ask the Court of Appeal to reconsider its July decision to deny him permission to appeal.

[www.senseaboutscience.org.uk/index.php/site/project/381](http://www.senseaboutscience.org.uk/index.php/site/project/381)

THE CLASH between science and the law is also the subject of HealthWatch committee member Les Rose's recent column for the online journal *Pharmafocus*. "For those of us in the business of bringing new medicines to market, we quietly shoulder steadily increasing regulations, while others who have no regard for evidence can carry on much as they always did. Meanwhile some of the lawyers seem to be doing quite well." Read the whole column online on [http://www.pharmafocus.com/cda/focusH/1%2C2109%2C22-0-0-0-focus\\_feature\\_detail-0-492913%2C00.html](http://www.pharmafocus.com/cda/focusH/1%2C2109%2C22-0-0-0-focus_feature_detail-0-492913%2C00.html)

HEALTHY SKEPTICISM is an international non-profit organisation made up of individuals concerned about the health effects of treatments marketed inappropriately. This can include unjustifiable claims in advertising, or drugs being promoted for uses for which they are not licensed, for example in the third world. Healthy Skepticism are planning an international conference in Amsterdam for October 2010 and would like to collect views from those who may have an interest in attending. To complete a brief survey please visit: <http://tinyurl.com/mda8zg>. For information about Healthy Skepticism see [www.healthyskepticism.org](http://www.healthyskepticism.org)

# TRUSTWORTHY TRIALS?



*John Garrow reports on the latest development in the case of whistle-blower cardiologist Peter Wilmshurst—an admission of errors and an expression of regret in the journal that published the original study. But, asks Garrow, does it go far enough?*

**H**EALTHWATCH PROMOTES the testing of treatments, whether “orthodox” or “alternative”, to see if the treatment really is effective. This year we’re presenting our annual award to Sir Iain Chalmers, who is world-famous for his tireless demonstration that many traditional treatments that have been justified by the collective experience of senior clinicians are mistaken. When they are subjected to “fair tests” (which often, but not always, means randomised controlled trials) it may show that they do more harm than good.

But a good trial design is not the only factor needed to produce trustworthy trials.

Another is that the data arising from the trial is honestly presented to the public. Clinical trials have conditions that researchers have no conflicts of interest which might cause them to apply a more favourable interpretation than the data really deserve. Medical journals have rules that require all authors to declare any conflicting interests, and to confirm that the research described in the manuscript truthfully matches the data generated by the study. Sadly, these ideals are sometimes not achieved, and the truth does not come out, because the people involved fear that blowing the whistle will seriously damage their career ambitions. We have just received notice of a new development in the history of a troubled clinical trial about which regular readers of the *HealthWatch Newsletter* will already know quite a lot.

Dr Peter Wilmshurst was given the 2003 HealthWatch Award “for his courage in challenging misconduct in academic medical research.” His career has been damaged by his whistle-blowing, but he continues to complain publicly when he meets dishonesty in clinical trials. For many months he has been facing a libel action by NMT Medical, a firm based in Boston, USA, which was testing the ability of a device called the STARFlex implant to close a patent foramen ovale (a heart valve which normally closes shortly after birth but in a small number of people remains open into adulthood), and thus reduce or eliminate migraine attacks believed to be associated with the disorder. The trial failed in this primary objective, and Wilmshurst (who was a principal investigator in this trial) was asked by a reporter for the online website <http://theheart.org> why it had failed. He suggested possible explanations—it may be that in some patients the device was misplaced, or that the patient had been wrongly diagnosed before the operation. NMT brought the legal action claiming that Wilmshurst’s criticisms were untrue and motivated by malice. Wilmshurst refused to withdraw them. He maintained that they were true, and that the published version of the trial had suppressed proper reporting of serious side effects in some patients. He was subjected to a barrage of criticism himself. If the libel case came to court, and was won by NMT, he would be bankrupt, since the legal costs already greatly exceed his total estate.

The situation has been dramatically changed by the publication this September of an article<sup>1</sup> in *Circulation*, the journal that had carried the original study report. It is a long “Correction” about “a number of errors and omissions” in the original article. On the face of it this document seems to undermine the basis of the libel claim that Wilmshurst’s criticisms were untrue and malicious, since the authors are admitting that many (but not all) of his criticisms are confirmed to be true. This is not the place to discuss the details of the errors admitted in the “correction”, but a more detailed and accessible account is given by Mark Pownall in the *British Medical Journal*<sup>2</sup>.

