



Registered Charity no. 1003392

HealthWatch

for treatment that works

Newsletter 77 April 2010

CONSUMER DIRECT AND THE CPUTR SCANDAL



Regulations introduced two years ago were expected to give consumers better protection from unfair trading. But, as John Garrow has discovered, the way they've been implemented has had the opposite effect—new barriers distancing the public from enforcement officers seem to have made it open season for vendors making unjustifiable product claims.

IN MY FINAL year as HealthWatch's first chairman I made an expensive (but interesting) mistake. In Issue 13 of the *HealthWatch Newsletter* I wrote: "It has become increasingly clear to me that local authority Trading Standards Officers are one of the most effective organisations for controlling health fraud."

My error was to use the word "fraud" when referring to the conviction of the vendors of a nutritional supplement, under the Trade Descriptions Act (TDA). That conviction did not in fact imply fraud, but was merely for applying a misleading description to their product. The error cost HealthWatch about £3000, and it taught me a lesson.

Re-reading that 1993 issue of the newsletter reminded me that for twenty years HealthWatch and Trading Standards Officers (TSOs) have worked together to control misleading descriptions for health products. The "scandal" in the title of this article is that recent changes in the consumer protection legislation have virtually severed this co-operation.

The most important change in consumer protection regulations arises from EU Directive 2005/29/EC. The effect in UK law was that from 28th May 2008 the Consumer Protection from Unfair Trading Regulations (CPUTR) became effective. This seemed a welcome advance. Under the old TDA the onus was on the TSO to show that a claim was false, which meant that the local authority had to pay for the prosecution and needed to employ an expert witness who could convince the court that the claim was untrue. If the prosecution was successful the court usually gave costs to the TSO, but if it failed it was a significant cost to the local authority. But under the new CPUTR the onus of proof is reversed: the vendor must prove that the claim was justified.

However the other change in the management of consumer protection was the installation in 2005 of a cluster of eight call centres called Consumer Direct (CD). The intention was to make basic advice available to everyone who was dissatisfied with the service they had received from a vendor of goods or services. But the public would no longer have direct access to TSOs: all complaints had to be filtered through the call centres.

Consumer Direct's web site says in large type: "Our regionally based advisors are specially trained to give practical advice on all kinds of consumer issues—from problems with cars to faulty household appliances." This may be fine for the consumers who are dissatisfied with their car or household appliance, and want a refund, but that is a matter for civil law, and under civil law the onus is on the consumer to prove that the product is defective.

In June 2008 Les Rose (a member of HealthWatch Committee) noticed a product called 'Skinny water' on sale in Tesco Express in Southampton. On the bottle, and on the related web site, there were improbable claims about the beneficial effects of the additives in the water (chromium and L-carnitine). To see how the new CPUTR performed he sent off his complaint, together with a report from me that the claims were almost certainly untrue. The result was unsatisfactory—the details are reported elsewhere².

"Prosecutions for misleading claims for health products under the new Consumer Protection from Unfair Trading Regulations, since May 2008, showed a total of zero. How can this be?"

I am very concerned about misleading claims for products that offer to help overweight consumers to lose weight or fat. For 25 years I ran an NHS outpatient clinic from Northwick Park Hospital, and later from St Bartholomew's Hospital. During that period I saw about 3,500 obese outpatients, and was able to admit more than 500 of them to a metabolic research ward. Almost all of these severely obese patients (BMI 30 to 55) had tried "magic" remedies that had

...continued on page 8

Contents

CONSUMER PROTECTION	<i>John Garrow investigates the Consumer Direct and CUPTR scandal</i>	1, 8
NEWS	<i>Parliament polarized and protestors galvanized over homeopathy; news in brief</i>	2
MEDIA	<i>Critics of evidence-based medicine do humanity a disservice, argues James May</i>	3, 7
MEETING REPORT: SCREENING	<i>Michael Baum on breast cancer screening and opening minds</i>	4, 5
EVIDENCE AND POLICY	<i>Reducing doctors' hours—Keith Isaacson argues it's not always better for patients</i>	6
DRUG SAFETY	<i>Caroline Richmond and Les Rose salute the late drug regulation pioneer James Goddard</i>	7

Homeopathy polarizes MPs and galvanizes protestors

MORE THAN four hundred sceptics nationwide took part in a mass homeopathic “overdose” in protest at Boots’ continued endorsement and sale of homeopathic remedies. Campaigners met on 30th January outside branches of the high street chemist across the UK to down an entire bottle of homeopathic tablets each¹. It seems that no-one was harmed.

The following week the GP’s magazine *Pulse* reported that of nearly 800 GPs responding to their survey, 80% said the NHS should not continue funding for homeopathy².

In a report published on 22nd February, the House of Commons Science & Technology Committee concluded that the NHS should cease funding homeopathy and that the Medicines and Healthcare products Regulatory Agency (MHRA) should not allow homeopathic product labels to make medical claims without evidence of efficacy³.

The backlash came fast. The *British Medical Journal*’s report of the MP’s conclusions appeared on 23 February⁴, and attracted 19 online rapid responses, most of which were from homeopaths

(excepting a tongue-in-cheek letter from Caroline Richmond) while MP David Tredinnick’s Early Day Motion⁵ opposing the Science and Technology Committee report has, at the time of writing, been signed by 70 out of the House’s 646 MPs.

