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## PUBLIC HEALTH

# MHRA - no evidence of action on medical device complaint

The Medicines and Healthcare products Regulatory Agency (MHRA) is one of our most important government agencies—indeed, according to its website it is “recognised globally as an authority in its field”. The ‘field’ in question includes, again according to its website, “ensuring that medicines [and] medical devices ... meet applicable standards of safety, quality and efficacy”. Sadly, my own recent experience leads me to conclude that the MHRA is a long way from being the stout defender of the public interest that it claims to be.

In June 2015 I began a correspondence with the MHRA about a product called the Asyra bio-energetic screening system,<sup>1</sup> which is marketed by NutriVital Health Limited of Petersfield in Hampshire. This is a machine, promoted to private health practitioners, which claims to be able to help them discover the causes of their clients’ health problems by: “provid[ing] you with information about the energetic origins of your client’s challenges”. It relies on a notion called bioresonance, which the website defines as: “the concept that our organism can recognise and respond positively to informational signals that have been tuned to our own unique pattern of responses”. The company also explains that the ‘bioresonance information’ gathered by their equipment can be given back, or fed back, to the patient, a process which it refers to as ‘digital homeopathy’.

In order to use this marvellous system the subject holds a brass cylinder in each hand; the cylinders are connected by wires to an electronic device which displays various numbers and graphs on a screen. The

device is said to be able to report on the body's physical, chemical, emotional and mental state by running "a response test on the meridian points connected to the major organ systems". It uses a database including "metabolic disturbance, TMJ stress, neurotransmitter disturbance, food sensitivity, hormonal profile" and a variety of others so the practitioner can devise a course of treatment to "help restore balance". The Asyra website tells private practitioners: "Whatever your approach to healthcare, it can enhance your practice, improve patient outcomes and increase your revenue."

It is obvious to anyone with an elementary knowledge of biology that this gadget cannot have the capabilities that are claimed for it—indeed, it is about as credible as a medical device as James McCormick's notorious fake bomb detectors are in the field of security.<sup>2</sup> Having pointed this out to the person at MHRA, whom I shall call Joseph, I assumed that I would receive a speedy reply and that MHRA would be passing the details of my complaint to the Crown Prosecution Service in short order. In fact, I exchanged a series of emails with Joseph, who, first of all, told me that the Asyra system did not fall within their remit as it was not a medical device—this opinion was based on a statement on Asyra's website to the effect that it is not a diagnostic device, despite the fact that its website refers to the device "helping you to identify root causes of health issues" and that it quite clearly falls within the EU definition of a medical device, whatever Asyra might say. Joseph then told me that, because of 'confidentiality', he could not tell me anything about their investigations (and I mean not anything—process, evidence, conclusions and action were all, apparently, off limits).

Having got nowhere with Joseph I took my concerns to the relevant minister at the Department of Health, only to receive a series of letters from a civil servant who took exactly the same line: that everything about the MHRA's actions in respect of Asyra was confidential. In case anyone is in any doubt here, let me just say that what I asked Joseph (and the civil servant) were three very simple questions:

- Does the MHRA accept that Asyra has a case to answer?
- Has Asyra provided any evidence to support their claims for their machine?
- If Asyra cannot provide evidence, what enforcement action do MHRA propose to take?

At no point did I ask for details of the internal workings of the machine, the algorithms it uses or any other technical information. Nor did I ask for the names or addresses of the directors of the company or details of its financial arrangements (which are in any case publicly available for free from Companies House ) or anything else which could remotely be thought of as confidential information. As of today (8th July, 2016) the issue remains unresolved, more than a year after my initial complaint.

The internet is littered with adverts for many similarly implausible devices (see, for example, the Vega test) and many 'complementary' health practitioners are only too glad to do large wallet biopsies in exchange for applying one of these machines to the hands or bodies of gullible subjects. Yet our MHRA operates at a grindingly slow pace, and behind a veil of secrecy so opaque that the public are not even permitted to know whether they are operating at all. How can we avoid the impression that MHRA has a total lack of concern, not only about this wide range of highly dubious 'medical' devices being offered to the general public but also about the basic principle that what a public agency does should be accessible to the general public?

