

British scientist challenges pharmaceutical company over research paper

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A British scientist, Dr. Aubrey Blumsohn, has criticised a major pharmaceutical company's "unethical behaviour" for putting forward a research paper in his name without giving him proper access to the data on which the investigation was based.

The case has international significance as it raises fundamental questions regarding the validity of scientific research that is funded by the major drug companies where data and analysis cannot be independently verified. Pharmaceutical corporations have been under scrutiny over the vast sums of money they spend on promoting their products regardless of patient needs, particularly after the case of Vioxx and other anti-inflammatory drugs. But this case raises the issue of science itself—in universities now largely dependent on finance from industry—and whether data and its statistical interpretation are being manipulated to give results favourable to business interests.

Dr. Blumsohn, well known as an expert in the medical field of osteoporosis, is a senior lecturer at Sheffield University. He has produced emails and taped telephone conversations demonstrating how in 2002 and 2003 he was prevented from seeing the full data of a study in which he was involved, despite the fact that his name would be used as the lead author in research publications.

In September last year he was suspended from his job at Sheffield, and it has since been revealed that he was offered a sum of £145,000 (\$256,000) by the university if he resigned and returned all clinical and research data back to them. He would also have had to agree to make no "detrimental or derogatory" statements about senior university staff. Sheffield University threatened the *Times Higher Educational Supplement*, which has revealed the details of the severance deal, with a legal injunction.

Dr. Blumsohn had been involved in a study looking at the impact of a drug, Actonel, manufactured by Proctor and Gamble, on women at risk of bone fracture. There is

no suggestion that the drug is not effective and safe. But Actonel, which earns some \$1 billion a year, is in competition with a rival drug and market leader, Fosamax, manufactured by Merck.

The research study took samples from thousands of women who were suffering from osteoporosis to examine which of the patients suffered fractures, and to match that to changes in bone turnover (the rate at which the body replaces its own bone material) and bone density. How drugs like Actonel and Fosamax work is still a matter of debate, but it is recognised that Fosamax is better at increasing bone density and reducing bone turnover. Proctor and Gamble hoped that the Sheffield research would show that once bone turnover had been suppressed by a certain amount (30 to 40 percent), further fall in turnover would not result in producing fewer bone fractures, thus boosting the case for Actonel.

As is standard in such research the data collected by Dr. Blumsohn's team was "blinded", i.e., it was coded so that the details could not be known to the researchers and hence not influence them. But a request from Professor Eastell, head of Dr. Blumsohn's research unit, to Proctor and Gamble to see the data after it had been decoded and analysed by the company's statistician was rejected. The company stated that it was "standard industry practice" not to give academics access to data.

Only after 18 months of Dr. Blumsohn making repeated requests was he allowed to visit Proctor and Gamble's UK headquarters to see graphs on a computer screen produced from analysis of the data, though still not to perform his own independent analysis. He expressed concern that the range on the axis of one of the graphs had been chosen to exclude 40 percent of the data, thereby supporting the case for Actonel. Proctor and Gamble since agreed to withdraw the graph from a presentation.

Proctor and Gamble deny they were manipulating the data, and claim that Blumsohn was given "access to all

the data related to his research.” But Blumsohn has a tape recording of his meeting with the company’s statistician, who complained that if the 40 percent were included it would benefit Merck. “Because that is contradicting our original manuscript. I just know what Merck are like. I think they are going to use it.”

Dr. Blumsohn and Professor Eastell had already been told by Proctor and Gamble’s statistician that it was intended that their research, although under their names, would be written up by the company’s own ghost writer. Significantly they were told that the ghost writer was “familiar with ... our key messages.” Such a procedure has become widespread in research sponsored by drug companies, ostensibly because a professional writer is more effective than academics.

Dr. Blumsohn became aware that in his problem with Proctor and Gamble over the access to data, he was increasingly coming into conflict with the higher levels of Sheffield University. He recorded a conversation with Professor Eastell, who told him, “The only thing we have to watch all the time is our relationship with P&G.” The financial support from Proctor and Gamble—Professor Eastell’s group had received £1.6 million (\$2.8 million)—he said, “is a good source of income, we have got to really watch it.”

Before he went public with his concerns last year, Dr. Blumshohn spent months attempting to get a response to his complaints from the university administration. The dean of his faculty and the vice chancellor passed the matter on to the head of human resources, to whom Dr. Blumsohn gave a full account of his concerns. After he told her he was going to talk to medical journalists, he received a threat of disciplinary action and then was suspended last September. The university claims that Dr. Blumsohn did not “raise his concerns through the proper channels.”

Concerns over research data from clinical trials and pharmaceutical companies not publishing adverse results is not a new one. In 2004 the New York attorney general, Eliot Spitzer, sued GlaxoSmithKline over allegations that it was holding back negative information about its antidepressant drug Paxil, also known as Seroxat. Unpublished results showed a possible increased tendency to suicidal thinking in some cases. An internal document from the company said it wanted to “manage the dissemination of data in order to minimise any potential negative commercial impact.” GlaxoSmithKline agreed to publish the results of clinical tests.

In April last year a study by the UK National

Collaborating Centre for Mental Health was published in the *Lancet*, accusing drug companies of suppressing negative data about Selective Serotonin Reuptake Inhibitors (SSRIs), the anti-depressant drug family to which Paxil (Seroxat) belongs.

Following the GlaxoSmithKline case, major pharmaceutical companies have agreed to publish the results of trials that they have sponsored, within one year of the drug being approved. This does not apply to drugs that are not being marketed, neither is it retrospective. The case of Dr. Blumsohn emphasises that there is no requirement for in-house research data and analysis to be vetted by independent authorities, or even to be seen by the academics or medical doctors who collaborated in the research.

Dr. Blumsohn’s case was raised during a House of Commons debate in December 2005 about a report prepared by the Parliamentary Health Committee entitled “The Influence of the Pharmaceutical Industry.”* The report raises a variety of concerns about the marketing techniques used by the drug corporations, and about medical research, including the practice of ghost writing—concerns which are highlighted by the Sheffield University research.

The Health Committee report recommended that the UK drugs regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), should be reformed to make it independent of the industry by which at the moment it is totally financed. This proposal was rejected by the Labour government of Prime Minister Tony Blair, which has made clear that it will see no serious criticism made of the pharmaceutical industry—the third most profitable in Britain after finance and tourism. The health minister declared, “It is in all of our interests that the industry maintains its currently strong position.”

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<http://www.publications.parliament.uk/pa/cm200405/cms/elect/cmhealth/42/42.pdf>



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