Mandy Payne

References

1. The media coverage can be viewed on <http://www.1023.org.uk/the-1023-overdose-event.php>
2. See <http://www.pulsetoday.co.uk/story.asp?sectioncode=23&storycode=4124908>
3. See http://www.parliament.uk/parliamentary_committees/science_technology/s_t_homeopathy_inquiry.cfm.
4. Kmietowicz Z. NHS should stop funding homeopathy, MPs say. *BMJ* 2010; **340**: c1091
5. Read the EDM and the list of signatories on <http://edmi.parliament.uk/EDMi/EDMDetails.aspx?EDMID=40517>

NEWS IN BRIEF

SCIENCE WRITER Simon Singh has won the right to rely on the defence of fair comment in the case of the libel action being brought against him by the British Chiropractic Association. The decision to allow his appeal, handed down at the Royal Courts of Justice on 1st April, followed the hearing in February in which the Law Lords examined the meaning of Singh’s 2008 *Guardian* article questioning the evidence behind claims that certain childhood conditions could be treated with chiropractic. Links to press reports are on <http://www.senseaboutscience.org.uk/index.php/site/project/473/>

JOHN GARROW brought the issue of the rise in uncontrolled health claims in ads (see his article, pp 1,8, this issue) to the attention of *British Medical Journal* readers in his rapid response to an article by Professor Gareth Williams reacting to the withdrawal of the anti-obesity drug Sibutramine in Europe. See http://www.bmj.com/cgi/eletters/340/feb09_3/c824#231638

EDZARD ERNST’S unit at the Peninsula Medical School in Exeter may close in June 2011 unless additional funds of £1.5m can be found. The university blames the financial climate but Ernst, the UK’s only professor of complementary medicine, suspects his public disagreements with the Prince of Wales’ Foundation for Integrated Health have made him unpopular with managers. See <http://www.guardian.co.uk/lifeandstyle/2010/mar/03/edzard-ernst-complementary-medicine>

“THE MAN Who Stopped Smoking” is a 10-minute documentary charting the remarkable life of the late Professor Sir Richard Doll (1996 HealthWatch Awardwinner), whose case control study, published in 1950, first identified smoking as an important cause of cancer and other diseases. The film, made by TV producer Martin Freeth, was made to promote the *BMJ* archive’s now being fully searchable back to 1840, and can be viewed online at <http://www.bmj.com/video/doll.dtl>

ANDREW HERXHEIMER, for many years a member of the HealthWatch committee and now a member of the UK Cochrane Collaboration, joined European experts recently to speak out on the European Commission’s legislative proposals on pharmacovigilance—the process of evaluating and improving the safety of medicines. At the meeting, organised by the Association Internationale

de la Mutualité and held at the European Parliament in Brussels on 27th January, concern was expressed that Member States’ own drug evaluating authorities could be increasingly bypassed in favour of pharmaceutical companies. However, legal provisions to allow direct reporting of adverse drug reactions by patients to health authorities were welcomed and Dr Herxheimer presented new evidence on the value of patient reports. The European Parliament votes on the pharmacovigilance proposal in May.

See www.aim-mutual.org/?page=17&id=201

CELEBRITIES such as Roger Moore and Heather Mills were named and shamed for offering daft health advice in Sense About Science’s “Celebrities and Science 2009” round-up, and the press had a field day. Read the report and the news coverage on <http://www.senseaboutscience.org.uk/index.php/site/about/444/>

ALAIN BRAILLON (contributor to *HealthWatch Newsletter* issue 73, April 2009) was fired from the public health dept of the university hospital of Amiens, France in January. He has been outspoken in his claims that the alcohol industry and other vested interests have undue influence over French health policy. His recent letter in the *British Medical Journal* protested against French urologists’ continued promotion of prostate cancer screening despite unproven benefits.

Brailion A. French exceptionalism *BMJ* 2009; **339**: b4285.

MICHAEL BAUM (HealthWatch Awardwinner 2002, and writing in the centre pages of this issue) has just published “Breast beating: a personal odyssey in the quest for an understanding of breast cancer, the meaning of life and other easy questions”. The book has a foreword by Nick Ross. Available in paperback at £35.00, published by Anshan Ltd.

IN RESPONSE to concerns that UK libel laws could be restricting freedom of expression, the government has set up a working group to examine the issues. See <http://www.wired-gov.net/wg/wg-wlabel-dti.nsf/wfArticle?ReadForm&unid=2DFBDE3F60EBD2BA802576B8005CEF22> Supporters of the campaign to reform UK libel laws in favour of more open public discussion of science can visit www.libelreform.org/sign. More than 40,000 have signed the petition so far.

EVIDENCE BASED MEDICINE AND ITS CRITICS



RECENTLY THERE has been a spate of articles in various journals criticising evidence based medicine, and in particular what has become known as the ‘hierarchy of evidence’. These articles—all by alternative practitioners, or those sympathetic to CAM—quote the following passage from the 2008 Harveian Oration¹ by Sir Michael Rawlins, chairman of NICE.

“The notion that evidence can be reliably placed in hierarchies is illusory. Hierarchies place RCTs [randomised controlled trials] on an undeserved pedestal for, as I discuss later, although the technique has advantages it also has significant disadvantages ... judgements are an essential ingredient of most aspects of the decision-making process.”