Until the legal situation is clarified it is hazardous to express opinions about the causes of these “errors”, but it is evident that

something went seriously wrong in the publication of this randomised controlled trial. Who is to blame for that? Is it the sponsor of the trial (NMT), or the authors of the manuscript, or the editors of the journal? Or perhaps all of them to varying degrees?

In my opinion it is unacceptable that NMT should react to Wilmshurst with a libel action brought on criticisms. In these circumstances most researchers would be crushed by such threats and keep quiet. But that is not how Wilmshurst responds.

The authors, in the final sentence of the “correction” write, “The authors regret the errors ...” and so they should, because they had signed off that the all the data are true, and some are not.

---

## “The editors had plenty of warning that things were not normal”

---

However, I think the greatest blame should fall on the editorial staff of *Circulation*, and the American Heart Association who own it. They had plenty of warning that things were not normal. Four versions of the paper were sent for publication, with changes in the authors, and one of the principal investigators was deleted. An editor would need an explanation of these events before considering the manuscript for publication. It is still not clear whether anyone had vested interests in the device being tested before and during the trial. It is almost unprecedented that a journal should have to publish such an extensive “correction” a year after the original version. The lead author, now removed from the listed authors, still claims that the corrections do not go far enough. But the crowning offence to good scientific journalism is that the editors and the AHA now announce that they “consider the matter closed”.

Who are they kidding? The general rule is, “The editor’s opinion is final”. But this does not apply when editorial probity is questioned. I am not qualified to judge the technical aspects of this trial, because I am not an investigative cardiologist, but I was for eleven years editor-in-chief of a clinical research journal. If an editor receives a complaint that something in his journal is seriously misleading he should immediately and openly investigate the grounds for the complaint. The matter can be considered closed when the whistle-blower—not the editor—is satisfied.

*John Garrow  
Emeritus Professor of Human Nutrition  
University of London*

### References

1. *Circulation* 2009; 120: e71-2, doi:10.1161/CIRCULATIONAHA.109.192626
2. Pownall M. *Circulation* prints correction to clinical trial at centre of libel action. *BMJ* 2009; 339: b3659, doi: 10.1136/bmj.b3659 (Published 8 September 2009).

## international view

# REGULATING TREATMENTS “DOWN UNDER”

Loretta Marron is a retired scientist in Australia. Diagnosed with breast cancer in 2003, she was appalled at misinformation on the Internet and the heartless exploitation of cancer patients in her own country by purveyors of unproven and sometimes dangerous treatments. She is known in Australia for her entertaining and sometimes hard-hitting media exposés of unscientific treatments and she was named Australia's Sceptic of the Year in 2007. Here she writes about attempts to regulate complementary medicine in a country which has much in common with the UK.



**N**EARLY TWO THIRDS of Australians regularly use complementary medicines (CM). Sold as pads, pills, sprays and lotions, they are in pharmacies, supermarkets, health food stores and alternative health clinics. Marketed as “natural products” they are meant to combat a wide range of real and imaginary health conditions with claims such as reducing stress, improving libido and boosting that mythical and seemingly chronic condition of severely depleted “well-being”. While the majority of pill poppers are women, there are products for men, children and pets. Now a two billion dollar industry, Australians are demanding better consumer protection and it seems that they are making progress.

The dark cloud of the 2003 PAN Pharmaceutical fiasco had a silver lining for improving CAM “down under”. Eighty-seven people suffered adverse reactions and 19 were admitted to hospital after taking Travacalm, PAN's over-the-counter travel sickness medication. An investigation identified substandard manufacturing processes (including ingredient substitution, excessive amounts of some ingredients in products and manipulation of test data)<sup>1</sup>. The Therapeutic Goods Administration (TGA) suspended PAN's licence<sup>2</sup> and ordered what may be the world's biggest medicines recall.

The storm that followed saw both consumers and health professionals raising issues about lack of confidence in product efficacy, poor standards of practitioner training and inadequate consumer information. Pressures on the Government soon led to the establishment of the 2003 Expert Committee on Complementary Medicines and six years on we are starting to enjoy some of the benefits of its recommendations. But there is still work to be done.

