FOR SCIENCE AND INTEGRITY IN MEDICINE

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WHY EVIDENCE MATTERS TO DR MARK PORTER

THE 23RD HEALTHWATCH AWARD was presented to Dr Mark Porter MBE; GP, journalist, media doctor and presenter of BBC Radio 4's 'Inside Health'. Receiving his award at the Medical Society of London, Dr Porter gave an insight into his unique career, and explained that his listeners, readers, and patients are why evidence matters.

"For me, it's not about the data, but how it influences clinical practice—what difference is made to the man or woman sitting in front of me in my consulting room.

Like most, I was a naïve young doctor who did what his boss told him, whose boss did what his boss told him because it was what his boss did, and that's how we based a lot of our practice. It's been a gradual transition to the importance of evidence, and now, I'm a complete convert.

My job is not to be an expert. It is to put experts into the public domain. It is to ask questions, and to give them the chance to explain the rationale behind evidence-based medicine; what it is and why it matters to the public, so that everybody out there can make an informed decision about their future.

I don't need to sell evidence to my listeners—they absolutely get it. Less straightforward is the way that research is reported. It's hard to see through the veneer of gloss that's put upon it by the journalists, or the journal, or by the researchers themselves. Press releases from journals 'big things up'—it's not surprising that the story gets slightly confused.

Significance is not well understood. I'm not talking about statistical significance here; I'm talking about what difference this finding might make to their lives. If something doubles the chance of you getting some condition, but your chance of getting it is pretty near zero in the first place, it's irrelevant.

"the evidence that we're looking at is not always pertinent to the people that we're treating"

Terminology is a struggle. I'm hopeful that there will be a third series of 'Inside Language', a series with Professor Carl Heneghan and Dr Margaret McCartney looking at terminology, from surrogate markers to t-tests, which has proved popular.

My job is to teach the public to be a little bit sceptical, a little bit cynical about what they read, look for vested interests, understand why something might be, and understand how to ascertain if it's relevant to them. But, I do have concerns, and I just want to share a couple of those with you.

The first is the relevance of the data.

As we bow to the altar of evidence-based medicine, sometimes we're blinded by the light. We need to be critical about the relevance of the data that we're looking at, in terms of clinicians like me, working at the coalface of the NHS. A lot of that data ends up informing and producing guidelines, and we need to look at how

Dr Mark Porter speaking at the 2015 HealthWatch Annual General Meeting

rigidly we adhere to those guidelines when faced with very different individuals.

The vast majority of patients that I see, perhaps 90%, wouldn't get into a clinical trial because they don't meet the criteria—yet they're the patients that we're treating. Still a large proportion of the data that we're looking at is coming from on high. We don't know how relevant it is to the people we're actually seeing on a day-to-day basis.

An example I use is that of the contraceptive pill. The early explanatory trials show a failure rate of 1 in 300, so if you had 300 women on the pill for a year, one would expect to get pregnant. But in the real world, where trial conditions don't apply and all sorts of things arise, that failure rate approaches 1 in 10. That's a huge, huge difference. But it's the sort of difference that patients can grasp straight away, and suddenly they see the rationale behind long acting contraceptives.

I'd like to see more pragmatic trials—but they're not the be all and end all, either. I just want to emphasise that the evidence that we're looking at is not always pertinent to the people that we're treating.

My second concern is that the selective data is then used to produce the guidelines. I'm all for guidelines. I'm all for best evidence based practice. But I worry about how rigidly we apply it, because of external pressures. We have QOF, prescribing initiatives, pressure to follow published guidance. Even if the guidelines were perfect—how do we know that we're applying them correctly to the person that's sitting in front of us?

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Prizes and a new committee member

TWO OF THIS YEAR'S student prize winners joined us at the AGM to receive their prizes, and one has now joined us on the Committee. Andrew Fulton (right) a student of dentistry at Barts and the London School of Medicine and Dentistry, took first prize in the 2015 HealthWatch Student Awards and we were pleased that he has agreed to be one of our student representatives.

This year, all of our winners are studying in London. Runner up was Wong Li Chin (left, with Nick Ross, who presented the prizes). Li Chin is a medical student at University College London. Our second runner up, Vivek Vijay, also a UCL student of medicine, was sadly unable to attend to receive his prize. We extend our admiration and warmest congratulations to them all.

The HealthWatch Student Prize Competition started in 2002 as a way to promote and reward high quality of training in evidence for UK healthcare professionals. The competition is open to all medical, dental, nursing and midwifery students, and students of professions allied to medicine in the UK. Entrants are invited to rank and critically evaluate a series of clinical trial protocols. Winners receive £500, and up to 5 runners-up may receive a cheque for £100.

In this, the fourteenth year of the competition, the number of entries continues to grow, but are still overwhelmingly from students of medicine. The lack of participation by nursing and midwifery students is of concern, especially as they are often the first point of call from members of the public seeking advice about the advisability of trusting media reports on the latest 'wonder-drug', particularly in the field of women's health.