An editorial from last year’s *British Medical Journal*² is representative of the types of argument being used, and produced a flurry of online responses from HealthWatch members and CAM practitioners alike. The authors write,

“Integrative interventions tend to involve potentially synergistic, multimodal, and complex interactions that are often dependent on the relationship between practitioner and patient, and on patients’ preferences, expectations, and motivations.”

Having quoted Rawlins, they go on to propose that:

“Within pragmatic trials it is possible to optimise rather than constrain patient-practitioner interactions, and by incorporating patient preferences into trial design, the effects of synergies between treatment and choice can be captured.”

One might hope that Sir Michael Rawlins has been quoted out of context, but this is not the case. Indeed it would seem that this passage is a fair summary of the rest of his 35 page oration. Rather what seems to have happened is that a carefully stated argument has been twisted and caricatured into providing a loophole which says that anything can constitute evidence. There is a gear change in the argument from the pages of the oration to the obfuscation of the *BMJ* editorial. Rawlins is careful about the circumstances which limit the use of RCTs, and proposes that judgements are required to evaluate the best evidence to use in each circumstance.

So what proportion of healthcare is evidence based? The shaky origins of the oft-quoted “10 to 20 per cent” are explained elsewhere³. More reliable is a 1995 study into the evidence base for inpatient general medicine which found that 82% of treatments were evidence based, out of which 53% had RCT support, and 29% convincing non-experimental evidence⁴. If the hierarchy is taken too rigidly then this could be interpreted as saying that 47% of practice awaits definitive RCT backing. However, if one listens to Rawlins carefully and looks at the details of the study we find that the greater part of these treatments is based on substantial evidence where RCTs may not be appropriate.

In Public Health it is well recognised that RCTs are not the final word in all areas:

“Randomized controlled trials (RCTs) are essential for evaluating the efficacy of clinical interventions, where the causal chain between the agent and the outcome is relatively short and simple and where results may be safely extrapolated to other settings. However, causal chains in public health interventions are complex, making RCT results subject to effect modification in different populations. Both the internal and external validity of RCT findings can be greatly enhanced by observational studies using adequacy or plausibility designs. For evaluating large-scale interventions, studies with plausibility designs are often the only feasible option and may provide valid evidence of impact. There is an urgent need to develop evaluation standards and protocols for use in circumstances where RCTs are not appropriate.”

Despite these affirmations, it does seem possible that Rawlins has,

probably unintentionally, opened the floodgates for misinterpretation. When asked to comment on the oration, Sir Iain Chalmers of the James Lind Library, and winner of this last year’s HealthWatch Award, wrote in an email to me that Rawlins wasn’t saying much that is new, and indeed has previously co-authored a paper with Chalmers on the subject⁶. However, he defended RCTs by saying “Random allocation is used for a good reason, it ensures that the comparison groups differ only by chance at the point of treatment allocation.” He concludes, “At the end of the day, one has to fall back on the use of logic to underpin one’s belief. And that’s why I worry about calls to abandon RCTs because they’re too difficult or too expensive. We owe it to patients to obtain trustworthy evidence.”

So has Rawlins gone too far, or has he perhaps inadvertently committed a PR blunder for campaigners for evidence based medicine? Personally I don’t think so. Criticising the hierarchy is a question of being even more careful about the evidence we use.

The science philosopher Thomas Kuhn contends that the settling of scientific disputes are not in principle the rote, mechanical processes that modernist theorists hoped they might be, but that scientific decisions often involve the application of judgements based on values. That RCTs have a central place in certain types of decision, and that the role of logic is fundamental in these instances does not seem to be in doubt in any of the examples used above. Where there is a short causal chain, where the outcome is uncertain and the effect margin is narrow, and where placebo effect and practitioner interference is likely to be significant, then RCTs are likely to be the gold standard. However, there remain other instances where they may not be the most appropriate tool. Even where RCTs are appropriate, however, the application of the evidence to the individual patient requires careful judgement by the clinician. There is no infallible logical chain from an RCT to the next patient in the consulting room.

“Criticising the hierarchy is a question of being even more careful about the evidence we use”

What Rawlins is surely calling for is greater care, not less in our search for the best evidence; for harder work, not for sloppiness; for greater humility in the face of reality, not for allowing our personal prejudices and biases to run riot. This seems to be where the loophole closes for the CAM practitioners. The most suitable form of evidence for many CAM therapeutic claims would seem to be RCTs. The claimed effect size is small if it exists at all and the practitioner’s influence potentially huge. The attempt in the *BMJ* editorial to blur the boundaries between the effect of the therapy and the practitioner’s impact is exactly why randomisation is important.

Edzard Ernst writes, “But the proponents of the anarchy of evidence go one decisive step further. If a treatment should not even pass the test of a pragmatic trial—those therapies which fail to generate powerful placebo effects might belong to this category—the standard must be lowered further. The general aim, of course, is to avoid the embarrassment of a negative result. Some complementary therapists already argue that observational studies without a control group might provide valuable data about the effectiveness of their intervention. Whenever a disappointing result from pragmatic trials emerge, this approach can be used to turn the negative into a (false)

...continued on page 7

SCREENING FOR BREAST CANCER: SOME INCONVENIENT TRUTHS



TWO RECENT high-profile peer reviewed papers^{1,2} and three meetings I attended recently show that the subject of mammographic screening for breast cancer is once again under public scrutiny. The polarity of opinions on the subject is illustrated by the fact that two of the meetings, an International Conference on Women’s Health held on November 11th at the Royal College of Obstetricians and Gynaecologists, and a debate on breast cancer screening at the AGM of Europa Donna on the 13th of January, ended up as ill mannered shouting matches.

