MEDIA WATCH Ben Goldacre

Why don't journalists mention the data?

Have stories about “electrosensitivity” simply been lifted from those promoting this new diagnosis?

Sometimes, as a doctor who also writes in the newspapers, a dark thought comes across me: wouldn't it be so refreshing—secretly, wouldn't it feel so free—to leave the medical thing behind, and just make stuff up, say what I want, spin any story that pleases me, or any story that sells, and gaily ignore the evidence?

For two years now the British news media has been promoting the existence of a new medical condition, called electrosensitivity, or electromagnetic hypersensitivity. The story—or in medical terms the hypothesis—is that a wide range of symptoms are caused by acute exposure to electromagnetic signals, and that these symptoms are ameliorated by this signal being removed.

The features have a lot in common with what might often conventionally be called “medically unexplained symptoms”: tiredness, difficulty concentrating, headaches, nausea, bowel complaints, aches in the limbs, crawling sensations or pain in the skin, and more, for which no explanation is found. Such symptoms have existed since long before the appearance of “electrosensitivity,” and the absence of a clear cause is extremely troubling to both patients and doctors.

If these symptoms were caused by electromagnetic signals, then it should prove possible to study that, ideally in double blind conditions: and yet the media coverage invariably focuses on the scandal of how research into this area has been neglected. But the research has been done. In fact, dozens of double blind studies have been performed, but they have been systematically ignored by almost every single journalist covering the issue.

A typical experiment would involve a mobile phone, hidden in a bag for example, and each subject—chosen from people who report that their symptoms are caused by electromagnetic signals—recording

their symptoms over time, without knowing if the phone is on or off.

There have now been 37 such double blind “provocation studies” published in the peer reviewed academic literature, and they are almost all negative, although you could argue that the evidence is unanimous. There are, to be clear, seven studies that did find some statistically significant effect for electromagnetic signals: but for two of those, even the original authors have been unable to replicate the results; for the next three, the results seem to be statistical artefacts (one tailed t-tests—presumptuous, you might say—and problems with multiple comparisons); and for the final two, the positive results are mutually inconsistent (one shows worsened mood with provocation, and the other shows improved mood: still sure a one tailed t-test is reasonable?).

These studies test the very hypothesis reported on repeatedly in the media: symptoms are brought on by exposure to a source of electromagnetic signals, and cease when the source is removed. And not only are the studies ignored, but sometimes it feels like the media are actively teasing us. A recent *Panorama* documentary on BBC 1 covered the possible dangers of Wi-Fi computer networks, and what little evidence the programme did present was flawed in a number of ways.

A large chunk of the programme was devoted to electrosensitivity. It covered the question of testing the phenomenon, in a double blind study. The programme makers even followed someone into a lab at Essex University where they had participated in one provocation study. We are told that this subject *did* correctly identify when the signal was present or absent two thirds of the time, to a visual backdrop of sciencey looking equipment.

But this was anecdote dressed up as data. The study is currently

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unpublished. We don't know the protocol, or whether 2/3 for one subject would be statistically significant (there may be only three exposures in total, for example). We don't know the results of the other subjects. But most crucially, there is no mention that this single selected subject in a single unpublished study produced a result that seems to conflict with a literature of 37 studies that have been completed, published, and are overall negative. If this whole Essex study was positive, while it might make an interesting small splash next to the other 37, it would need to be replicated and considered in the context of the negative findings. The alternative is chaos, and being blown in the wind by every Type I error.

So why doesn't the media ever mention this data? Perhaps they deliberately and mischievously leave it out. Perhaps they never came across it, and are incompetent. Or perhaps they simply lifted their stories verbatim from aggressive and well coordinated lobbyists who promote this new diagnosis (some of whom also sell expensive equipment to sufferers, such as insulating paint at £50 a litre, and insulating beekeeper hats for trips outdoors).

Not only do these lobbyists observe a monastic silence on the issue of the provocation studies, but they also viciously attack anyone who even dares to mention the data, accusing them of insensitivity, of attacking sufferers, and of denying the reality of their symptoms. Symptoms, of course, stand as real, regardless of their cause; and if you were going to offer guilt trips around, you could fairly argue that those who obfuscate on the causes are themselves hindering better understanding and treatment, and so harming patients.

Ben Goldacre is a doctor and writer, London ben@badscience.net

MEDICINE AND THE MEDIA

Don't blame it all on the bogey

UK and European policymakers and journalists could learn a lot from the way in which their US counterparts are ready to turn the heat on drug regulators, not just on big pharma, writes **Michael Day**

The newspapers love a bogeyman. And big pharma fits the bill perfectly. The image of obscenely well paid executives ripping off the NHS and poisoning the masses for the sake of quick profits has united newspapers of all political persuasions in a deep-held suspicion of the companies' method and motives.

During my stint as the *Sunday Telegraph's* health correspondent, under the impeccably right-wing and laissez-faire reign of Dominic Lawson, bashing drugs companies always guaranteed you space in the paper. And bear in mind this was a publication that considered global warming something invented

by Marxists in order to undermine the oil industry. If, however, you tried to move the argument on a little from "drugs companies are evil" to "the regulators are to blame," news editors' eyes would glaze over.

The British press has been quick to report concerns about "disease mongering" by the drugs industry as well as safety fears over Vioxx (rofecoxib), Seroxat (paroxetine), Avandia (rosiglitazone), and others. But it has largely been left to campaigners such as Charles Medawar in Social Audit to tackle the failings of the Medicines and Healthcare products Regulatory Agency—and to call for

the heat to be turned up on the people who regulate drug companies, rather than simply demonising these profit-making organisations for cutting corners and doing what they do best . . . making profits.