We thank Cambridge University Press for their generous sponsorship of the 2015 competition; and David Bender, Sally Gordon Boyd, Walli Bounds, Roger Fisken and John Kirwan for their administrative and scientific contributions.

Ban on homeopathic prescriptions in sight?

A BAN ON GPs PRESCRIBING homeopathic remedies could be on the horizon, as the Department of Health is to consider blacklisting the treatments, thanks to pressure from the Good Thinking Society.

The consultation will consider having the remedies added to Schedule 1 of the NHS (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004—otherwise known as 'the Blacklist'.

The Blacklist, maintained by the Department of Health, lists products that cannot be reimbursed at a pharmacy using NHS funds, effectively making it impossible for GPs to prescribe them. The Good Thinking Society, founded by Simon Singh, has been in correspondence with the department for the last year, arguing that homeopathic remedies meet many of the criteria for inclusion on the list, including a lack of evidence of clinical efficacy, a lack of cost-effectiveness, the availability of the product over the counter at low cost, and the availability of cheaper alternatives.

In June, the Good Thinking Society threatened the Department of Health with judicial review after they continued to reject the arguments. However in November the Department of Health responded by announcing plans for a consultation in 2016 on the subject of blacklisting homeopathy. The Good Thinking Society have been told they will be invited to be part of that consultation.

Media coverage on the case can be found at http://goodthinking-society.org/about/good-thinking-media-coverage/

The Guardian, 13 November 2015
http://www.theguardian.com/lifeandstyle/2015/nov/13/homeopathy-prescription-banned-from-nhs

NEWS IN BRIEF

IN AUSTRALIA popular but unproven 'natural' therapies could be stripped of the partial subsidy currently received through private health insurance, following the publication of a long-awaited review. The Review of the Australian Government Rebate on Natural Therapies for Private Health Insurance, released in November, examines the evidence for 17 therapies, including aromatherapy, ayurveda, homeopathy, kinesiology, naturopathy, reflexology, and yoga. It concludes that the rebate should be paid for insurance covering such services "only where the Chief Medical Officer finds there is clear evidence they are clinically effective. Such clear evidence has not been found." More than half of Australians—about 13 million people—have general treatment policies, many of which currently provide cover for alternative medicines.

http://health.gov.au/internet/main/publishing.nsf/content/phi-natural-therapies

ALLTRIALS: *The Economist* has built an interactive publication bias simulator to show how hiding clinical trial data impacts medical evidence. Run a few clinical trials yourself, decide which trials to publish, and see how easy it is to distort the evidence by withholding results.

http://www.alltrials.net/news/the-economist-publication-bias/

THE JAMES RANDI Educational Foundation has shared a free 10-part video lecture series which compares science-based medicine with complementary and alternative methods. Topics include: acupuncture; chiropractic; energy medicine, homeopathy, and science-based medicine in the media and politics. The lectures range from 32 to 45 minutes.

https://www.youtube.com/playlist?list=PL8MfjLNsf_miVcNu6eJMNigAMNwQkk_B9

CHAIRMAN'S REPORT *by Dr James May*

THE LAST YEAR has been characterised by increasing joint working between HealthWatch and organisations which share our goals such as Sense about Science and The Nightingale Collaboration. The number of issues which HealthWatch is contributing to seems to increase year on year. We have always had a broad focus on promoting evidence based medicine across healthcare. However our focus shifts as time passes and new challenges appear.

Alternative medicine, the behaviour of drug companies, political support for screening programmes, corruption within orthodox medicine, support for whistleblowers and the regulation of medicines through trading standards and medical regulation bodies have all been and continue to be areas of action for HealthWatch. With such diverse activities it is very helpful to have other organisations working alongside us contributing their resources. Our expertise in health is often a resource for them too—and we have contributed to publications and projects by Sense about Science in particular.

Alan Henness from the Nightingale Collaboration has joined the HealthWatch committee, and has been reconstructing the HealthWatch website to make it more user friendly, for which we are very grateful. We recommend revisiting the website if you haven't done so recently to see the progress that has been made.

The Medical Innovation Bill, proposed by Lord Saatchi, almost became law under the last parliament. In March we held a debate at King's College London with Nick Ross and Nigel Poole QC opposing the Bill and our patron Mike Rawlins and parliamentary lawyer Daniel Greenberg supporting the bill. The Bill's premise is that current law restricts medical innovation, although the opposition argued strongly that liberalising the law risks a quacks charter where the only restriction on innovation after a few administrative hurdles is the whim of an individual clinician. Only three people voted in favour of the Bill, whilst 130 people voted against with 13 abstentions. The video of the lively debate is on the KCL website (see http://www.kcl.ac.uk/nursing/newsevents/news/2015/The-Healthwatch-Debate-The-Saatchi-Bill.aspx) and is recommended viewing. Afterwards there was some hopeful talk that the debate may have taken the wind out of the sails of those drafting the Bill. Sadly however, the Bill has been resurrected with some changes and had its second reading in the House of Commons on the 16th of October. Concerns remain, over weakening of negligence provisions which provide immunity to irresponsible doctors, despite protests from those proposing the Bill.

