

# British doctor faces action over claims of 'ghost writing' for US drug company

- Medics credited with work of firms' employees
- US court documents reveal 'author' culture
  - [Sarah Boseley](#), health editor
  - [guardian.co.uk](#), Friday 18 September 2009 21.56 BST

**This article is the subject of a complaint made on behalf of Professor Eastell.**

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[Doctors](#) have been agreeing to be named as authors on studies written by employees of the pharmaceutical industry, giving greater credibility to [medical research](#), according to new evidence.

The Guardian has learned that one of Britain's leading bone specialists is facing disciplinary action over accusations that he was involved in "ghost writing".

The wider phenomenon has come to light through documents disclosed in the US courts which have revealed a culture in which doctors agree to "author" studies written by employees of drug firms. The doctors may have some input but do not have access to all the evidence from the drug trial on which the paper's conclusions are based, the documents showed.

The General Medical Council will call Professor Richard Eastell in front of a fitness to practice committee. Eastell, a bone expert at Sheffield University, has admitted he allowed his name to go forward as first author of a study on an osteoporosis drug even though he did not have access to all the data on which the study's conclusions were based. An employee of Proctor and Gamble, the US company making Actonel, was the only author who had all the figures.

Experts believe the practice is widespread in Britain. In another alleged example, a consultant cardiologist claims an expert listed as an author on a medical paper died before the research began. Peter Wilmshurst, a heart specialist at the Royal Shrewsbury hospital, is involved in a dispute over a study which he helped design, which involved the insertion of a device to close a hole in the heart.

He claims the manufacturers refused him access to data and he had concerns about the accuracy of the paper, so he refused to sign it off and is not listed as an author. One of those who is named, Wilmshurst said, is a true ghost author. Anthony Rickards, a cardiologist, was involved in preliminary discussions but died before the research was conducted.

The company which sponsored the research, the US firm NMT Medical, is suing Wilmshurst for remarks in a lecture that he made about outcomes in the trial, which were published on a medical journal website. A UK charity, HealthWatch, has launched a fund to support

Wilmshurst, who was in 2003 a recipient of its award for challenging misconduct in academic medical research.

The US documents show that Wyeth, one of the biggest companies involved, employed a medical writing agency with the purpose of getting favourable studies about its HRT drug Prempro into prestigious medical journals.

The agency dreamed up ideas for papers about the benefits of the drugs and then wrote an outline and even a first draft before offering it to a doctor who might agree to have his name attached as the author. Although the doctor would see drafts and revisions, critics say that control of the content and message were in the agency's hands. The memos and emails show that many busy academics signed their approval to the finished paper.

Many of the documents are records of planning meetings, where agency staff list articles that will be written, suggesting possible authors and targeting journals. Concern about ghostwriting caused the UK-based open-access journal PloS Medicine, part of the Public Library of Science, to intervene in a court case brought by women who claim they were harmed by the HRT drug. PloS Medicine, with the New York Times, argued that the public should know what was going on. A US judge agreed to place the documents in the public domain.

Ginny Barbour, editor in chief of PloS Medicine, said she was taken aback by the systematic approach of the agency. "I found these documents quite shocking," she said. "They lay out in a very methodical and detailed way how publication was planned." Other documents released through US court action show that [GlaxoSmithKline](#) employed a ghostwriting programme named Caspper in which doctors could take credit for medical journal articles written by the company's consultants.

The project was aimed at boosting the US sales of an antidepressant called paroxetine, which goes by the brand name Paxil in the US and Seroxat in the UK.

Caspper stood for Case Study Publication for Peer Review. It enabled doctors with positive experiences of Paxil to get into medical journals. A busy doctor could sit back and let a medical writing agency paid by GSK do all their work, from the first draft to getting it accepted for publication by a journal.