No so in the United States, where thorough newspaper reporting of the Food and Drug Administration's inadequacies has prompted members of the US Congress to now push for proper post-marketing surveillance of new medicines, and even for the FDA to be split into two separate bodies—one that awards drugs licences, and another that continues to monitor safety and has the power to rescind them.

The real impetus behind these calls for change has been the Vioxx disaster. The agency's failure to act more quickly on Vioxx, and the behaviour of key figures within the organisation are probably the most alarming aspects of a new investigative documentary on the dark side of the pharmaceutical industry, *We'll Take Care of You* by Lattanzio Firmian and Alberto Baudo.

The film makers begin with some predictable attacks on big pharma. Drugs company executives are portrayed as Wild West villains and predatory animals. Victims of drug side-effects are nice, ordinary Joes who were just fine until they started taking the tablets—though it's worth recapping the extent of the Vioxx scandal. Merck's own paper in the *New England Journal of Medicine* in June 2000 found that the drug increased users' risk of stroke or heart attack by four to five times. But despite this risk being in the public domain in June 2000, Merck continued to promote and sell the osteoarthritis treatment until its withdrawal in September 2004. By this time an estimated 60 000 people who had been prescribed the drug in the US alone had died from stroke or heart attack.

But it's when the film focuses on the FDA's role in the affair that things get really interesting. Despite the publication in June 2000 of the pivotal *NEJM* paper highlighting the cardiovascular risk posed by Vioxx, the FDA took no action.

In September 2001, the FDA said in a

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letter to Merck that the company's assertion that Vioxx was safe for the heart was "simply incomprehensible." Still it took no action. The following year, the warning label on the Vioxx packets was finally changed to alert patients to cardiovascular risks.

Seen squirming under questioning by Congressional investigators in the documentary, Steven Galson, the director of the FDA's Center for Drug Evaluation and Research, agreed that even this modest label had taken "longer than it should have." And his explanation for the delay? "We were trying to work out exactly what was acceptable to both sides."

Yes, you read that correctly. The issue of a mass-market medicine for a non life-threatening disease raising the risk of heart attack by 500% in millions of people was not a public health emergency in the FDA's eyes, but simply a source of 18 months' polite negotiation—with the protection of the manufacturer's commercial interests evidently high on the agenda.

Almost as bad, the documentary showed how one of the chief whistleblowers at the FDA, David Graham of the FDA's Office of Drug Safety, needed Congressional protection in order to keep his job after threats and abuse culminated in his sacking from the agency.

Galson has retained his job of head of the Office of New Drugs at the FDA. The FDA's Commissioner, Lester Crawford, who also came under fire for his role in the Vioxx scandal, quit the agency and has since taken up a job lobbying on behalf of the pharmaceutical industry.

Cynics would say this is why FDA executives make life easy for big pharma—they're thinking of a cushy six-figure salary there in the not too distant future.

Some of the campaigning elements of the US Congress have the bit between their teeth now—one of the key movers, Democrat Henry Waxman, is leading the attack on the FDA over its handling of rosiglitazone, the GSK diabetes treatment that is also under suspicion for raising patients' heart attack risk.

And there's little sign of the press relenting. It would appear that even Washington DC's mighty pharmaceutical lobbying machine will have its work cut out to prevent some major changes to drug regulation.

Given the depressing similarities between US and European drug regulation—the reliance on industry funding, the dearth of post-marketing surveillance, etc—perhaps it's time for our policymakers and journalists to start asking a few more questions this side of the Pond.

Michael Day is a freelance journalist, London
miday@f2s.com

WHATS ON THE WEB

What's so precious about originality?

Research aside, the efforts contributors to medical and science journals are forced to go to to avoid self plagiarism are just a waste of time, writes **Simon Chapman**

The ethics of banning smoking outdoors (I am opposed) is something that I have written on several times, most recently at length in a forthcoming book (*Public Health Advocacy and Tobacco Control: Making Smoking History*. Oxford: Blackwell, 2007).

This issue has got up some worrying momentum lately and so I find myself being asked to increasingly speak and write about it. I tell those asking me that I have little more to add than I have already written in my previous contributions, yet they insist they want yet another, "different" piece. What is the point, precisely, in me spending hours manicuring, paraphrasing, and in every other way trying to express the same basic arguments that I originally felt I expressed as well as I could? All in the name of not "self plagiarising." I can play around with trying to top, tail, and middle things differently, but if the core of what I'm wanting to say is essentially the same, and I'm running into agendas about originality, what is more important here?

Media outlets all over the world daily buy exemplary articles, syndicated columns, features, etc, in recognition that their readerships will not have read a piece that was originally published elsewhere, the web notwithstanding. Why do we in the health and medical specialist journal media feel so precious about originality? When it comes to

original research I well understand the point, but many editors on this list are editing journals whose standard fare goes beyond original data into policy analysis and contributions designed to leverage change in some of the world's most pressing problems (climate change, violence, poverty, obesity, etc). Anyone who thinks that only data, rather than interpretation and commentary, change the world should get off at the next stop.

Ought we not to differentiate between original data and analysis/commentary? Do we really believe that humanity is best served by the straitjacket of requiring debates, policy advocacy and commentary to always be wholly original? Do we really believe that significant contributors to these debates really only deserve one bite at expressing their best shots, and if the rest of the world happens to miss out on their original contribution in "Calathumpian Journal of Significant Issues," this is just too bad . . . all in the name of preserving publishing integrity?

Simon Chapman is professor of public health, School of Public Health, University of Sydney
sc@med.usyd.edu.au

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