LES ROSE has after some considerable challenges managed to recruit a full team of investigators to the CPR2 study which is designed to see how effective consumer legislation is at regulating claims made for marketed health products, and the extent to which Trading Standards legislation is actually enforced.

HealthWatch has continued to raise concerns about national screening programmes, ably supported by our previous award winners Michael Baum and Margaret McCartney among others. There is far wider acceptance now that breast screening has significant risks, and that the benefits have been overstated. However, breast screening and the national cardiovascular risk screening programmes remain in place and clinicians are encouraged to promote them despite the evidence.

Homeopathy has long been a test case target for HealthWatch, symbolising as it does the core problems of alternative medicine—the lack of a rationale and the lack of supporting evidence. In 2010 the parliamentary Science and Technology Committee concluded that the NHS should cease funding homeopathy because of lack of evidence of efficacy. Since then NHS information has been clear on the lack of evidence for any homeopathic claim, and yet funding continues. In the current financial climate we need to keep up the pressure for common sense to prevail in cutting services we know have no benefit as a first priority.

In September HealthWatch ran a stall at the European Skeptics Congress at Goldsmith's college, and Susan Bewley and I contributed to a panel discussion on the question of whether there are orthodox medical practices we should be sceptical of. We raised issues of bias in clinical trials and the medicalisation of society. There were also lectures by HealthWatch award winners Simon Singh and Edzard Ernst as well as a lecture by Sense about Science promoting their 'Ask for Evidence' campaign and chaired by Alan Henness. Medicine was therefore a central point of discussion at the Congress.

We have yet to make use of £50,000 which was given to HealthWatch to fund research. Our medical student representatives are compiling suggestions of projects which could be undertaken by students which might make worthwhile use of this generous fund. We are open to suggestions and ideas from anyone else too.

The Newsletter continues to provide penetrating and relevant articles of very high quality, and Mandy Payne our Newsletter editor also contributes the majority of our twitter account activity which is well worth following. If you have articles up your sleeves or as a student would like to have something published then please contact Mandy. As always, we are indebted to our barrister, Caroline Addy, who helps us steer clear of potential libel.

I am very grateful to the support of the committee, to the vice chair Debra Bick, to our secretary David Bender who keeps the show on the road, to our treasurer Anne Raikes, to other Committee members Susan Bewley, Les Rose, Diana and Malcolm Brahams, Keith Isaacson, John Illman and Alan Henness. We have also had very helpful contributions from our Medical Journalist representatives James Illman and Tom Moberly as well as considerable involvement from our student and trainee doctor representatives Kenneth Chan, Sofia Hart, Ruth Lamb and Jolene Galbraith.

James May
GP, London, and chairman of HealthWatch

Why evidence matters to Dr Mark Porter ... *continued from front page*

External pressures mean that guidelines get rigidly applied. They become tramlines. And I think that's a problem.

I recently met an elderly gentleman with a humeral fracture in a falls clinic. He had diabetes, atrial fibrillation and other conditions, and had felt lightheaded for months. A number of doctors, consultants, had seen him and treated him according to the guidelines. He was taking sixteen different medicines, including six that lowered his blood pressure. I have no doubt that getting blood pressure to target improves outcomes for 1,000, 10,000, even 100,000 diabetic patients. But that doesn't tell me what's going to happen to the patient sitting in front of me. He could have fallen and hit his head, or broken his hip. We could have killed him. That's something that we need to consider in general practice.

Scepticism doesn't stop once you have some evidence, or have guidelines. I don't have answers. If pushed, I'd like to revert to that basic tenet of clinical practice: *Primum non nocere* or, as I say to my patients—if in doubt, do nowt."

Mark Porter spoke on accepting the HealthWatch Award at the Annual General Meeting, 20 October 2015 at the Medical Society of London.

His speech was captured here by Sofia Hart

EDZARD ERNST MUST HAVE BEEN A SHOO-IN FOR THE JOHN MADDOX PRIZE!

THE 2015 JOHN MADDOX PRIZE for Standing up for Science, awarded every November to "scientists under fire", went to Edzard Ernst, Emeritus Professor at Peninsula Medical School, and Susan Jebb, Professor of Diet and Population Health at the University of Oxford. Professor Ernst was nominated by HealthWatch Committee member Les Rose, and seconded by our president Nick Ross who here shares his nomination letter.

Sir John himself must have seen in Edzard a kindred spirit: an indefatigable champion of scientific methodologies, a deeply humane thinker and writer, and a researcher with such intellectual strength and personal humility that he abandoned his own ingrained attitudes in the light of scientific findings. Above all, he is a courageous advocate of science who faced ridicule and denigration from the highest levels—a personal campaign of vilification that significantly damaged his career—and yet who refused to retreat in the face of this hostility.

