GABRIEL SZABO/GUZELIAN

Aubrey Blumsohn

Academic who took on industry

Aubrey Blumsohn forfeited his job after going public with concerns about access to Procter and Gamble's research data on the osteoporosis drug risedronate. **Clare Dyer** talks to him about his experience

"Scientists since Galileo have realised you can't be a scientist without data," observes Aubrey Blumsohn. It seems a statement of the obvious, but he welcomes the General Medical Council's recognition in the case of Richard Eastell, the former colleague whom he reported to the GMC, that "data" mean raw data, not summary data produced by a drug company's in-house statistician.[1 2]

That recognition, he believes, vindicates the stand he took when he fought US based Procter and Gamble (P&G) Pharmaceuticals, which refused him access to the raw data for research Professor Eastell and he were leading on the company's osteoporosis drug risedronate between 2002 and 2005. His determination eventually forced the company to release the data in 2006, but it cost him his job as senior lecturer in metabolic bone medicine at Sheffield University and led him to abandon his career as a clinical researcher.

The GMC cleared Eastell, director of the bone metabolism research unit at Sheffield University, of dishonesty and misconduct but found that he had failed to correct before publication an untrue statement that all the authors in an earlier study he led, published in the *Journal of Bone and Mineral Research* in 2003, "had full access to the data and analyses."[3] That research was also for P&G and on an overlapping set of data from the same 1990s clinical trials as Blumsohn's work.

The GMC panel concluded that there was an "evolving understanding of access to data" in 2002 when the statement was added to the research paper by a P&G medical writer, but held that "data" meant raw data and therefore that the assertion was misleading. Although the panel said Eastell might have been negligent, he had not acted dishonestly and was not guilty of misconduct. The unit at Sheffield, which he still heads, has won substantial government funding for its research.

The charge faced by Eastell at the GMC related only to his 2003 paper and not his joint research with Blumsohn. Although it was Blumsohn who originally reported Eastell to the GMC, he subsequently withdrew as a complainant in protest at the glacial pace of the investigation and what he described in a letter to the GMC's then president Graeme Catto as its "apparent tolerance for indiscretions of highly placed individuals." Blumsohn insists nevertheless that he wishes Eastell no ill, describing the professor, his former PhD supervisor, as "an impressive academic; a very bright guy."

Academic and commercial relations

The saga of Sheffield and P&G highlights the tension between commercial imperatives and scientific integrity in a system in which researchers depend heavily on drug companies to fund their work. P&G was a major sponsor at Sheffield, where several posts were funded by the company.

Blumsohn, now 48, was born and qualified as

a doctor in South Africa. He was among dozens of doctors who left the country when their contracts were not renewed after they refused to apologise for a letter they wrote to the *South African Medical Journal* protesting about conditions at Baragwanath Hospital in Soweto.

After taking a PhD in Eastell's unit, he worked in Dundee for five years before returning to Sheffield, where he held a senior lectureship and headed the laboratory in Eastell's department. After Eastell's initial work on risedronate, published in the *Journal of Bone and Mineral Research*, Blumsohn and Eastell signed a contract with P&G in mid-2002 to carry out further measurements on blood and urine samples stored from the clinical trials held during the 1990s.

The intention was to follow up Eastell's paper with two more papers. P&G sent Blumsohn two abstracts based on its statistical reports, with Blumsohn listed as first author. The company subsequently submitted these to an international meeting. But when Blumsohn requested information concerning the randomisation codes showing who had taken the drug, who took a placebo, who had fractures, and who had not, the company refused to supply it, so he was unable to check the reported findings. As a result of the stand-off, the papers were never submitted for journal publication.

At the time, risedronate was in fierce competition with Merck's osteoporosis drug alendronate, which was thought to be a stronger drug in reducing bone turnover and increasing bone density. Merck was about to publish a head to head trial of the two drugs. "Everyone knew it was going to show that the Merck drug was a more powerful drug," recalls Blumsohn—though, ironically, he says, "I'm not sure a more powerful drug is better."

But the results of Eastell's research, which formed the basis of the 2003 paper,[3] suggested that risedronate's lesser potency should not make it less effective because there was a threshold beyond which further reduction in urinary crosslinked N-telopeptides of type I collagen (NTX), a key marker of bone turnover, did not reduce the risk of fracture in patients taking risedronate.