**Roger A Fiskin, Consultant Endocrinologist, Friarage Hospital, Northallerton, Yorkshire**

## References

1. Text quoted from Asyra website: <http://www.asyra.co.uk/the-asyra-system/>
2. Fake bomb detector seller James McCormick jailed. BBC News, 2 May 2013. <http://www.bbc.co.uk/news/uk-22380368>

3. Nutrivital Health Limited filing history at Companies House:  
<https://beta.companieshouse.gov.uk/company/04283340/filing-history>
4. Roy Health Consultant website: <http://www.royhealthconsultant.com/vega-test/>

### **Further to receipt of Dr Fiskens article for publication, HealthWatch contacted the MHRA, and they replied:**

I can advise that compliance cases are confidential as the information is subject to the Enterprise Act 2002 and therefore we are unable to share updates on compliance cases with those who refer them to us.

Section 237(2) of the Enterprise Act 2002 applies to specified information, which is defined in section 237(1) and section 238 (by reference to Schedule 14 and the regulations made under section 11 of the Consumer Protection Act 1987) to include information held by MHRA and relating to any business of an undertaking. Section 237(2) provides that such information must not be disclosed while the undertaking continues in existence. There are a number of exceptions to this general rule in Part 9 of the Enterprise Act 2002. These include disclosure required to fulfil the functions of this or other public bodies, European community obligations, consent and criminal investigations or proceedings etc. The MHRA's position is that none of the exceptions in Part 9 apply to the information apply at this present time.

MHRA review all allegations of non-compliance with The Medical Devices Regulations 2002 and the MHRA will investigate breaches of the Regulations identified and take action as appropriate to resolve them.

### **We then asked:**

*Q. If a device falls outside the Medical Devices Regulations 2002, but nevertheless poses a possible risk to public health because it is used by health practitioners as a diagnostic device without evidence of efficacy, would it be investigated?*

A. The agency has a statutory obligation to investigate products that fall within the definition of a medical device as outlined in the UK Medical Device Regulations 2002. This means that the powers we have as an enforcement body under the Consumer Rights Act 2015 and Consumer Protection Act 1987 would not be extended to products and services that fall outside of the definition of these regulations. We would however refer the case to the enforcement body that do have the responsibility to investigate and enforce under the applicable legislation whilst also offering our assistance in the form of regulatory advice and technical expertise.

*Q. What possibilities exist for MHRA under "appropriate action" in the case of medical devices?*

A. What constitutes as appropriate action is entirely specific to the situation. In the case of minor non-compliances that do not present a high risk, we may work with the manufacturer to help them achieve compliance with the regulatory requirements. However, for more serious infringements MHRA has powers under the Consumer Protection Act 1987 (CPA) and General Product Safety Regulations 2005 (GPSR) to issue the following:

1. prohibition notices (Section 13 CPA) to ban the supply of any medical device which is considered unsafe or does not comply with regulations
2. notices to warn (Section 13 CPA) which requires a manufacturer to issue a warning at his own expense about any relevant medical device, which are considered unsafe

3. suspension notices (Section 14 CPA) to suspend the supply of any goods for up to six months, where it is suspected that a safety provision has been contravened - compensation may be payable if it is later established that there was no contravention
4. forfeiture orders (Section 16 and 17 CPA) for goods where there has been a contravention of a safety provision
5. recall notice (regulation 15 GPSR) to remove dangerous products already supplied to consumers

The most serious offences could result in prosecution, which can carry a penalty of up to £5,000 per offence and/or 6 months imprisonment

## John Garrow, a passion for evidence

JOHN GARROW died at his home in South Cave, Yorkshire, early in the morning of Wednesday 22nd June 2016. He had been in good health until he suffered a stroke six weeks before. An eminent medical nutritionist with a passion for research, John was a member of the original HealthWatch Committee when it was formed in 1988 (HealthWatch went on to be registered as a charity in 1991) and our chairman for many years.

Ever modest, he wouldn't have appreciated a lengthy or extravagant memorialising of his achievements, but they were many. Professionally, John was emeritus professor of Human Nutrition at the University of London, honorary consultant physician at St Bartholomew's, St Mark's, the Royal London and Northwick Park Hospitals; head of the Nutrition Research Unit at the MRC Clinical Research Centre, member of the UK Department of Health Committee on Medical Aspects of Food Policy, chair of the Joint Advisory Committee on Nutrition Education and chair of the Association for the Study of Obesity. He was editor in chief of the European Journal of Clinical Nutrition from 1988 to 1999.