As Edzard Ernst describes in his beautifully written, humorous and accessible autobiography, A Scientist in Wonderland, he was brought up by alternative practitioners into a world of alternative medicine where evidence-light concepts like hydrotherapy, homeopathy, naturopathy and Kneipp therapy were part of his life. They were, as he discovered, even regarded as normal even when he enrolled at medical school.

Yet while it did not then occur to Edzard to challenge these shibboleths he was never one to be cowed by what others thought. He was a natural questioner, and from early in his career he discovered that asking questions, even through honest and diligent research, did not always endear itself to everyone. Having been brought up in postwar Germany he wanted to know what doctors, medical schools and supposedly learned journals did in the Nazi era—an inquisitiveness that was not popular with many of his German and Austrian compatriots, especially when he revealed that Nazi sympathies had persisted in medicine after Hitler's downfall. His first job on the wards in 1970s Munich was the start of a gradual realisation that even contemporary medicine might need to be questioned. He was expected to learn about neural therapy, herbal medicines, cupping, and leeches and watched in awe as a colleague practiced dowsing to select the right course of treatment. It began to occur to him that some of his colleagues, "used homeopathy and other alternative approaches because they could not quite cope with the often exceedingly high demands of conventional medicine."

"Time and again Prof Ernst and his colleagues found ingenious ways to put complementary medicine claims to the test and time and again found them wanting. Each time they did so he was pilloried"

Thankfully, other seditious thoughts soon dawned on him and after spells in Germany, Britain and Austria as a medical researcher (exploring the viscosity of blood), in rehabilitative medicine and in clinical academic management, he applied for the job that would make him revered and reviled in equal measure. In 1992 Sir Maurice Laing, a passionate believer in complementary medicine, endowed the UK's first professorial post which was intended to reveal the true value of alternative treatments. Edzard Ernst, alternative practitioner and rigorous scientist, was the obvious choice. But whereas complementary treatments had been an unremarkable part of his career up to now he quickly found himself an object of contempt. He was deeply mistrusted by complementary and alternative medicine (CAM) enthusiasts but not entirely accepted by conventional practitioners, and was soon to be despised by pseudo-scientific colleagues whom he found teaching what he came to regard as a steady stream of claptrap including faith healing, various forms of traditional Chinese medicine and homeopathy. And while at first he was thrilled that the Prince of Wales, no less, had requested a copy of his inaugural lecture, he was unprepared for a battle with the prince and his supporters that would last two decades and result in the closure of his unit.

Those two decades are a story that John Maddox would have relished: of scientific resourcefulness and stoic courage in the face of adversity, accompanied by mounting frustration about whether reason can argue on level terms with unreason. Time and again Ernst and his colleagues found ingenious ways to put complementary medicine claims to the test and time and again found them wanting. Each time they did so he was pilloried, and on the few occasions where his team did find some substance to apparently quirky treatments he found little comfort among conventional clinicians.

But it is his stand against Prince Charles that shows Edzard Ernst as such a champion of true science and brave defender of scientific logic, methodology and integrity.

The same year that Ernst took his chair at Exeter the Prince of Wales launched his Foundation for Integrative Medicine. It was as though two battleships had been put to sea, both commissioned by believers in CAM and intended by their founders to be part of the same flotilla. But while one continued to be powered by credulity and backed with the imperial might of royalty the other had been hijacked by a mutinous captain bent on charting a sceptical course.

Open hostilities broke out in 2005. Prince Charles's Foundation persuaded the Department of Health to publish a complementary medical guide for patients, a booklet whose implied claims for alternative therapies so appalled Ernst that he denounced it as "frankly inaccurate" and "misleading". He expected the worlds of science and medicine would be equally outspoken but found (with the most notable exception of HealthWatch) he was a surprisingly lonely voice.

Things quickly went from bad to worse for Professor Ernst. He was interviewed for a report compiled by Christopher Smallwood, a retired economist who had been asked by the Prince of Wales to look into the cost-effectiveness of CAM, and as a result was sent a copy of the draft report. What happened then is open to different interpretations. According to Ernst he was contacted by a trusted journalist on *The Times* who asked him to break the press embargo. He refused to do so but he did condemn the vacuity of the Smallwood's conclusions, and his criticisms made headlines. According to Sir Michael Peat, Prince Charles's private secretary who wrote to the Vice Chancellor at Exeter, Ernst had breached confidentiality and was therefore, implicitly, dishonest.

The effect of this regal intervention was electrifying. It laid a smokescreen across intellectual deficits of the Smallwood report and placed Professor Ernst under formal review and threat of dismissal. After a year-long investigation he was grudgingly cleared of wrongdoing but, bizarrely, although he had been exonerated, he was warned that if he did such a thing again he would be sacked.

In short, he had embarrassed the university, had offended people in high places, had caused controversy which could threaten financial sponsors and was, it could be reasonably supposed, never to be trusted by the vice chancellor again.