The TGA—which has parallels with the UK's Medicines and Healthcare Regulatory Authority (MHRA)—is the regulatory body responsible for “the supply of safe, high quality and efficacious complementary medicine”. With the exception of some extremely dilute homeopathic remedies, all CM's marketed must have an approval listing (Aust L). This can be obtained in a few days using the TGA's vending machine type on-line computer-based electronic listing facility (ELF)<sup>3</sup> which merely checks that the ingredients correspond to TGA's approved list of those regarded as “relatively safe” and that the appropriate fee has been paid. While every product listed requires the sponsor hold “evidence” to support the claims made, that can be either traditional or scientific and this information is rarely checked by the TGA. More recently, in response to pressure for greater transparency, a public summary<sup>4</sup> of both sponsor and product detail is available from the TGA's website.

The end result is that consumers can pay \$1,000 per kilo for pills containing garden weeds for therapeutic benefits based on unsubstantiated third-world traditions. Even when science is referred to, it may involve research on “two rats and a guinea pig”<sup>5</sup>, could be written in Chinese and does not have to be peer reviewed. Only one in five newly listed CM's are checked through a random audit and with, “assists in well-being” and, “may assist in [indication]” as acceptable claims, with a growing number of consumers eager to try new products it has become a free-for-all.

There are more than 16,000 CM's in the TGA's database. Although over 3,000 are now considered ineffective by reputable clinical trials, requests to delist these products are ignored<sup>6</sup> and consumers, seeing the Aust-L's on labels, continue to assume they work. Like the UK's MHRA, the TGA is funded by the industry it is meant to be regulating, so getting them to clean up these placebo products remains a challenge.

Self-regulation means that the responsibility rests with the stakeholders whose income would be reduced if their CM's were delisted, so there is little incentive for the TGA to change anything that

would compromise their funding. The TGA guidelines for obtaining Aust-L's states that, “should scientific evidence be contrary to the evidence based on traditional use, the claim used must reflect the truth, on the balance of the evidence available”<sup>7</sup> but those words fall on deaf ears.

New guidelines for both homeopathic and herbal weight loss remedies have recently been rewritten supposedly to address the concerns of the 2003 Expert Committee on the lack of efficacy in these now disproven products. However, they were written in consultation with the stakeholders and sadly, despite their inviting public comment, and receiving many demands that the products conform to the standards of evidence-based medicine, the *status quo* of a growing number of scientifically challenged remedies continues. Ask the TGA for “evidence” and you will be met with terms such as “commercial-in-confidence”, high “freedom of information” fees or dismissive pre-rehearsed statements.

Media advertisements for CMs are approved by the Complementary Healthcare Council (CHC). While they claim to “advocate appropriate government” and to provide “safety, quality and efficacy standards necessary to ensure consumer confidence”, when asked to comment on Aust-L products that don't work their CEO, rather than supporting the removal of them, was only concerned that it would mean that “thousands of complementary products would be removed from the shelves”<sup>8</sup>.

### **“Research may have been on ‘two rats and a guinea pig’, could be written in Chinese and does not have to be peer reviewed”**

But there are a few rays of sunshine bringing light in this ‘age of endarkenment’.

An independent Complementary Medicines Evaluation Committee (CMEC)<sup>9</sup> was established in 1997 to provide scientific and policy advice relating to controls on the supply and use of complementary medicines. They assess the safety of new ingredients and investigate safety concerns of old ones, such as hepatotoxicity associated with Black Cohosh<sup>10</sup>. The CMEC has an “expert advisory panel” which includes health practitioners trained in medicine, pharmacy, science, acupuncture, aromatherapy, homeopathy and naturopathy. Regrettably, they are not tasked to assess product efficacy. However, the fact that Australia classifies these products as medicines and regulates the ingredients they contain does provide a basic level of consumer protection.

There are three tiers of controls on the advertising of therapeutic goods to consumers. At the top is the TGA with overall responsibility, then a co-regulatory level (a partnership between government and stakeholders, including consumers, industry, advertising agencies and healthcare professionals), which includes the Complaints Resolution Panel (CRP), established in the legislation to deal with advertising in the main forms of direct-to-consumer media (TV, radio, internet, newspapers, magazines, outdoor displays, together

commonly known as 'above-the-line' media) and, lastly, a self-regulatory level for all advertising directed to healthcare professionals and advertisements directed to consumers in other forms of media such as leaflets, brochures, shelf wobblers ('below-the-line' media). It is illegal to advertise prescription medicines to consumers in Australia.