The medical writing agency would prepare drafts using whatever material the doctor sent them and create figures and tables. These would go to the doctor for approval. "The author ensures accuracy of material, updates references, supplies missing information, etc," says the leaflet. Eventually the doctor would complete a sign-off form and the agency would send the paper for publication.

Caspper came to light when internal GlaxoSmithKline documents were released in court action in the US brought by the legal firm Baum Hedlund on behalf of patients who claim they were harmed by Paxil. GSK says the programme was discontinued some years ago and that the names of medical writers were included on any published papers.

But Caspper shows there was no dividing line at the time between science and marketing - the leaflet states its purpose is to "strengthen the product positioning and overcome

competitive issues". Doctors and medical journals became part of a promotional campaign, aimed at selling more drugs.

The disciplinary move in the Eastell case comes after he admitted that a statement he signed declaring that all six authors had access to all the statistical data was wrong.

In a letter published in the Journal of Bone and Mineral Research, which carried the original study, he stated: "In the original paper one of the authors, a statistician working for P&G, Ian Barton, had full access to all the data." The authors had full access to all the analyses of the data that they requested, he said – but those analyses were carried out by the company.

The letter, published in 2007, also acknowledged flaws in the study. A later independent analysis of the data "identified some errors and poor practice", he wrote. The study was designed to show the strengths of Actonel which was in fierce competition with a rival bone-strengthening drug called Fosamax, made by Merck.

Eastell's paper concerned a study carried out on behalf of Proctor and Gamble, comparing the bone density of women prescribed Actonel with others who were not. Only the company knew which women were on the drug and which were taking something else.

Eastell's colleague, Dr Aubrey Blumsohn, wanted the codes which would say which of the patients who suffered fractures had been on the drug. The company refused. Blumsohn took his concerns to Eastell, but in a conversation which Blumsohn says he taped, Eastell said he was concerned that persistent requests might damage the relationship they had with the company. Eastell is said to have told him: "The only thing that we have to watch all the time is our relationship with P&G. Because ... we have the big Sheffield Centre Grant [from P&G] which is a good source of income, we have got to really watch it." .

Tim Kendall, joint director of the National Collaborating Centre for Mental Health, says the problem is the close relationship between doctors and the industry. "Some doctors don't seem to see the relationship ... as problematic."

A study of 4,000 physicians found that 96% received money from drug companies, and yet "the majority did not see it as a conflict of interest", he said.

"I do think there needs to be a national debate in this country about the interpenetration of medicine and the pharmaceutical industry."

Ghost writing was one manifestation of a bigger problem which he believed was the institutional bias of doctors who work closely with and for drug companies. "In mental health 85% of all published trials are funded by the drug industry," he said. Allowing for the unsuccessful trials the industry does not publish, the figure is probably nearer 95%, he said. Studies have shown that drug company-funded trials are five times more likely to come out with a positive result for the drug than independent trials.

The GMC is criticised by doctors like Wilmhurst and Blumsohn for failing to take a tougher line against doctors involved in dubious research practices.

Jane O'Brien, head of standards and ethics, said that their research guidance specified the importance of honesty in the attribution of authorship. "We would see that as an important

issue. If somebody's name is on something it gives research a credibility that it wouldn't otherwise have. If somebody had not been involved, we would see that as misleading people as to the credibility of the research."

She added that the GMC felt it important to play a role in ensuring good conduct in research. About a year ago, she said, they took soundings of bodies that regulate and support research, such as the Medical Research Council, asking whether the GMC should be involved. "The response was yes, because we are the people who can strike doctors off in the end."

Eastell declined to discuss the hearing. "I do not wish to comment on the case. The proceedings have yet to commence," he told the Guardian in an email. A spokesperson from the University of Sheffield, where Eastell is professor of bone metabolism, said they were aware of the investigation. "We will be informed by the GMC of any outcome and cannot comment further until we receive this."

- This article was amended 22 September 2009. The original referred to a law firm as Baum Hedland. This has been corrected.