Requests by Blumsohn for the raw data were repeatedly rebuffed by P&G, which claimed the data belonged to the company and that it was standard industry practice to limit access to raw data by external researchers. Although P&G would not allow Blumsohn to do an independent analysis, he was invited to the company's UK headquarters at Egham in Surrey to look at the company's analyses.

"I went down to Egham for a day, and it was at that point that the whole thing fell apart. I wanted to see the data plotted out on diagrams, so I could look and see whether anything looks plausible. There was this plot that showed immediately that everything we'd been told was just nonsense. A substantial proportion of patients taking risedronate fell off the end of the graph."

Maintaining integrity

Blumsohn's story, documented in his Scientific Misconduct blog,[4] is cited as a cautionary tale about what can happen to whistleblowers. But he doesn't see himself as a whistleblower and was annoyed when the university, with which he raised the problem, kept referring him to the head of human resources. He thought it was a clear case of breach of contract by P&G and that Sheffield should act to enforce its rights.

"The university said, 'This is an issue of research misconduct.' I said, 'It's not an issue of research misconduct, it's a company flouting the terms of its contract with the university.' We had a contract with the company; they refused to give the data. From the point of view of the university there was no more problem than that—it couldn't have been made more obvious to them."

"This contract was a model contract. It said the academics would be able to interpret the data and write a report, and there would be no restrictions on publication"

He engaged lawyers himself to write letters asking for the data, to no avail. Losing patience that anything would be done through official channels, he gave the university notice in mid-summer 2005 that he was going to the press, and contacted the *Lancet*, the BBC, and the *Times Higher Education Supplement*.

He was suspended from the university and found himself unemployed for six months. The university presented him with a draft agreement with an extensive gagging clause it wanted him to sign as part of a severance package with a pay-off of £145 000; he refused and took it to the press. He won't discuss the final terms on which he left, but the *Times Higher Education Supplement* says he accepted a six figure sum.

Along with the university job, he lost his NHS post at Sheffield Teaching Hospitals NHS Trust. "I couldn't resign from just my university job; I had to resign from everything." A two day a week NHS job in pathology was salvaged for him at Sheffield, where he survives on tenuous fixed term contracts. He didn't want to leave Sheffield, where his children were in school and his wife works as a staff grade paediatrician.

In 2006, after the media publicity, the company finally released the data to the researchers and produced a "bill of rights" for scientists. After independent analyses of the data, a letter from Eastell and his coauthors to the *Journal of Bone and Mineral Research* acknowledged "some errors and some poor practice" in the study.[5] The journal published an editorial stating that both extremes of the original graphs had been cropped, and that the reanalyses did not show a level below which further reduction of NTX was not associated with greater reduction in the incidence of fracture.[6]

P&G told the *BMJ* it regretted the "misunderstanding" with Blumsohn over the data. "At the time, it was common practice in the industry to provide access to data to outside researchers through a company statistician. Since then, however, we initiated a researcher bill of rights, which explicitly states that all researchers are given direct access to all data, upon request."

Eastell said: "The conclusion of the 2003 paper was that the evidence for a non-linear relationship between fracture risk and bone resorption markers was present. That conclusion was confirmed for CTX [crosslinked C telopeptide, another marker of bone resorption] but not for NTX after the reanalysis which was published in 2007.

"The GMC recognised that there was never any intention on my part when I wrote the paper along with others in 2002 to deliberately mislead about our access to the raw data used in the study. Following concerns raised in 2005 over the paper, I took every step I could to address these issues as quickly as possible.

"I have spent the last 30 years conducting research into the cause, diagnosis, and treatment of osteoporosis, publishing around 295 papers. I am committed to continuing with medical research and hope that this work will hasten the development of better treatments for patients with osteoporosis."

Would Blumsohn have done anything differently if he had his time back? "I might not have done it in the same way. But I have no regrets that I prevented the two further proposed papers from being published.

"It's hard to encourage anyone to speak out about poor practice in the current environment. This case sums up what has gone wrong with systems set in place to ensure safety and integrity in scientific medicine. It would help if regulators put as much effort into responding to serious critics and whistleblowers as they do producing glossy brochures and yet more guidance."

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From the archive: For more on whistleblowing, see "The price of silence," *BMJ* 2009;339:b3202