There is a biological model of the natural history of breast cancer that is rarely explicitly stated in debates on this topic. One of these rare occasions was at the EUROPA DONNA meeting. Professor Lazlo Tabar, the principal investigator of Sweden’s “Two County trial”³, is one of the leading proponents of screening in the world. He described a growth pattern with predictable transitions from *in situ* to early invasive disease, from early invasive to localized advanced disease and from that stage to distant metastases. It’s more or less the same belief system that inspired the development of the radical mastectomy⁴.

This “screening theory” has lead to the mantra of “catch it early, save a life and save a breast”. If that strategy were effective it would follow that:

1. An increased detection of duct carcinoma in-situ (DCIS) would lead to a subsequent fall in the incidence of invasive duct cancer (IDC).
2. An increasing detection of lymph node negative breast IDC would be associated with a fall in the incidence of lymph node positive IDC.
3. An increased detection of small foci of both DCIS and IDC would eventually lead to a reduction in the mastectomy rate in the screened population as a whole.

Surprisingly none of these necessary conditions have been met. Before I discuss that in detail I must warn of the three sources of bias in screening for breast cancer that can obscure the truth:

- Lead-time bias prolongs the period of observation as a result of earlier detection without necessarily affecting the date at which the woman dies of her disease. At its most extreme following the over-diagnosis of “latent” cancer, the lead-time is the woman’s natural expectation of life.
- Length bias describes the observation that slow growing tumours hang around long enough to be picked up at screening, whilst the aggressive cancers slip through the net and appear in the intervals between one screening round and the next. These so called interval cancers tend to be of higher grade than screen detected disease.
- Attendance bias describes the fact that women who accept the invitation to be screened are different to those who fail to turn up. The latter tend to be of a lower social class—on its own a powerful prognostic factor. Two possible explanations have recently been suggested. Firstly the same women who fail to turn up at screening are the ones who fail to comply with the advice on taking adjuvant therapy. Secondly, although deprivation alone doesn’t cause breast cancer, it can affect prognosis when gene p53 is damaged as a result of lifestyle choices commonly associated with deprivation⁵.

For those reasons the only way to estimate the value of screening is to conduct randomized controlled trials (RCT) of screened versus non-screened women with the “intention to screen” analysis of cause specific and all cause mortality. If you only look at the women who attend and if you only measure survival from the point

of diagnosis, you will be misled. Furthermore ignoring other causes of death may hide the fact that the over-diagnosis of latent cancers might increase deaths in the long term from, say, ischaemic heart disease as a consequence of radiotherapy to the chest wall. No amount of mathematical modeling or wishful thinking can get round these inconvenient truths.

In fact experience with population-based programs fails to satisfy the three necessary conditions described earlier to fulfill the promises of screening:

1. Once screening starts in any community the incidence of DCIS shoots up from about 2% to about 20%. This is not followed by a falling incidence of IDC, in fact the reverse is true. Screening is associated with an increase in the incidence of IDC².
2. This increase in incidence of IDC is predominantly those that are node negative but this is associated with only a marginal fall in the incidence of node positive cases⁶.
3. Once screening is introduced on a population basis the absolute rate of mastectomy increases!⁷ This counter-intuitive observation is largely a result of the fact that close on 50% of the excess of cases of DCIS are multifocal⁸.

I submit that the increased incidence of DCIS, many of which are multifocal, and the increase in the incidence of node negative cases of IDC, are all due to the over-diagnosis of latent disease that to my mind is the major toxic unintended consequence of the uncritical adoption of screening. I will return to this.

“All screening programmes do harm; some can do good as well.”
Sir Muir Gray, director of the UK Cancer Screening Programme⁹

There is in fact a modest advantage to screening looked upon in those terms, as described in the recent publication, “Breast screening: the facts—or maybe not” by Peter C Gøtzsche and his colleagues from the influential—and independent—Nordic Cochrane Centre¹. They report a synthesis of all the papers that describe both the benefits and harms of screening using absolute rather than relative numbers that make it easy for women to comprehend and conclude as follows. If 2000 women are screened regularly for 10 years, one will benefit from the screening, as she will avoid dying from breast cancer. (The independent United States Preventive

Absolute value of screening 10,000 women for 10 years		
10,000 women aged 50 screened for 10 years	25% relative risk reduction (hazard ratio 0.75)	15% relative risk reduction (hazard ratio 0.85)
Cancer incidence (2 per 1,000/year)	200	200
Cancer deaths without screening at median follow up 5 years ¹²	20	20
Cancer deaths with screening (20 x HR)	15	17
Absolute benefit	5	3

Assumes two estimates of relative risk reduction, and assumes that unscreened symptomatic women receive the best of modern therapy

Services Task Force derived a similar number in 2004¹⁰.) The NHS BSP prefer the figure 1:1,000 derived from a somewhat selective reading of the literature³, but whatever the agreed figure the principles of this paper remain the same. However even the figures 1:1,000 or 1:2,000 might be an over-estimate. Remember these data were derived from the trials that were mostly started in the 1970s and reported in the late 1980s. Since then improvements in treatment, such as the adoption of tamoxifen and adjuvant chemotherapy, have narrowed cancer's window of opportunity and we have witnessed a drop in mortality of 30 to 40% both in the age group that are invited for screening (>50) as well as for the younger woman¹¹. So perhaps the correct number might be nearer to 1:3,000 (see calculations in table, below left).