In 2007 a television programme called 'The Meddling Prince'

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THE HUNT FOR THE PINK VIAGRA

I'VE BEEN CHALLENGING the hunt for the pink Viagra since the hunt began—which was as soon as it was clear that the blue Viagra would be a financial blockbuster in 1998. The field has been crowded and the hunt has seemed interminable as first one drug and then another and another failed to show safety and efficacy during clinical trials and was discontinued.

In 2015, however, the industry finally achieved victory in the US with the Food and Drug Administration's (FDA) approval of flibanserin (brand name Addyi™) as a treatment for 'female hypoactive sexual desire disorder'. It's useful to dig into the history of this whole 'pink Viagra' story for what it shows us about changes in the drugs industry, in the relation between scientific experts and commercialization, and in the cultural meaning of sexuality. The full explanation for why flibanserin was finally approved in 2015 involves many unexpected participants and unexpected events and deserves a book-length description, but here's a brief narrative.

In 1998 Viagra was approved by the FDA to treat male sexual arousal disorder (erectile dysfunction) following cooperation between urologists and a drug industry newly interested in sexuality as a medical subject. Urologists had lost surgical opportunities to treat kidney stones and benign prostate hypertrophy as a result of the innovation of lithotripsy (a procedure that uses shock waves to break up stones) and new medications in the 1980s, and they became interested in the new area of sexual medicine which was becoming legitimized in the 1990s. The extraordinary financial and cultural acceptance and success of Viagra stimulated established companies and new investors and even more urologists to look into developing a comparable female market.

Over the next 15 years, numerous international medical meetings sponsored by drug companies were held to debate shifting diagnoses and emerging potential treatments for women's sexual complaints. Conferences, organizations and journals multiplied as more researchers were attracted to the new subspecialty area and its backdrop of generous commercial funding. The drugs under consideration moved from blood flow products like Viagra to androgenic hormones to brain transmitter drugs. The focus of intervention shifted from sexual arousal, as with erectile dysfunction, to sexual desire, which was hard to pin down, much less to measure, and increasingly emphasized distress about sexual problems as well as the sexual problems themselves. The development of questionnaires to measure subjective elements such as distress, sexual satisfaction and sexual desire became a subsidiary industry in itself.

A PARALLEL DEVELOPMENT has been the FDA's increasing interest in consulting not just with scientist and medical experts as part of their work, but also with patients. One of several initiatives in recent years, Patient-Focused Drug Development (PFDD) began in 2012, and recruited patients' participation to illuminate areas of "unmet medical needs," where diagnoses were evolving or no effective medications were available, especially with regard to serious or life-threatening conditions. Female Sexual Dysfunction (FSD) was identified as such an area following a process of public petition and comment, and a 2-day PFDD meeting on FSD was scheduled in October, 2014, that would be open to interested patients, advocates, industry representatives, and the public. A group of perhaps two dozen patients and doctors representing an advocacy group, Even the Score, participated in that meeting. Even the Score had connections with Sprout Pharmaceuticals, manufacturer of the as yet unapproved new drug, flibanserin.[1-4]

Sprout, a one-product company, had been formed specifically for flibanserin. Previously owned by major German drugs company, Boehringer-Ingelheim, rights to flibanserin were sold in 2011 after the drug was rejected by the FDA because of poor efficacy and a worrisome safety profile. Normally, such a rejection would be followed by the discontinuation of research and promotion, but, according to *Mother Jones'* recent investigative research,[3] crusading urologist Irwin Goldstein persuaded investors who had previously owned a testosterone drug to consider taking on flibanserin. They formed Sprout, but again the drug was rejected by the FDA.

The final act occurred when Sprout hired a former FDA official and a public relations company, and Even the Score, a supposedly spontaneously formed grass-roots campaign, was formed.[1] They created a website and lots of buzz as they recruited some noted feminist organizations and women's health groups, and sent letters to Congress and the FDA urging "equal" consideration for women's sexuality drugs, given that several (the group inaccurately said "26") drugs were available for men.[5,6] They even recruited some Congress people to write to the FDA.[4]

The PFDD meeting on FSD in October, 2014 at the FDA was as much rally as scientific meeting, as the pro-drug patients brought to Washington by Even the Score told their stories. The air was full of irrelevant calls for "gender equity" as if the FDA were engaging in some misogynist war on women's sexual fulfillment. Many of the pro-drug patients in fact complained of a lack of sexual drive (not responsiveness), and probably would have been ineligible for trials had the FDA insisted on the new DSM-5 nomenclature (approved in 2013, but resisted by Even the Score) that deleted 'hypoactive sexual desire disorder' (HSDD).

"Boehringer-Ingelheim sold the rights to flibanserin in 2011 after the drug was rejected by the FDA because of poor efficacy and a worrisome safety profile. Normally, such a rejection would be followed by the discontinuation of research and promotion"

Throughout 2015, following the PFDD meeting, Even the Score kept up its publicity (social media, Congressional briefings, CME courses, etc.) while a feminist health coalition formed in 2014 (New View Campaign*, National Women's Health Network**, Pharmed-Out***) persisted with evidence-based challenges. The climax of all this activity occurred on June 4, 2015, at an expanded Advisory Committee Hearing convened by the FDA to evaluate the safety and efficacy of flibanserin for the treatment of HSDD.