The CRP is the only complaints committee for the co-regulatory level. Anyone can submit a complaint to the CRP—helped by a consumer-friendly online central complaints mail box<sup>11</sup>—and, provided the panel finds that the complaint is justified, they can request that across-the-board advertising and/or representations be withdrawn and/or a retraction or correction published.

Over the past ten years the number of complaints processed by the CRP has increased from four per month in 1999 to over thirty received per month in the first half of 2009 with the majority of all complaints submitted being upheld as breaches of the Regulations, Advertising Code or the Therapeutic Goods Act.

If the advertisement appears to contain claims about serious diseases, conditions or disorders to the extent that there may be a threat to public health and safety, or if there is any failure to comply fully with its determination, the CRP may decide to pass the complaint onto the TGA for immediate or for further investigation or for an order to comply.

At the third tier, the self-regulatory level, complaints are dealt with by the industry associations' own complaints mechanisms. The industry codes include the Therapeutic Goods Advertising Code (TGAC) among others, and the industry organizations whose responsibility it is to uphold them include the Australian Self-Medication Industry association, the Complementary Healthcare Council (CHC), the Medical Technology Association of Australia and, for prescription medicines, Medicines Australia. Most of them report on their complaints handling in their publicly available annual reports, and where there is a failure to comply the matter is referred to the TGA.

There are growing calls for reform of CM regulation including strengthening the advertising complaint system<sup>12</sup>.

The Government funded National Prescribing Service (NPS)<sup>13</sup> is charged to ensure the quality use of all medicine. The NPS is a non-profit, independent organization which funds the Adverse Medicines Events line (AME)<sup>14</sup>, a free service available during business hours and manned by pharmacists to provide consumers with 'a mechanism to report adverse experiences with medicines' and who also offer free advice about all medicines, including CM, to Australians. In 2008 the NPS conducted research to identify and resolve issues relating to the use of CM's and in March

this year they announced<sup>15</sup> that they had identified the "highest quality resources" on CM which could be referred to "with confidence". They anticipate that within 12 months both consumers and health professionals will have free access to reliable and accurate CM information.

On April 18th 2009 the CHC announced that they are currently working on advertising reform<sup>16</sup> to improve consumer protection. They claim these reforms will benefit consumers but they will undoubtedly be more about promoting the industry and justifying their own existence.

While the CM industry stays self-regulated, product efficacy will remain unimportant, so expensive placebos will increasingly keep flooding the marketplace. Fortunately, the complaints system has seen the CRP removing many questionable advertisements and the AME line is there to provide CM information. Also, once the NPS recommended websites become available, Australians will be able to do their own CM research with confidence, so at long last, we will really be able make informed choices.

Loretta Marron

#### References

1. <http://www.tga.gov.au/media/2003/030824pan.htm>
2. <http://www.tga.gov.au/cm/cm.htm>
3. <http://www.tga.gov.au/online/elf.htm>
4. <https://www.ebs.tga.gov.au/ebs/ANZTPAR/PublicWeb.nsf/cuMedicines?OpenView>
5. <http://www.theaustralian.news.com.au/story/0,25197,23035005-23289,00.html>
6. <http://www.australiandoctor.com.au/news/8f/0c046a8f.asp>
7. <http://www.tga.gov.au/docs/pdf/tgaccevi.pdf>
8. <http://www.australiandoctor.com.au/news/24/0c053824.asp>
9. <http://www.tga.gov.au/DOCS/HTML/cmec/cmec.htm>
10. Black Cohosh and liver toxicity—an update [www.tga.health.gov.au/adr/aadrb/aadr0706.pdf](http://www.tga.health.gov.au/adr/aadrb/aadr0706.pdf)
11. [www.tgacrp.com.au](http://www.tgacrp.com.au)
12. Harvey K. A review of proposals to reform the regulation of complementary medicines. *Aust Health Rev* 2009; **33**(2); 279–285.
13. <http://www.nps.org.au/>
14. Adverse Medicines Events line <http://www.mater.org.au/ame/>
15. [http://www.nps.org.au/news\\_and\\_media\\_home/media\\_releases/repository/Highest\\_quality\\_complementary\\_medicines\\_resources\\_identified](http://www.nps.org.au/news_and_media_home/media_releases/repository/Highest_quality_complementary_medicines_resources_identified)
16. CHC Proactively Formulating Advertising Policy to Best Serve Industry <http://www.chc.org.au/view/document.shtml?b02084-igbzvqt>