Whatever the number, that one woman who benefits from a decade of screening has a life of infinite worth and if screening were as non-toxic as wearing a seat belt there would be no case to answer. However there is a downside and that is the problem of the over-diagnosis of "pseudo-cancers"¹³. By this I don't just mean the harms from false positive results, but the over-diagnosis of indolent disease that includes the detection of a cancer not destined to present clinically in that patient's lifetime.

It is deduced by the Cochrane report that for every life saved, ten healthy women will, as a consequence, become cancer patients and will be treated unnecessarily. These women will have either a part of their breast or the whole breast removed, and they will often receive radiotherapy and sometimes chemotherapy.

Over-diagnosis of breast cancer means the detection and treatment of cancers that, left undetected, would never threaten a woman's life and with which she would live, in blissful unawareness until she died naturally of old age. We had always assumed that there was an over-diagnosis of duct carcinoma in-situ (DCIS), some of which had the potential of progressing to an invasive and life-threatening phenotype. However, there is now clear evidence that anything between 10% and 50% of invasive cancers detected and treated radically as a result of screening, would never threaten life^{14,15,16}. As a result the overall mastectomy rate rises after any country implements screening. The message in the NHS BSP leaflet, "Breast cancer the facts", implies that screening saves breasts. It doesn't.

"anything between 10% and 50% of invasive cancers detected and treated radically as a result of screening, would never threaten life"

Some of these earliest stages of "cancer" if left unperturbed, would not progress to a disease with lethal potential. These "cancers" might have microscopic similarity to true cancers but these appearances are only a necessary rather than sufficient condition for a fatal disease. I would also like to suggest that many of the "risk factors" for the development of cancer are in fact the promotional agents of a latent condition that Welch has described as pseudo-cancers¹³.

We have now reached the point in the evolving history of breast cancer screening where one is allowed to question the merits of this public health intervention without having your sanity challenged. The third meeting, organized by Cancer Research UK and held on the 18th of January, was a closed round table conference to consider whether they should change their advice on breast cancer screening. The fact that they might even contemplate this represented a chink in the carapace of certainty that had until recently protected this dogma. This last meeting was better mannered and reached a point where some progress seemed possible although the meeting's tragic sequel could never have been anticipated.

It is clear that the benefits of mammographic screening have in the past been exaggerated and it is now widely accepted that the relative risk reduction of breast cancer mortality is between 1:1,000 and 1:3,000 women screened for 10 years. (There is as yet no evi-

dence to support an impact on all cause mortality.) This modest gain is accompanied by the over-diagnosis and over-treatment of up to 10 women for every breast cancer death avoided and, finally, the mastectomy rate escalates in a screened population. It was against that background that CRUK invited a group of experts to advise on whether or not they should change the guidance they offer to women in their leaflets and web site.

We agreed to disagree on the extent of benefit versus harm but decided the correct way forward was a consensus development meeting to be brokered by CRUK. Towards the end of the meeting, Dr. Joan Austoker, reader in primary health care at Oxford University, spoke to us on the revisions she had already made to the leaflets sent out when women are invited for screening. She was due to present her recommendation to the NHS BSP executive the following morning. At the end of her talk I congratulated her on a job well done. The next day Joan collapsed in the middle of the meeting and died that afternoon. (The cause of death was from a splenic haemorrhage). At her funeral I met up with Julietta Patnick and Dame Valerie Beral, the two most important voices in the screening programme. United in our grief for the passing of such a brave and brilliant woman, we agreed to work together in future towards peace and reconciliation amongst the screening camps.

Michael Baum

Professor Emeritus of Surgery, Visiting Professor of Medical Humanities
University College London

References

1. Gøtzsche PC *et al.* Breast screening: the facts—or maybe not. *BMJ* 2009; **338**: 446–448.
2. Jørgensen KJ, Gøtzsche PC. Who evaluates public health programmes? A review of the NHS breast screening programme. *JRSocMed* 2010; **103**: 14–20.
3. Tabar L, Yen M-F, Vitak B *et al.* Mammography service screening and mortality in breast cancer patients: 20-year follow-up before and after introduction of screening. *Lancet* 2003; **361**: 1405–10.
4. Fisher B. Biological Research in the Evolution of Cancer Surgery: A Personal Perspective. *Cancer Res* 2008; **68**(24): 10007–20.
5. Baker L, Quinlan PR, Patten N *et al.* p53 mutation, deprivation and poor prognosis in primary breast cancer. *Br J Cancer* 2010; **102**(4): 719–26.
6. Rethinking screening for breast cancer and prostate cancer. Essereman L, Shieffii Y, Thompson I. *JAMA* 2009; **302**(15): 1685–92.
7. Welch HG, Schwartz L and Woloshin S. What's making us sick is an epidemic of diagnoses. *The New York Times* Jan 2, 2007.
8. NHS Breast Screening Programme & Association of Breast Surgery at BASO. An audit of screen detected breast cancers for the year of screening April 2003 to March 2004. NHS Cancer screening programmes 2005.
9. Muir Gray JA. "Evidence-based health care: how to make health policy and management decisions." London: Churchill Livingstone 1997. p53.
10. US Preventive Services Task Force. Screening for breast cancer: recommendations and rationale. *Ann Intern Med* 2002; **137**: 344–6.
11. Baum M. Should routine screening by mammography be replaced by a more selective service of risk assessment/risk management? *Women's Health* 2010; **6**: 71–76.
12. Forbes JF, Czuzick J, Buzdar A *et al.* Arimidex, Tamoxifen, Alone or in Combination (ATAC) Trialists' Group, Effect of anastrozole and tamoxifen as adjuvant treatment for early-stage breast cancer: 100-month analysis of the ATAC trial. *Lancet Oncol* 2008; **9**(1): 45–53.
13. Welch HG. "Should I be tested for Cancer?" University of California Press 2004. ISBN 0520239768.
14. Zackrisson S, Andersson I, Manjer J and Garne JP. Rate of over-diagnosis of breast cancer 15 years after end of Malmö; mammographic screening trial: follow up study. *BMJ* 2006; **332**: 689–92.
15. Jørgensen KJ, Gøtzsche PC. Overdiagnosis in publicly organised mammography screening programmes: systematic review of incidence trends. *BMJ* 2009; **339**: 2587–90.
16. Welch HG. Overdiagnosis and mammography screening. *BMJ* 2009; **339**: 1425.