Flibanserin is a central nervous system compound that affects several neurotransmitter levels in the brain in ways and locations not yet identified. The drug must be taken daily for an indefinite period of time, and the clinical trials showed trivial benefits over placebo (e.g., one additional sexually satisfying event per month, improvement on distress questionnaires). Drinking alcohol while taking flibanserin exacerbates its adverse effects such as dizzyness and fainting, and it was clear that FDA approval would have to be accompanied by usage warnings and special prescriber and pharmacist training. Nevertheless, the advisory committee voted in favor of approval—with warnings—and made it clear in their post-vote comments that they were swayed by the emotional presentations by pro-drug patients and physicians who were again brought in by Even the Score.[7]

The FDA accepted the committee's recommendation, and approved flibanserin, now Addyi, on August 18, 2015. Two days later, it was announced that Sprout Pharmaceuticals had sold Addyi to global giant Valeant Pharmaceuticals, for $1 billion.[8] Billion with a B. The drug was made available on October 17, and now, only

** http://newviewcampaign.org/, ** http://pharmedout.org/, ***https://www.nwhn.org/*

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CONSIDER THE HARMS

From Margaret McCartney, GP, author, and HealthWatch patron, Glasgow

TO THE EDITOR,

It's difficult to know where to start to respond to Nick Ross' essay on his piles and medical confidentiality. The accusations of "groupthink"? Or the assertion that "in socialised medicine, epitomised by the NHS, we have exchanged the privilege of being a private customer with the benefit of sharing our risks and burdens equitably ... individual rights, and even autonomy, must be balanced explicitly against the needs of others".

Ross argues against medical privacy, or as he puts it, "secrecy" even when applied to medical records. He argues that medical records should be published publicly.

Ah, if only it was all about haemorrhoids. In the NHS front line life is somewhat different. Here in general practice we hear about everything. Domestic abuse and violence, abortions, HIV, sexual infections, genetic screening, child abuse. None of this should be embarrassing, but any of it could lead to further abuse, violence, unemployment, the loss of a family home, rented accommodation; this is not just about the feelings that one has about one's own medical history but what others could do with knowledge of it. Employers can be good but also can be discriminatory; as can landlords, workmates, friends, potential marital partners.

Ross provides no evidence that citizens will be unafraid to speak to their doctors of matters they consider to be important were they to know that all their medical records would be made public. Ross crucially does not make an assessment of likely harms or show interest in investigating what those harms might be. How many people will be afraid of asking for an HIV test publicly were his proposals enacted? How many is acceptable for the benefits he supposes?

For I am not sure that the benefits he foresees are so great. There is no doubt that NHS IT is a mess. The current priority is for a record that health professionals and patients can access across secondary and primary care. There is no doubt about this, but Ross wants something more. Big data may be very useful, but only when its uncertainties are appreciated. The current furore in the *BMJ* regarding weekend mortality statistics is a case in point: the figures are misleading because they have not been adequately corrected for case mix, something that practitioners on the ground recognise instantly as problematic. The crux is not of big NHS data being used by bone fide trained researchers who understand confidentiality (and it already is used widely for this purpose). It is of data mining by commercial companies seeking quick fixes and financial opportunities but lacking the knowledge of the uncertainties big data presents.

Surprisingly, while Ross calls himself a natural sceptic, he relies on name dropping to make his case that medical confidentiality "delays progress". This is nonsense, as is the claim that using the NHS somehow means a moral case for giving up ones' privacy. Already we have seen a large public uprising against 'care.data', for citizens do not trust what the government is offering. What will happen if the NHS offers the same? Who will die because they do not seek timely help for concerning symptoms? The enemies of progress are elsewhere, and if the people who concern themselves with medical progress do not also consider the harms that good intentions can do, we are condemned to go forever in circles.

Yours,
MARGARET MCCARTNEY

RELIGIOUS DISCUSSIONS IN THE MIX

From Frank C Odds, Emeritus Professor of Medical Mycology University of Aberdeen Fungal Group

TO THE EDITOR,

I am not sure that HealthWatch is the appropriate forum for discussions of religious belief. But the die has been cast, and I cannot let James May's article (Scepticism and Religion, *HealthWatch Newsletter* issue 99, Autumn 2015) pass without comment.

The article rehearses the tediously familiar tropes of those who wish to justify their superstitious beliefs held in the absence of evidence, right down to listing great scientists of the past who were Christians. Great: so now argument from (long dead) authorities is the sort of thing we can look forward to in future issues of Healthwatch?

Like most defenders of a Christian faith, May does not deign to enlighten us why he believes in the Jesus trinity, and not Allah, Yahweh, Vishnu, Shiva, Lakshmi and the rest. Nor does he advise us exactly what his faith consists of. If, like most Christians of my acquaintance, he believes in a personal god who responds to prayer with miraculous interventions then he needs to explain why he associates with an organization dedicated to evidence in medicine. There can be no scientific medicine if a god can intervene supernaturally to influence the outcome of disease.