John's work was characterized by intellectual rigor and honesty, and he wrote with a simple but precise elegance. Edzard Ernst, in his blog of 23 June 2016,<sup>1</sup> recalls with pleasure working with him on what may have been the first ever randomised controlled trial of the peer-review system. Sending dummy manuscripts to 400 unsuspecting reviewers solicited a wide range of responses, and the conclusion that reviewers showed a small bias towards the orthodox.

Peter Wilmshurst remembers John as a champion of the highest ethical standards in medicine and research. They met in 1977 at Northwick Park Hospital—John designed and funded a study that Peter was researching, but when it was finished John declined to put his name on the paper. He said that he thought that he had not contributed enough. John's scruples over the amount of contribution required for authorship were admirable and, sadly, unusual. A decade later, when Peter was sued for libel after flagging misleading reporting of the results of a clinical trial, John had Health Watch set up a whistleblower support fund, priming the fund with a large personal contribution, and attending the High Court hearings to give moral support.

John had himself had problems with libel issues. Ben Goldacre's 2008 book "Bad Science" reproduces a courteous letter from Professor Garrow inviting the celebrity nutrition guru Gillian McKeith to subject her "living food powder" to a simple controlled trial of efficacy, adding a gentlemanly wager of £1000 to boot. The response from the McKeith family was a telephone call from her lawyer husband with a threat of legal action for defamation. John, who Goldacre describes as "an immensely affable and relaxed old academic", shrugged it off with the words, "Sue me". She never did.

Past and present members of the HealthWatch Committee have been swift with their tributes and recollections. Caroline Richmond: “I’ll remember John for his humour, directness and fine sense of irony. He embodied Occam’s razor, saying, ‘I’m a simple minded man ...’ and then cutting to the quick.”

Walli Allen worked with John to establish the HealthWatch Student Prize competition, which he funded personally in 2013. She remembers him as an excellent teacher, as does Diana Brahams: saying: “For many years, HealthWatch meetings were held at Barts’ premises that John arranged without any charge to HealthWatch. John had true gravitas combined with kindness, a wry humour and sharp wit and a huge fund of experience and knowledge. Those who had him as their treating clinician or tutor were very lucky.”

James May, our current chairman, said: “Despite being a great man, he had the heart of a servant, and would routinely ensure that wine cups were kept topped up throughout our meetings. He would say, ‘to prevent blood alcohol dropping to dangerously low levels’, and who was I, given his credentials, to ignore these dire warnings?”

I was privileged to join his family for a small memorial service after his funeral, where I learnt that he had for many years indulged his scientific curiosity by using himself as a n=1 trial subject—when he first met his wife Katherine he was experimenting with the azo dye Evans blue as a tracer for human plasma albumin. It had turned his skin blue. And that it was he who conceived the chart which has, since the 1980’s, been used to assess obesity by body mass index (BMI), though he never sought credit for it. And that he played the cello—not well, by all accounts.

We toasted John Garrow with cups of tea (he liked it with plenty sugar) and his favourite meal—a mountain of deep-fried scampi followed by freshly baked scones heaped with jam and fresh cream.

A final tribute from HealthWatch’s president Nick Ross: “He was a fine clinician and a popular teacher; a loyal, astute and knowledgeable comrade, a good-natured but forceful colleague. Perhaps the trait I liked and admired the most was his ability to see through bullshit as bats see through the dark.

“For all of us in HealthWatch this is a death in the family.”

For those who wish to pay their respects to John Garrow, an informal memorial toast will be held at 17:30 on 20th October at the Medical Society of London, 11 Chandos Street, London W1G 9EB before the start of this year’s HealthWatch AGM.