## UK and Australia: issues shared, lessons to learn

LES ROSE, HealthWatch committee member, sees some close parallels between regulation of complementary and alternative medicine (CAM) in Australia and the UK. "For example, traditional use is accepted in both countries as 'evidence' in order to obtain a product licence, but the very term seems self-defeating. Millions of people read their horoscopes daily, without the slightest evidence that astrology can predict anything. It is a strong tradition, and I hope that the regulatory authorities don't consider that in this case it signifies validity. Yet they are prepared to accept tradition to validate a therapeutic claim for CAM."

The regulatory bodies in both countries are also beset with conflict of interest—they are funded by the industries they are meant to be regulating. "Thus it was hardly surprising that in 2006 the UK's MHRA oversaw the introduction of new legislation allowing therapeutic claims for homeopathic products, while admitting that in part the reason was to allow the homeopathic industry to expand."

Rose suggests that one area where we might learn from Australia

is advertising. "At present, this is regulated in the UK by the Advertising Standards Authority on a voluntary basis. Sanctions available are limited largely to adverse publicity and pressure on the media to refuse advertising from guilty suppliers. There is no formal linkage between the ASA and any other public agency. Also, repeat offenders suffer even less adverse publicity, as the ASA refuses to publish the outcomes from such cases, which bypass the normal adjudication and go straight to its Compliance Team. I have never been able to find out exactly what the Compliance Team does.

"But Australians have achieved a degree of success by ramping up the number of complaints. We in the UK are far too tolerant of suppliers who lie to the public."

A question remains. "Why does CAM need all this special treatment? Governments could simply apply common standards to the registration of all products making therapeutic claims, whatever they call themselves. If it works, it's real medicine, if it doesn't, it's not. Or is it a case of bread and circuses?"

## opinion

# FIVE DIFFERENCES BETWEEN THE BCA AND THE BMA



**A**LL HEALTHCARE professionals have or should have institutions which protect their interests. For doctors, this is the BMA; for chiropractors, the largest such organisation in the UK is the BCA. Recent events made me wonder to what degree the two might be similar and how they differ.

The BMA state on their website that they “look after the professional and personal needs of [their] members. The BMA represents doctors in all branches of medicine in the UK” ([www.bma.org.uk/about\\_bma/index.jsp](http://www.bma.org.uk/about_bma/index.jsp)). The BCA state on their website that their aim is “to promote, encourage and maintain high standards of conduct, practice education and training within the professional in the UK. The BCA also supports and encourages the development of chiropractic research projects, supporting the progression of the profession in the UK and worldwide” ([www.chiropractic-uk.co.uk/default.aspx?m=8&mi=14](http://www.chiropractic-uk.co.uk/default.aspx?m=8&mi=14)).

So, both organisations represent and protect their members. But, I think, there are also important differences. Here are just some which occurred to me when the BCA decided to sue for libel my co-author Simon Singh (Trick or Treatment?: Alternative Medicine on Trial. Bantam Press, London, 2008.) after he questioned whether some of the claims the BCA made on their website were evidence-based ([http://www.bmj.com/cgi/content/full/338/jun03\\_1/b2254](http://www.bmj.com/cgi/content/full/338/jun03_1/b2254)).

1. The BCA makes (perhaps “made” is the better word, because the claims in question have been taken off their website after being challenged by Simon Singh) promotional statements about the effectiveness of chiropractic. I am not aware that the BMA states anywhere “we can effectively treat asthma and otitis” or anything remotely similar.
2. The BMA promotes evidence-based medicine through a large raft of activities. Does the BCA do that too? If you think that chiropractic effectively treats asthma and otitis you may agree—if not,

you might disagree.

3. The BCA has decided to sue a science writer for publishing words which they feel are libellous. I am not aware that the BMA has ever sued any such individual for a similar “offence”.
4. The BMA promotes open discussion of all healthcare issues. When there are differences of opinion (which, of course, happens regularly), they tend to put the evidence on the table and discuss it until, hopefully, some sort of solution emerges. All this would normally happen without undue delay. The BCA has been asked to provide the evidence that might back up their assertions. For over a year they did not do so. Recently, with pressure mounting, they did provide it. Sadly it is less than convincing ([http://www.bmj.com/cgi/content/extract/339/jul08\\_4/b2782](http://www.bmj.com/cgi/content/extract/339/jul08_4/b2782)).
5. To the best of my knowledge, the BMA does not run *ad hominem* attacks on people who happen to disagree with them. The vice president of the BCA has attacked me personally for just that (<http://www.pulsetoday.co.uk/story.asp?sectioncode=20&storycode=4123015&c=1>).