Most concerning of all is May's assertion that "science is not the only field of knowledge". One is used to hearing that religious belief is somehow a different form of knowledge (Gould's 'non-overlapping magisteria'), but history, law, politics and economics?! History and law ever-increasingly turn to science to solve their problems, because of the unreliability of personal testimony as evidence. Economists also base their work on the scientific method; it's just that their hypotheses have yet to reach the strength of a decent scientific theory.

If politics is a 'systematic field of knowledge' then surely we should accept every opinion of David Tredinnick as a valuable insight into the field of medicine. Indeed, it is surprising that 'medicine' was not included on May's list of different fields of knowledge. Those who favour homeopathy, acupuncture, chiropractic and the rest often argue their systems represent a different type of knowledge. Why should they not have equal access to the pages of Healthwatch?

"Poetry, music or visual arts often communicate true knowledge far more profoundly and economically than science"? No: they communicate emotions, not truth or reality; so does religious faith. Emotions are the product of the nervous system; the province of neuroscience.

HealthWatch stands for the real world, for people with their feet on the ground who favour robust clinical evidence over testimony, anecdote and superstition. Throwing religious discussions into the mix opens the door to every kind of evidence-free irrational belief and certainly drives a coach and horses through my perception of the organization.

Yours,
FRANK ODDS

"Kwakzalverij en valkuilen voor wetenschappelijk onderzoek" ... sounds Dutch to me!

IN DECEMBER 1989, 26 years ago, I sent a letter to a Dr Cees Renckens in the Netherlands in response to an enquiry regarding a partnership between "The Campaign against Health Fraud" (later to be known as HealthWatch) and the "Vereniging tegen des Kwakzalverij en de Nederlandse" (see below). As I wasn't quite sure whose side they were on I was naturally a little suspicious. With the wisdom of hindsight I think I was a bit offhand with the good Dr Renckens and I heard no more from him until the 26th June last year. In this letter he honoured me with an invitation to address the annual general meeting of his organisation in Amsterdam at a symposium entitled "Alternatieve Behandeling van Kanker: Is er nog een probleem?"

Now without understanding a word of Dutch even I could translate those words. "Is er nog een probleem?" You betcha, er nog umpteen probleemer!

In his letter of invitation Cees Renkens added the following:

"You are well known amongst Dutch quackbusters and/or oncologists by your long standing dislike of alternative healers and their fellow travellers like HRH Charles. We hope you can give us a report on the state of affairs regarding 'CAM' and cancer in the UK. This could hopefully give us some insight in prevalence, trends and risks of CAM in this field. We are also interested in the popularity of CAM in the UK in general and would like to know the position of CAM in regulations and in the debate around the Saatchi Law."

I could hardly refuse such a flattering invitation from an organisation that, translated into English, appeared to be "The Dutch Society Against Quackery." After a couple of e-mail exchanges we decided to narrow the focus of my talk and settled on "Quackery and the Pitfalls of Research: The Saatchi Case", and the date, Saturday October 3rd.

Before I describe my delightful weekend in Amsterdam, a few words about the Dutch Society against Quackery from their website:

> Discontentment with the massive violations of the influential Dutch prime minister's (Johan Rudolf Thorbecke) health laws led to the foundation in 1880 of the Dutch Society against Quackery. Within a few years the Society had over 1100 members. Initially quackery mostly consisted of the unauthorized practice of medicine and the peddling of industrially manufactured 'secret remedies'. After World War II, however, the energy of the Society focused mainly on magnetizers, especially after they gained support from the field of parapsychology, lay-manipulators of the back and herb doctors. The most important object of the Society since 1980 has been the fight against so-called 'alternative medicine,' of which Chinese acupuncture, homeopathy, manipulative therapy, anthroposophical medicine and naturopathy are prominent targets. Despite numerous costly lawsuits the Society still survives and is probably the oldest as well as the largest of its kind in the world.

They are therefore worthy of our respect as the senior society, the largest of its kind, with the guts to use the word "quackery" in their title and the courage to take on the quacks despite costly lawsuits. Their definition of quackery that has allowed them to retain their charitable status is as follows.

"Quackery is any way of professional acting, providing advice or giving assistance in relation to the health of humans or animals which:

- *is not based, founded on verifiable logical or empirically sustainable hypotheses and theories;*
- *is actively disseminated to the public, without prior verification within the profession on efficacy and safety;*
- *are often applied without contact and/or consultation with fellow practitioners of regular medicine.*

The Dutch Society against Quackery (VtdK) emphasizes that the term 'quack' or 'quackery' does not necessarily imply the accusation of cheating or fraud."