**Mandy Payne, Editor, HealthWatch Newsletter**

## Reference

1. Edzard Ernst’s blog, 23rd June 2016. <http://edzardernst.com/2016/06/john-garrow-1929-2016/>

## NEWS

### Sugar tax debaters win by narrow margin

A LIVELY EVENING was had at King’s College on 23rd May, and the audience at this year’s HealthWatch Debate was split almost exactly down the middle. After hearing arguments for and against the motion: “This house believes sugar is harmful so all sugary foods should be taxed, not just soft drinks” the voting was so close that our chairman, the comedian Robin Ince, had difficulty counting the raised hands for each side, before concluding the “Aye’s had it”—just.

First on had been cardiologist Aseem Malhotra, of the National Obesity Forum, with a barrage of statistics on the dangers of sugars. Richard Tiffin, University of Reading, calmly cited evidence that taxing

undesirable health behaviour is ineffective. Carwyn Rhys Hooper of St George's Medical School took a philosophical perspective, and our own David Bender seconded Professor Tiffin's argument against.

The audience discussion threw up contradictory views. One of the most persuasive was from medico-legal expert Diana Brahams who suggested that it is not so much the tax itself, but the existence of such a tax, which sends out a message to all that regular consumption of sugary food is not to be encouraged and so implicitly lends support to measures which would otherwise be opposed, such as improving the quality of food in schools and hospitals.

Our thanks to our invited speakers, and to our patron Robin Ince, for giving up their time and giving us all an entertaining evening and sending us away with—literally—food for thought.

**Mandy Payne, Editor, HealthWatch Newsletter**

## **New online tool helps people tell good science from bad**

A NEW WEBSITE offers a free, interactive service to help the public better understand complex health research and “go beyond the headlines”. Understanding Health Research has been created by the University of Glasgow and academic advisors. It will be useful for patients, carers, students, policymakers, health professionals and researchers. Users are taught critical thinking on what to look out for in research, such as funding sources, peer review, and ethics. Go to: <http://www.understandinghealthresearch.org/>

## **NEWS IN BRIEF**

JOHN ILLMAN was a winner in this year's Medical Journalists' Association awards, walking away with Feature of the Year (Specialist Audience) for his “superbly written” piece titled “The danger in a second opinion”, published in the British Journalism Review. The article is about the concept of balance in journalism. The judges described it as “thought provoking on an issue that is vitally important for medicine and medical reporting.”

ANOTHER WINNER is Dr Ken Harvey, of Friends of Science in Medicine (FSM), who's just been awarded the Australian and New Zealand Association for the Advancement of Science (ANZAAS) Medal for 2016. The medal recognises services for the advancement of science and its teaching. Dr Harvey publicly champions evidence-based medicine and treatment—see his article in HealthWatch Newsletter 83, October 2011, on his legal battles over the weight loss product SensaSlim.

NEVER RESTING, FSM have published “Is there any place for acupuncture in 21st century medical practice?”, an expert assessment of the evidence around needling therapy at [www.scienceinmedicine.org.au/images/pdf/acupuncturereview.pdf](http://www.scienceinmedicine.org.au/images/pdf/acupuncturereview.pdf). They have also written an open letter to Australian private health insurance companies, calling for an end to funding for treatments that do not have a strong evidence base. FSM took action in the wake of outrage over a distressing video of a Melbourne chiropractor manipulating the spine of a premature 4-day-old infant which was seen by 1 million people before being removed. The Victorian Health Minister has called for action against “rogue chiropractors”. Read more in FSM's latest newsletter: <http://www.scienceinmedicine.org.au/images/pdf/newsletter13.pdf>



## MEDIA

### The power of people stories

ABLE TO COMMUNICATE with anyone from politicians, dignitaries and world leaders to the poorest beggars, Mother Teresa of Calcutta is reported to have said: “If I look at the mass, I will never act. If I look at the one, I will.” This observation coined a new phrase—the Mother Teresa effect—about the power of people stories. It has been cited in research into what persuades donors to give to charity. The results may disappoint researchers and clinicians who rely on the power of numbers—the statistical, the methodological, the analytical and the objective.

One study found that the better statistically informed donors were, the less money they gave. Those who read a short emotional appeal—a story—about an African child at risk from hunger gave twice as much as those who just saw raw statistics about the threat to millions of Africans. The facelessness of statistics, a major strength in science, may be an abject weakness in public relations...

