# HEALTHWATCH NEWSLETTER HIGHLIGHTS
# Issue 98, Summer 2015

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## NEWS FEATURE

# Who's in charge of this runaway train?

Following sustained pressure from HealthWatch and others, information for prospective patients taking part in the ill-conceived Age Extension Trial of Breast Cancer Screening has at long last been updated on Cancer Research UK's website. But our concerns over the many ethical issues raised by the trial are still not being acknowledged by those who should oversee ethics in UK clinical trials, and we have gone public yet again in the British Medical Journal1 to protest that there is still no assurance of informed consent in this screening trial which is the largest human experiment ever undertaken.

First, some good news: Cancer Research UK are now describing the trial more openly.2 It is now clearly stated on their website that the policy on screening the extended age ranges will depend on the outcome of this trial, although that won't be known until 2022.
But the issue of screening for breast cancer remains deeply controversial. An example is a recent WHO summary which concluded in favour of screening for women aged 50-743 but has drawn criticism over its handling of the evidence and the way its experts have been selected. The WHO report, which was summarised in June in the New England Journal of Medicine,3 will be published in full at the end of 2015. However, a WHO panel member has told the BMJ4 that his colleagues did not adequately take into account bias or confounding factors. Cochrane author Karsten Juhl Jørgensen questioned the panel's impartiality: "they look at a selection of research and find that their own is the most reliable", while HealthWatch's Susan Bewley told the BMJ, "This is bad science and lazy communication about it. This

report has no new evidence, is methodologically unsound, and can safely be consigned to the bin."4 Professor Bewley took the opportunity of the news coverage of mammography to highlight once more the lack of proper informed consent in the NHS Age Extension Trial of Breast Cancer Screening. In a 15th June rapid response in the BMJ, she wrote "We believe women are put in harm's way as they continue to be deceived about the nature of breast screening, especially whilst staff are not trained nor obliged to discuss and obtain formal, written consent for this unscientific and unethical randomised clinical trial."1 A response on 4th July from retired doctor JK Anand was headed: "We are Public Health England. Informed consent be blowed".

The least welcome news is that our concerns about the Age Extension Trial of Breast Cancer Screening have been dismissed by the National Research Ethics Advisors' Panel (NREAP), the body charged with oversight of decisions of the research ethics committee (REC). They have allowed the study to proceed unconditionally.

Believing that our earlier concerns to the REC had not been taken seriously, we appealed to the Health Research Authority (HRA) in December 2014, itemising 20 valid and carefully evidenced points to be addressed by the REC. The HRA's response, received on 20th March after much prompting, is now publicly available on our website5 and raises more questions than it answers.

Details about ethical shortcomings are dismissed. For example, it is a mandatory requirement of Good Clinical Practice (GCP) that REC members present at a relevant meeting must be documented in the Trial Master File. Yet names are redacted, so there is no way of knowing whether, for example, a competent statistician was present. Referring to the absurdly brief 8-page protocol we are told, "The panel further noted that the length of a protocol is not related to its quality." There is doubt as to whether the matter of proper informed consent was ever fully discussed by the REC, and there is the REC's puzzling insistence on calling this an epidemiological study. It is not, it is a randomised controlled trial.

Two points stand out:

- The REC assert, "The researchers have always been in a position of equipoise—hence the reason for the trial." Yet the original trial summary (at http://www.isrctn.com/ISRCTN33292440) reads: "The age extension will proceed regardless of whether this study goes ahead or not, and therefore regardless of whether the phasing-in is randomised or not."
- GCP compliance is not the concern of the REC. So whose is it? For a trial of a drug or a device, it would be the MHRA. Who inspects publicly funded trials? Will there be an audit?

The NREAP has made it clear that this is the end of the road, hence we have not replied, and have been mulling over the implications. HealthWatch is eager to learn what you think. Let us know at newsletter@healthwatch-uk.org

Mandy Payne

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5. Age extension trial of mammography screening—update June 2015 http://www.healthwatch-uk.org/news/83-age-extension-trial-of-mammography-screening-update-june-2015.html