REDUCING JUNIOR DOCTORS' HOURS: BETTER FOR PATIENTS?



THE NUMBER of hours worked by junior doctors has been progressively reduced and in 2009 the European Working Time Directive (EWTD) was implemented with a maximum working week of 48 hours despite opposition by the medical profession. The Royal College of Surgeons was particularly concerned by the impact this would have on the training of our future consultant surgeons¹.

In a traditional on-call arrangement, a team of junior staff led by their consultant was responsible for a group of emergency patients. They would all be on call, with the house surgeon or registrar being resident. Clinical problems were dealt with according to the experience of the individual who could seek advice from the next more experienced person. The consultant took the ultimate responsibility.

From my own experience living in the hospital for a week at a time, and residing in a doctors' mess, enabled rapid exchange of clinical information with other junior staff. There is no doubt that the process of admitting a patient, taking their history, examining them and deciding how to investigate and manage them at first hand results in gaining considerable clinical experience. Continuing to be responsible for that patient's care over the next few days (rather than delegating the concerns to another junior doctor) consolidates the process of evaluating and managing the changing state of that patient's clinical problems in a way that has been uniquely beneficial to the junior doctor who could not sit on unresolved problems simply to pass them on to another doctor at the end of the shift.

"The ASIT found that shift working led to more mistakes than 24 hours on call"

When the EWTD was fully implemented the on-call arrangement was stopped and trainees' timetables altered to give them 48 hours split into six eight hour shifts in a week. These new timetables make it difficult to accommodate regular sessions with their consultant for operating or outpatient clinics. Often there are insufficient medical staff to cover a full week's rota so some Trusts employ the same doctors as locums to work extra sessions—usually at night—to make up for the shortfall. Hardly what was intended with the new regulations.

The European Working Times Directive was debated in the House of Commons in March 2009² when a study by Warwick and Harvard Universities was quoted³. The study clearly did not set out to find out whether working more than 48 hours is itself a risk, but only to find out whether a reduction in hours caused harm.

Was it a good study? The sample was small: it only followed 19 junior doctors and the patient groups sampled were in no way comparable. In one group, 10 doctors were working in a respiratory ward with a traditional on-call pattern; in the other group nine doctors were working the new 48 hour rota split into eight hour shifts on an endocrinology ward. The outcome was, "60 patient safety incidents over the course of the study": 30 in each of the study groups. Of the 60 patient safety incidents reported, those that could be attributed to preventable errors by clinicians amounted to five in the traditional working group and four in the European Working Time Directive group. The majority of the remainder were due to falls.

What has been used in the past as a measurement of fatigue is the number of hours an individual works. However this may be too simplistic a measure. In a survey in 2005 by the Royal College of Physicians of trainees on a full-shift system⁴, 81% reported excessive fatigue on night shifts and 74% had fallen asleep at work.

The new arrangements have necessitated full-shift rotas of six eight-hour sessions during the week, during which the doctor will be working all the time, and has no cause therefore to be resident in the hospital. Unfortunately the sessions are not necessarily spread evenly through the week, making it difficult for the doctor to establish a sleep pattern. It also means that their hours of duty no longer coincide with their consultant's regular weekly operating or outpatient sessions. The Association of Surgeons in Training found that shift working led to more mistakes than 24 hours on call⁵. Over 70% of the trainees found that there was no improvement in work/life balance and the shift system pressurised their social lives.

The traditional medical and surgical firm has been fractured by the introduction of the new shift system and trainees are disassociated from their consultants with an adverse impact on their training. It also makes it more difficult to gain advice from experienced clinicians at times that might be critical for patients. A recent National confidential enquiry into Patients' Outcome and Death⁶ found that instead of patients recognising "their" doctor during a stay in hospital, the doctors were "transient acquaintances during a patient's illness rather than having responsibility for continuity of care".

It seems that the new 48 hour week is of little benefit either to doctors in training or their patients.

*Keith Isaacson
Senior consultant orthodontist
North Hampshire Hospital, Basingstoke*

This article is based on a paper, "Do reduced hours create better safety for patients?" With acknowledgements to Matthew Worrall, Media Communications Manager to the Royal College of Surgeons of England.