**John Illman, Author and Journalist, London**

*This article is extracted with the author’s kind permission, from his new book Handling the media: communication and presentation skills for healthcare professionals, by John Illman. JIC Books, £14.99. Available from <http://www.jicmedia.org/shop/>*

## NUTRITION

### Foods and supplements to boost the immune system

I WAS RECENTLY asked to speak to a group of immune-compromised patients about nutrition and the immune system. I fear that what I discovered and what I told them, will not have given them much hope. To prepare my talk I started, as one does these days, with a Google search on ‘foods and immune system’, then opened a serious nutrition text book that was on my bookshelf, and then searched through nutrition review journals using PubMed.

The Google search threw up lots of delightful nonsense, starting with several sites that stressed the importance of drinking water to boost your immune system. The boost-immune-system-naturally website<sup>1</sup> tells us that water is the:

*“single most important nutrient, helps your cells to properly communicate the healing messages, critical for an effective detox, vital for all your body systems to function correctly to boost immune system, helps maintain healthy energy, dehydration promotes cancer cell growth, drink ½ your weight in ounces of pure water, if using distilled water add minerals back to it”*

I have a problem here. To me, who once trained in chemistry, pure water is distilled water, although I know that the chlorinating tablets I take with me when travelling in countries where the tap water may not be safe to drink, are known as water purifying tablets...

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

### References

1. Boost-Immune-System-Naturally.com website at: <http://www.boost-immune-system-naturally.com/boost-immune-system.html>

## BOOK REVIEWS

### 31 CAM secrets revealed

*Real Secrets of Alternative Medicine: An Exposé* by Richard Rawlins

Placedo Publishing, Dartmouth, Devon

375 pp, ISBN-13 151934-585-1, available from Amazon (£12.99) and as a Kindle ebook (ISBN-13 978-84396-2, £5.99)

RICHARD RAWLINS IS both an orthopaedic surgeon and a magician and member of the Magic Circle. He is also, as is obvious from this book, very widely read. The first part of the book is an account of how modern medicine developed from traditional magicians and priests—a combination of sleight of hand and faith that underlies much of CAM...

David Bender

### An inspirational woman of medicine

*Beulah Bewley: My life as a woman doctor* by Beulah Bewley, edited by Susan Bewley

Published by SilverWood Books Ltd (9 March 2016)

252 pp, ISBN-10: 1781324190, ISBN-13: 978-1781324196, from Amazon as hardcover (£25.00) and Kindle ebook (£3.99)

Born in 1929 in Derry, Northern Ireland, Beulah Knox knew very early she wanted to be a doctor, and her local GP nurtured her interest by letting her accompany him on home visits to sick children. Beulah disliked the prevailing notion that women were second-class people. When an uncle advised her to do dentistry as it would be difficult to manage family responsibilities as a doctor, she said she would prefer medicine...

Mandy Payne

## LAST WORD

### Homeopathy on the NHS: withering on the vine

THANKS TO Alan Henness and the excellent Nightingale Collaboration (<http://www.nightingale-collaboration.org/>), we can happily report that in 2015 the annual number of homeopathic prescriptions fell for the 18th successive year. This was a 95% drop from its peak of 172,000. There were 8894 prescriptions in 2015, the first year in which the figure dropped below 10,000. The data are compiled by the Health and Social Care Information Centre.

The cost per item has, however, crept steadily upwards from £4.97 in 1995 to £10.60 in 2015. This is about the same as a paracetamol prescription and mainly represents admin expenses ...

Caroline Richmond, Author and Journalist, London



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**HealthWatch is the charity** that has been standing up for science and integrity in medicine since 1991

We promote:

1. The assessment and testing of all medical and nutritional treatments, products and procedures
2. Consumer protection in regard to all forms of health care
3. The highest standards of education and evidence-based health care by practitioners
4. Better understanding by the public and the media of the importance of application of evidence from robust clinical trials

We challenge and expose misleading advertising of health products, the sale of unproven remedies to the vulnerable and desperate, unethical marketing by pharmaceutical companies, misconduct in clinical trials, media misinformation on health and nutrition, and government promotion of health and screening programmes unsupported by evidence.

HealthWatch welcomes membership enquiries from those who share its aims. Join at <https://www.healthwatch-uk.org/about/join-healthwatch.html>

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