I was collected at Schiphol by Dr Renkens and transported to a quaint old townhouse converted to a boutique hotel overlooking the floating flower market and within easy reach of the Rijksmuseum and the Van Gogh museum, both of which were on my agenda for the weekend. The Rijksmuseum was first on my list because it had recently undergone a huge refurbishment and also housed some of my most favourite paintings. The interior of the building is spectacular and I enjoyed the way Rembrandt's huge painting "The Nightwatch" was displayed in all its histrionic glory.

IN THE SAME gallery I found Vermeer's small, modest and quiet painting of the kitchen maid poring milk from a jug, you could almost hear the tinkle as the milk hit the bowl. Nearby I discovered a painting by Jan Steen entitled the Quack doctor. As one is allowed to take photographs without a flash I added this picture to my collection that includes a number of Dutch genre pictures of quack doctors including my favourite by Rembrandt's gifted student, Geritt Dou, that was to be the first slide in my presentation the next day. As I pointed out in my talk, it is a moot point whether the patient was better off in the hands of a proper doctor instead of a quack in the "Golden Age" of 17thC Holland.

That evening I was treated to a jovial dinner in the Amsterdam Arts Club and that night I was kept awake by the quarterly chiming of the famous bell tower spire of Oude Kerk, opposite and on a level with my garret room.

Saturday morning dawned bright and beautiful and armed with a timed entry ticket, thanks to the thoughtful secretary of the Dutch anti-quackery society, I revisited the Van Gogh museum for the first time is 10 years. It is truly wonderful. But as often is the case I was reminded of a painting that would serve as a visual aid in my lecture. Van Gogh close friend and personal physician was Dr Gachet, a homoeopathist of course! Sadly Dr Gachet was unable to cure Vincent's melancholy and prevent his suicide.

On my way into the beautiful conference centre, another converted townhouse on the canal side, I was waylaid by pickets protesting against a conference dedicated to exposing the fraudulent claims of cancer quacks. I found this an energising experience and I look forward to the day when the entrance to the Medical Society of London involves running the gauntlet of a line of angry homeopathic physicians; that would certainly be a token of success.

The hall was packed with about 250 registrants and my presentation of the quack's charter also know as the Saatchi Bill, was well received. Sadly all the other talks were given in a tongue that sounded Dutch to me, so I have nothing more to tell you other than to offer their fraternal greetings.

I think it's time we had a joint meeting with the Vereniging tegen de Kwakzalverij en de Nederlandse, in many ways we speak the same language.

Michael Baum
Professor Emeritus of Surgery and visiting Professor of Medical Humanities, University College London

last words

Edzard Ernst and the John Maddox prize ...*continued from page 4*

finally caused significant numbers of scientists to rally to Edzard Ernst's defence. Clarence House was sufficiently embarrassed to seek to distance Prince Charles from Sir Michael's letter, but in the eyes of Exeter University their professor was a busted flush. Funds promised by Exeter to match Sir Maurice's Lang's endowment failed to materialise.

AT LEAST MORE people in the scientific community were now trumpeting his value, including Sense About Science and writers like Ben Goldacre and Simon Singh, and when Ernst was unrelenting in his battle with flimflammery in general and Prince Charles in particular—once memorably describing his Duchy Originals brand "dodgy originals"—he generally had the media onside. On another occasion, when asked by the Daily Mail if Prince Charles was a "snake-oil salesman" Ernst answered "yes" and, instead of being belittled, the subsequent coverage was neutral if not favourable.

Yet Exeter was to stab him in the back. The Prince of Wales' Foundation for Integrated Health announced that the Peninsula Medical School was to establish a postgraduate course in "integrated medicine", led by Michael Dixon, a prominent CAM believer who acknowledged both that he was endorsed by Prince Charles and that there was potential funding from a company that specialised in "natural remedies". Ernst fought this off but the atmosphere became increasingly difficult and, finally, with dwindling financial support from the university he and his supporters felt that early retirement was forced on him, and his entire department was closed down.

Retirement from his formal post has not meant retirement from combat. Professor Ernst continues to contribute to academic journals and his social media profile is formidable. He is the quiet believer who, through science, came to loudly question his own beliefs and stand up for what he had discovered. He is also, incidentally, a native German-speaker who has late in life taken British citizenship and writes more fluently in English than many people born in Britain. But above all he is a man with many scars as testament that he has championed science when others flinched and hid.

If John Maddox met Edzard Ernst today he would surely embrace him.

Nick Ross
Author, journalist and broadcaster, president of HealthWatch

The hunt for the pink Viagra ... *continued from page 5*

weeks later, the press is full of "I told you so" stories about abysmal sales—227 prescriptions in the first month, as contrasted with 600,000 prescriptions for Viagra in its first month.[9] Maybe the public got the message that the very limited benefits of flibanserin were outweighed by its often harmful side effects. More likely, it took a look at the pricetag (approximately $26/per pill, and that's for a daily drug).

Meanwhile, much damage has been done, not least to the credibility of sexology and the public's understanding of the causes of sexual problems. Most worrisome, perhaps, is the danger that Sprout's pressure tactics using poor evidence and emotional testimonials to recruit political support for bad drugs becomes routine.

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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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