These differences, I think, are quite clear. Less clear is what we make of them and what they tell us about the professionalism of the BCA. I would like to write about this too—but, considering the present climate, I think the libel lawyers will have to wait.

Edzard Ernst

*School of Complementary Medicine, Peninsula Medical School  
Universities of Exeter & Plymouth*

## Who is this “anti-CAM brigade” anyway?

I CAME ACROSS this term only recently<sup>1</sup>. At first, I thought it was quite funny, particularly as its author evidently tried to characterise me as a member of this elite troop! On reflection, however, I find it not helpful.

As I have repeatedly tried to point out, I am neither pro nor anti-CAM—I am simply hoping to establish the facts. Once this job is done, I think it’s my duty to be as open as possible about the results. This is how science works, and I don’t see why the study of CAM should be an exception.

But CAM research is in its infancy. Consequently it lacks confidence, maturity, expertise and professionalism. Many CAM researchers seem to think that science is a tool for proving their hypotheses to be correct. The fact that it is a tool for testing whether they are correct has not yet sunk in, I fear. Therefore CAM researchers tend to be in favour of openness—but only as long as this openness does not get in the way of promoting their pet therapy.

The lack of maturity of CAM research is nicely depicted by calling people like me, the “anti-CAM brigade”. The word implies that there is some sort of battle going on. I find this notion most regrettable; finding the truth should not be a war!

The term “anti-CAM brigade” tries to classify those who are capable of critical analysis as somewhat demented outsiders who should not be listened to. The implication is

that the “anti-CAM brigade” is against CAM in general and whatever the evidence shows; that they are dogmatic and therefore their arguments are not worthy of consideration.

The danger is that those who publish such nonsense might eventually be taken seriously. This would stifle necessary debate and the facts would thus take longer to establish. In the end, I’m sure, it would be even CAM itself that suffers.

We should conduct CAM research unemotionally and discuss the results openly so that the truth can be established. It would certainly not show that all of CAM is perfect. Neither would it demonstrate that it is all rubbish (<http://ecam.oxfordjournals.org/cgi/content/abstract/nep044v1>).

Those treatments that are valuable could be used; those that are not would be abandoned. All this could eventually result in improvement of healthcare. But, I fear, that this approach requires a maturity and professionalism which currently are not a predominant feature of CAM.

Edzard Ernst

### Reference

1. Lewith G. Alternative medicine. *New Scientist*, 5 June 2009—online comment [www.newscientist.com/article/mg20227110.200-alternative-medicine.html](http://www.newscientist.com/article/mg20227110.200-alternative-medicine.html), accessed 2009.

# LATEST IDEAS ON GENES MADE EASY

## 50 Genetic Ideas you really need to know by Mark Henderson

Published 2009 by Quercus, London, UK. Hardback, 208 pages, £9.99  
ISBN-10:184 724 6710 ISBN-13:978-184 724 6714

**T**HIS IS the sixth in a series of books entitled "50 ... ideas"; other subjects include Psychology, Physics, Philosophy, Mathematical and Management. They provide an introduction to the subject so will appeal to the interested layman rather than the expert.

This book contains 50 chapters or essays each four pages in length. Areas covered include classical genetics, molecular biology, the genome, behaviour and technologies. Within these broad areas the essays discuss topics ranging from the theory of evolution to epigenetics (the study of heritable changes in gene function that occur without change to the DNA sequence) and artificial life.

The author Mark Henderson is the Science editor of *The Times* newspaper. Regular readers of that paper will be familiar with his style which is clear, concise and informative. He is able to convey difficult ideas and concepts to readers with limited knowledge of the subject under review.

The essays are well displayed with a timeline at the bottom of the page noting the dates of remarkable discoveries or developments. The pages also contain inserts which are brief paragraphs on a topic relevant to the chapter. For example, in the essay on genetic genealogy there is a short piece on crusaders and Muslims which explains the origin of the Western European Y chromosome found in Christian men in

Lebanon, concluding that it was probably carried to the region by the Crusaders. I found these inserts entertaining and interesting, and they helped my understanding of the topic under discussion.