## NEWS

# French whistleblower sued for libel by his own hospital

French neurologist Christian Marescaux is being sued for libel by his own hospital after blowing the whistle on equipment shortages which he said endangered patients.
Every second counts when a stroke is suspected, and a delay in accurate diagnosis and treatment can lead to complications with a risk of severe neurological damage. Professor Marescaux heads the neurovascular unit at the Strasbourg University Hospital (HUS), in the north-east of France. For years now his colleagues have reported difficulties and delays in accessing magnetic resonance imaging (MRI) examinations for emergency patients. For example an e-mail to the hospital's director, sent in 2010 by the then chief of neurosurgery, now deceased, reported patients being hospitalized several days while waiting for MRI.
Earlier this year, frustrated by the continuing difficulties and disappointed by the response of the HUS, Professor Marescaux spoke to French media. Marianne, Mediapart and Rue89Strasbourg all reported shocking cases of patients who Marescaux believed had been harmed as a result of delay in receiving MRI scans. HUS responded by suing Marescaux for defamation. A hearing scheduled for June 15 in the Criminal Court of Strasbourg was deferred after questions over the admissability of the hospital's complaint, and will now take place in September. In the meantime, according to an online report in Rue89Strasbourg, Professor Christian Marescaux has been relieved of his responsibilities in the department of Neurology and his nameplates removed from the doors.
Rue89Strasbourg, 15 June 2015. http://www.rue89strasbourg.com/index.php/2015/06/15/societe/lanceur-dalerte-le-pr-christian-marescaux-poursuivi-par-lhopital/
Marianne, 29 June 2015 http://www.marianne.net/christian-marescaux-lanceur-alerte-strasbourg-ne-veut-pas-se-taire-100234950.html

## FSM concern over CAM chair for Sydney

Australia's Friends of Science in Medicine (FSM) are troubled by the news that the University of Sydney is to create a Chair in "Integrative Medicine" funded by Blackmores, a leading provider of complementary medicines and supplements. The Chair will enable the university to "honour Maurice Blackmore (who was founder of the company), a pioneer of Australian naturopathy".
While welcoming the university's commitment to exploring the evidence base (or lack thereof) for alternative and complementary approaches, they are concerned by the University's announcement: "It is our hope that our support for this Chair will contribute towards a holistic approach in medical practice that combines modern western medicine with established and proven practices in the area of integrative medicine"…

Friends of Science in Medicine www.scienceinmedicine.org.au/

## NEWS IN BRIEF

A six-year-old boy is being treated for diphtheria in a Barcelona hospital—Spain's first recorded case of the disease for 29 years. Eight other children who came in contact with the boy have tested positive for the bacteria but have not become ill. The boy's mother and father told reporters last week that they "feel terrible guilt" for not vaccinating their child and said they felt hoodwinked by the anti-vaccination movement that convinced them not to immunize their son.
The Local ES, 5 June 2015
http://www.thelocal.es/20150608/eight-more-children-infected-with-diphtheria

Ben Goldacre, doctor, author and past HealthWatch Awardwinner, says the chief medical officer is looking for answers on statins and oseltamivir in the wrong places. There was extensive news coverage in June of a leaked letter from the CMO Dame Sally Davies, to the Academy of Medical Sciences, asking them to undertake an expert review to shore up public confidence in the safety and effectiveness of medicines, in the wake of controversy around statins and Tamiflu. Writing in a BMJ editorial Goldacre says, "To restrict a review of these problems to the interpretation of inadequate existing data—as the academy apparently proposes—would be recklessly backward looking."
BMJ 2015;350:h3397 http://www.bmj.com/content/350/bmj.h3397

Public understanding of screening is a long way from what screening actually delivers, so Sense About Science have launched a new edition of their guide "Making Sense of Screening", downloadable free from their website.
http://www.senseaboutscience.org/pages/making-sense-of-screening.html

# EVIDENCE

## Treating addiction: science vs dogma

Addiction is rarely out of the news but articles about addiction are often notably ill-informed. Partly, that may be because journalists are unsure whether addiction is a disease or a moral defect. After treating addicts for 40 years, I'm not entirely sure myself but it doesn't matter much. What does matter, as in other conditions, is whether particular addiction treatments have more than placebo and non-specific effects.