References

1. Black J. We enter the second decade. *Ann R Coll Surg Engl (Suppl)* 2010; **92**: 42–43.
2. HC Deb 10 March 2009 c233. View at: www.theyworkforyou.com/debates/?id=2009-03-10b.220.0
3. Cappuccio FP, Bakewell A, Taggart FM et al. Implementing a 48 h EWTD-compliant rota for junior doctors in the UK does not compromise patients' safety: assessor-blind pilot comparison. *QJM*, 2009; 102(4): 271–282.
4. Douglas NJ. Sleep, performance and the European working time directive. *Clin Med* 2005; **5**: 95–6.
5. The Association of Surgeons in Training. Optimising Working Hours to Provide Quality in Training and Patient Safety. A position Statement by the Association of Surgeons in Training, London: ASIT; January 2009.
6. National Confidential Enquiry into Patient Outcome and Death. Caring to the End? A review of the care of patients who die in hospital within four days of admission. London: NCEPOD; 2009.
7. Worrall M. Do reduced hours create better safety for patients? *Bulletin of The Royal College of Surgeons of England* 2009; **91**(7): 224–225.

JAMES GODDARD, DRUG REGULATION PIONEER

IN JANUARY the New York Times published an obituary of Dr James L Goddard, a “brash, crusading” commissioner of the Food and Drug Administration in the 1960s who helped revolutionize the US government’s methods of evaluating drugs. From 1966 to 1968 Dr Goddard strove to put the FDA onto a sounder scientific footing to better serve the consumer. He cracked down on exaggerated drug advertising and delayed approval of new drug applications until manufacturers had backed them up with more laboratory and clinical testing. And he campaigned to take ineffective drugs off the market.

Shortly after he assumed leadership of the agency, Goddard told pharmaceutical executives that many of them were dishonest in their applications for new drugs and promised or threatened reform. He went on to push the FDA into a new era. Before Goddard, the FDA was toothless, had no medically qualified staff, poor standards of evidence and largely subservient relations with the pharmaceutical industry.

In the 1960s Dr Goddard wrote and implemented legislation requiring drugs to be tested for efficacy as well as for safety. The law mandated testing of new drugs for efficacy, and pre-1962 drugs for both safety and efficacy. He contracted the National Academy of Sciences to review 4,000 already-introduced drugs. On the strength of this he banned 250 antibiotic preparations, particularly throat lozenges, from the market because drug makers had not proved their effectiveness. He started an investigation of possible criminal violations in the testing of new drugs.

He also longed to test new drugs against one another and existing drugs to ensure they were more effective than ones already approved, but was blocked by political and economic interests.

James Lee Goddard was born on April 24, 1923 in Ohio, served in the Army during World War II and completed his medical degree at George Washington University in 1949. After a brief stint in private medical practice, he joined the Public Health Service in 1951, interrupting this work to earn a master’s degree in public health from Harvard in 1955. For five years he studied automobile safety for New York State and the federal government, doing research that

helped buttress the push for mandatory seatbelts. He moved on to the Federal Aviation Agency, where as medical director he did research that resulted in compulsory retirement at 60 for pilots. When he learned that no flying qualifications were required for hot-air balloon pilots he applied for and got a license, and even made a few balloon flights. The FAA soon set qualifications for balloonists.

In 1962, aged only 39, he was named assistant surgeon general and chief of the Communicable Disease Center (now the Centers for Disease Control and Prevention) in Atlanta. He hoped to become surgeon-general but was recruited to the FDA as part of an overhaul to improve morale.

He did this spectacularly well: drug industry executives complained to the White House about Dr. Goddard’s aggressive approach. His penchant for offhand remarks offended many and helped him with almost no one.

He upset vice president Hubert H Humphrey, a former pharmacist, by remarking that the corner drugstore was probably a fading institution. When pharmacists offered \$100,000 to the Democrats’ 1968 campaign with the suggestion that Dr. Goddard was expendable, Humphrey and President Johnson were receptive. Goddard moved to the pharmaceutical industry as an executive, then as a consultant. From 1970 to his retirement in 1972 he directed the Ford Foundation’s family planning programme in India.

Caroline Richmond, medical journalist

Reference

1. *New York Times* 1 January 2010. View on <http://www.nytimes.com/2010/01/02/health/02goddard.html>

How Goddard made treatments safer in Europe

AS EVER when the USA sneezes the first to catch a cold overseas is the UK. Goddard left the FDA in a vastly stronger position than he found it, but there was another revolution around the corner. The USA had not allowed thalidomide onto the market, and was congratulating itself on that when it was discovered that the drug had been used in many US clinical trials without the FDA knowing anything about them. The agency’s deep investigation of clinical trial practices shook it to the core, because patient protection turned out to be minimal and accountability for investigational drugs was chaotic. Thus in 1977 Good Clinical Practice (GCP) was launched by the FDA. For nearly ten years the rest of the world seemed large-

ly unaware of it, but eventually one by one other countries started replicating the idea. Today, the GCP guidelines of the International Conference on Harmonisation (ICH) provide a *de facto* global standard, and are the model for statutory legislation in most of the developed world. It is widely acknowledged that the UK implementation of the EU Directives on Clinical Trials and on Good Clinical Practice is among the most rigorous of all member states. It would be hard to determine that none of this would have happened without Goddard, but it seems very unlikely that the weak FDA that he joined could have got the process started.