I am not an expert so cannot comment on the accuracy of the information; however I was surprised by the remark in the Sex Genes chapter which stated that Alzheimer's Disease is the only major disease which commonly affects both sexes for which women have the higher risk. This is not the case. Women have a higher incidence of auto immune disease and depression to name just two.

I must not end on a negative note. I enjoyed the book; it was challenging in places and for a novice like myself would probably be better used as a reference or dipped into rather than read continuously. It is also remarkably good value at £9.99 for a hardback copy.

Gillian Robinson  
Associate Specialist in Sexual and Reproductive Health  
St Giles Hospital in London

## WHO cares about the dangers of homeopathy? by Nick Ross

...continued from front page

the danger of downright crooks and charlatans who flourish amid the desperation of illness. (A friend of mine died from cancer having spent a great part of his family's savings on quack remedies.) But perhaps the greatest menace comes from the well-intended alternative practitioners. The danger is belief itself.

I, like many other HealthWatch supporters, became involved in this issue when I met women who had been offered "alternative" treatments for cancer and had missed out on therapies that would probably have saved their lives and certainly could have prevented appalling suffering. In rural African and China I learned how primitive faith in traditional medicine effectively results in many diseases not being treated at all, with resulting disfigurement and miscarriages. But perhaps the most striking example of how "natural" and "safe" treatments can do harm is that of the most "natural" and, ostensibly, the safest therapy of all. Homeopathy.

Homeopathy is simply water, adulterated only by a drop of credulity. How can that do harm? But the Voice of Young Science network realised it could, and did. The young medics (among them biochemist Evelyn Harvey who wrote for the last issue of the *HealthWatch Newsletter*<sup>4</sup>) cited examples of homeopathy being used as a preventative or as a therapy for a whole range of life-threatening conditions including HIV, TB, malaria, influenza and infant diarrhoea. And they have just won an important victory.

For many years the World Health Organisation appeared to equivocate about the use of complementary medicines, and was sometimes cited by folk therapists as a justification for their practices. The WHO is a highly political organisation, subject to all sorts of governmental pressures and trying to juggle competing views of the world with the scientific realities of medicine and disease. It was easy to prevaricate in the hope of pleasing everyone. But in June the Voice of Young Science wrote to the WHO<sup>5</sup> and asked them to come

off the fence. Specifically they asked the organisation to make it clear that people with conditions like HIV, TB and malaria should not rely on homeopathic treatments<sup>5</sup>. A few weeks later the WHO finally agreed<sup>6</sup>.

So it's now official. Homeopathy can kill, has probably killed thousands, and maybe tens of thousands round the planet. Now perhaps we should reflect on how astonishing it is that an ostensibly rational world could have thought anything different.

Nick Ross  
Journalist and broadcaster

### References

1. Harmon K. Deaths from avoidable medical error more than double in past decade, investigation shows. *Scientific American* 10 August 2009. View on <http://www.scientificamerican.com/blog/60-second-science/post.cfm?id=deaths-from-avoidable-medical-error-2009-08-10>
2. Richard Smith, Reducing medical error and increasing patient safety. Presentation can be viewed on <http://resources.bmj.com/files/talks/medicalerror.ppt>
3. Sir Liam Donaldson, quoted in Hall S. Medical error death risk 1 in 300. *The Guardian* 7 November 2006. View on <http://www.guardian.co.uk/society/2006/nov/07/health.lifeandhealth>
4. Harvey E. Homeopathy and the developing world: dangers and lessons. *HealthWatch Newsletter* Jul 2009; 74: 1.
5. For details of the letter see <http://www.senseaboutscience.org.uk/index.php/site/project/331/>
6. For details of the response see <http://www.senseaboutscience.org.uk/index.php/site/project/392/>

## last word

# SWINE 'FLU: WHAT WE WILL NEVER KNOW

**F**OR PERFECTLY sound operational reasons in July the NHS announced that people with swine 'flu (influenza H1N1) need not visit their GP to obtain a prescription for anti-viral medication, but could telephone the National Pandemic Flu Service on 0800 1513 100 or go online at <http://www.direct.gov.uk/pandemicflu>

This was obviously sensible to avoid GPs being overwhelmed with 'flu victims, and indeed also to prevent people with swine 'flu from going out and spreading the infection further. All you had to do was telephone or go online and describe your symptoms, and you would be given a code number to send a friend or relation to collect your antiviral medication for you.