Some of the best and earliest research in this field was British. In 1977, an insufficiently famous paper1 described a trial of 'treatment' vs 'advice' in 100 married male alcoholics requesting help for the first time. Their being married meant that the researchers could seek independent progress reports from the often long-suffering wives. The 'treatment' group received conventional interventions (including Alcoholics Anonymous, or AA, meetings) while the 'advice group just had monthly follow-ups for information-gathering, not therapy. Both groups showed equal improvement. In half, the improvement was considerable. When celebrities check in to rehabs, many do well, or use much less. Others abstain for a while and then relapse. Some walk out or relapse quickly after typical 28-day, '12-step', NA (Narcotic Anonymous) or AA-based treatment. This largely mirrors that pioneering British study…

Colin Brewer
Colin Brewer is research director of the Stapleford Centre, London, a private clinic that concentrates on evidence-based treatments for addiction, including both methadone and naltrexone.

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## NUTRITION

# Protein supplements for body building, athletes and slimming—what is the evidence?

There is a considerable market for protein supplements, promoted for sportspeople, body building and weight reduction. Most of these supplements are comprised of whey protein. From an environmental point of view, this market is a good thing. Whey is the watery fluid from milk after the casein proteins have been coagulated in cheese making, and contains about 20% of the protein of milk. Historically, it was an unwanted by-product, and was difficult to dispose of, although it can be used for pig feed. It cannot simply be put into rivers, for obvious reasons, and as I recall, at one time some cheese manufacturers poured much of it into disused mines…

David A Bender
Emeritus Professor of Nutritional Biochemistry
University College London

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## RESEARCH

## CPR2: your chance to support HealthWatch, stand up for fair tests, and get published

Unscrupulous advertisers continue to make unsupportable and misleading claims for health products, apparently unhindered. That was the experience of many frustrated HealthWatch members, and so a few years ago we initiated a small research project to see exactly how effective the legal protections really are. In 2012 a team of HealthWatch volunteers published a research paper in the Medico-Legal Journal1 reporting the results of their systematic efforts to engage UK authorities over misleading health claims made for three products. The findings from this small-scale study exposed disappointing responses from Trading Standards departments, and concluded that the European Directive designed to prevent misleading health claims in UK consumer products is "largely ineffective"….

Interested in making a difference? Don't wait. Contact study lead Les Rose directly at lesrose@ntlworld.com

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## STUDENT'S VIEW

## NHS protocol under student scrutiny

Every year HealthWatch awards prizes to students of medicine, nursing and allied health professions, for their critical evaluation of trial protocols that HealthWatch experts design—with integral hidden flaws—for our annual competition. At last year's HealthWatch AGM we suggested to the winners that they might like to critique the protocol of a real-life trial in progress—the NHS Age Extension Trial of Breast Cancer Screening. Physiotherapy student Lynette Fox of Nottingham University, last year's winner in professions allied to medicine; and Arthur Woo of Glasgow University, runner up among the medical students, rose to the challenge. Their assessments appear below…

Lynette Fox, University of Nottingham
Arthur Woo, University of Glasgow Medical School

## PUBLIC HEALTH

# NICE recommendations: why no disinvestment recommendations to offset investment decisions?

Whilst the major political parties have pledged manifesto commitments to increase investment in the NHS1 questions remain over how these are to be funded.2 Growing demand, alongside ever increasing drug costs, means that funding for new treatments is a particular area of concern. While the NHS in England and Wales is legally obliged to fund and resource medicines and treatments recommended through the NICE technology appraisal (TA) programme,3 NICE has no budgetary responsibilities over the funding of its recommendations…

Dyfrig A Hughes, Professor of Pharmacoeconomics
Eifiona Wood, Lorna Tuersley
Bangor University Centre for Health Economics & Medicines

This is the full-length version of the article, a shortened version of which appeared on 5 May 2015 in The British Medical Journal: BMJ 2015;350:h2311 and appears here with their kind permission. (see http://www.bmj.com/content/350/bmj.h2311/rr-0)

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## BOOK REVIEW

### Is Gwyneth Paltrow Wrong about Everything?: how the famous sell us elixirs of health, beauty & happiness

By Timothy Caulfield

RRP £16.47 (Hardcover: 272 pages). Published 5 May 2015 by Beacon Press (MA) US ISBN-10: 0807057487 ISBN-13: 978-0807057483

Whether it be through modelling, music, movies or sports, award-winning University of Alberta-based academic, Professor of Health Law & Science Policy and a Canada Research Chair, Timothy Caulfield, loves celebrity culture. His book "Is Gwyneth Paltrow wrong about everything?" is a journey unravelling the considerable influence of celebrities on what we think and on our resulting health and life choices…

Loretta Marron
Friends of Science in Medicine, Australia

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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.

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