Les Rose, freelance consultant clinical scientist

Evidence-based medicine and its critics

positive ... purely on the strength of the natural history of diseases and the regression towards the mean.”

If judgement does have a place in evaluating evidence, it cannot be to allow prejudices that certain CAM interventions do (in spite of current evidence) work and that RCTs are the simply the wrong tool for the job. Rawlins’ oration is being used to hide behind complexity, rather than to address it. Yet his intention rather is surely to increase our epistemic care, to help us to be wiser in our use of judgement, and to increase our knowledge of effective medicine.

Evidence-based medicine is among the greatest achievements of science, and has saved millions of lives. Seeking to undermine its progress, with specious arguments and misinterpretations, does humanity a great disservice.

James May, HealthWatch chairman and general practitioner

...continued from page 3

References

1. Sir Michael Rawlins, Harveian Oration 2008, Royal College of Physicians.
2. MacPherson H, Peters D and Zollman C. Closing the Evidence Gap in Integrative Medicine. *BMJ* 2009; **339**: b3335.
3. See <http://www.veterinarywatch.com/CTiM.htm>
4. Ellis J, Mulligan I *et al.* Inpatient general medicine is evidence based. *Lancet* 1995; **346(8972)**: 407–10.
5. Victoria CG, Habicht JP & Bryce J. “Evidence-based public health: moving beyond randomized trials” *Am J Public Health* 2004; **94**: 400–405.
6. Glasziou P, Chalmers I, Rawlins M and McCulloch P. When are randomised trials unnecessary? Picking signal from noise. *BMJ* 2007; **334**: 349–351.
7. Ernst E. The Anarchy of Evidence. *Br J Gen Pract* 2010; **60(571)**: 135.

Consumer Direct and the CPUTR scandal

...continued from front page

done them no good—they wasted money and caused depression and disappointment. The situation concerning obesity is getting worse year by year: the Department of Health now rates obesity as the greatest threat to public health, having overtaken cigarette smoking as a health hazard. I hoped that the new CPUTR rules would stem the flow of misleading claims for obesity cures, but it did not.

DESPITE our previous failure to get any TSO to take action on Skinny Water, I decided to try again. To see if other complainants were having more success I asked, in December 2009, under the Freedom of Information Act 2000, how many prosecutions there had been since 28th May 2008 under CPUTR for misleading claims for any health product, especially those promising weight or fat loss.

On 19th January 2010 I received the answer to my question. A list of prosecutions under CPUTR regulations is kept by the Office of Fair Trading. Prosecutions for misleading claims for health products since May 2008, showed a total of zero.

How could this be?

I had learned that the only way a consumer can get access to the Office of Fair Trading or TSO is through Consumer Direct. I therefore made another attempt to get the OFT to enforce the CPUTR concerning false claims that the product would make the consumer lose fat. I chose Skinny Water again, because there was no ambiguity about the claim. It was written on the side of the bottle:

“Skinny Water’s ingredients have been shown to suppress appetite, block carbohydrates from converting into fat, and increase fat burning...”. My modest objective was to get a TSO to require the vendor of Skinny Water (Bio-Synergy Ltd) to show this claim was true, because its veracity had been challenged by a well-informed consumer. I assumed that the CD staff would be aware that this was what the CPUTR rules required, but that assumption proved to be misguided.

I called my local TSO, but was immediately transferred to the East England CD, where my call was taken by Laura. The whole conversation was recorded, and the CD have kindly sent me a copy of the recording. It lasted 17.24 minutes: if you want to hear every

word it can be accessed on the HealthWatch website.

The interesting bit starts at 1.45 minutes, where Laura asks me to briefly describe my complaint.

I explained that I believed the claim that Skinny Water increased fat burning etc. was not true. She took notes, and then (at 2.56) asked me if I had been using the product for long? Otherwise how could I show that the claims were not true? I said I understood that the CPUTR rules put the onus on the vendor to validate claims, not for the consumer to disprove them.

At this stage the rapport between us deteriorated. She asked me what I paid for the water (3.27), and said she would pass on the information to the TSO, but there was no commitment that they would communicate with me unless they wanted further information (5.58).

Despite continuing the conversation for another 10 minutes it was obvious that my ambition to get a TSO to test the claims about fat burning, etc. were far too optimistic. Laura assumed that my ambition must be to get a refund on my money (£1.60) that I paid for the water. Whatever information she passed on could not have made any sense to the TSO, since when we parted Laura had not grasped that fact that I was not seeking a refund of £1.60, but a prosecution of Bio-Synergy.

I think that the present situation is a scandal. Far from the new CPUTR making it easier to control false claims for slimming products by putting the onus of proof of claims about efficacy onto the vendor, the insertion of the CD in the information chain has made it virtually impossible for a legal challenge to those claims to get to the people whose job it is to enforce the law.

John Garrow
Emeritus Professor of Human Nutrition
University of London

References

1. Consumer Direct website www.consumerdirect.gov.uk
2. Rose L, Garrow J. False claims in health care: outlawed at last? *Medico Legal Journal* 2009; 77 (Pt 2): 66–68.

Published by HealthWatch

Press enquiries to Professor John Garrow: 01923 710665
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. Ross Mirvis, 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. Please note new address: newsletter1@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

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