Newspapers printed check-lists of symptoms<sup>1</sup>, so if I wanted a week off work all I had to do was memorise the list and fill in the check-list online. Cynics suggested that there would be a considerable increase in cases of swine 'flu in Birmingham in July and Leeds in August to coincide with the test matches at Edgbaston and Headingley. On August 10th *The Independent* reported that "Tens of thousands of people were faking swine 'flu symptoms to stock up on Tamiflu" in case they needed it later—or perhaps to sell it<sup>2</sup>.

All this raises a serious problem. How do we know how many people have contracted swine 'flu? Apart for the small number who are hospitalised and/or die, and have blood samples analysed to determine whether or not they are infected with H1N1, we have no information that is even remotely reliable. We know how many people have requested prescriptions, we know how many people have been signed off work for a week with a (self) diagnosis of swine 'flu, but we do not know, and never will know, how many



*David A Bender  
Professor of Nutritional Biochemistry  
University College London*

people were infected.

In an ideal world we might invest a considerable sum of money to screen the population for H1N1 antibodies in order to determine how widespread it really was. However, we have no baseline data from before the outbreak, and it seems likely that many middle-aged and elderly people will have had antibodies before the current outbreak, because unlike seasonal 'flu, older people are less likely to contract swine 'flu, or less likely to have severe symptoms. (Or, are middle-aged and elderly people less likely to want a week off work?).

### References

1. <http://www.guardian.co.uk/lifeandstyle/besttreatments/2009/jul/30/swine-flu-the-definitive-guide>
2. <http://www.independent.co.uk/life-style/health-and-families/health-news/tens-of-thousands-fake-swine-flu-symptoms-to-stock-up-on-tamiflu-1769941.html>

## There's something funny going on

THREE DIFFERENT HealthWatch members have already sent the editor the link to the YouTube clip of the hilarious homeopathic A&E department sketch from *That Mitchell and Web Look*. If you haven't yet had a chuckle at this you can see it on:

[www.youtube.com/watch?v=HMGibOGu8q0](http://www.youtube.com/watch?v=HMGibOGu8q0). In the next issue we'll review some others. If you find any clips that fellow members will find interesting or entertaining please e-mail the details to [newsletter@healthwatch-uk.org](mailto:newsletter@healthwatch-uk.org) to include in the review.

### Published by HealthWatch

Press enquiries to Professor John Garrow: 01923 710665  
[www.healthwatch-uk.org](http://www.healthwatch-uk.org)

President: Nick Ross

Chairman: James May  
Vice-Chairman: Keith Isaacson  
Secretary: Gillian Robinson  
Treasurer: Anne Raikes  
Newsletter Editor: Mandy Payne

Committee: David Bender, Susan Bewley, Walli Bounds, Diana Brahams, Malcolm Brahams, John Garrow, John Illman, Caroline Richmond and Les Rose. Alison Myers, Ashley Simpson and Joanna Smeeton are Student Representatives.

Opinions expressed in letters and articles published in the HealthWatch Newsletter belong to the authors and do not necessarily reflect the views of HealthWatch. The editor reserves the right to amend text if necessary but will, where possible, consult the author to ensure accuracy is maintained. Letters and articles for publication are welcomed and should be addressed to:

**The Editor, HealthWatch Newsletter, 8 Eagle Close, Amersham, Bucks HP6 6TD**

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

HealthWatch promotes:

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

HealthWatch welcomes membership enquiries from those who share its aims. Membership costs £30.00 per year, including hard copy newsletter sent by post (£40.00 for members outside Europe); or £25.00 for members anywhere in the world who agree to receive the newsletter by e-mail only. Student membership, which includes the newsletter by e-mail only, is free. Questions about membership should be sent to membership secretary Kenneth Bodman, at [kenneth.bodman@btinternet.com](mailto:kenneth.bodman@btinternet.com)

Extra newsletter copies are available at £5.00 each.



Registered Charity no. 1003392

**Patrons:**  
**The Baroness Greenfield OBE**  
**Professor Tom Kirkwood**  
**Lord Walton of Detchant**  
**Lord Dick Taverne QC**