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The tightening grip of big pharma

When Prof Martin Cormican, a bacteriologist at University College Hospital, Ireland, wrote to Bayer in November last year asking for a supply of pure ciprofloxacin and related products for his research into antibiotic resistance, he was asked to sign a document stating that, "We declare that we will inform Bayer AG in writing of our test results and will not publish or commercialise them without written permission of Bayer AG". He replied that he was "concerned in respect to the restriction on publication without permission".

A Bayer employee, Dr Andrew Saich, called Cormican to say that he could neither waive nor remove the restriction, but he was sure it would not be enforced. Dissatisfied with this response, Cormican wrote to the European Commission seeking their support for his unfettered right to publish whatever results he obtained. Philippe Jean replied on March 13, 2001, describing the matter as "delicate". All he could do was remind pharmaceutical companies of "the potential public interest of this type of research". Dr Matthew Kiln raises similar concerns in a letter on p 1209.

Nobody would deny a pharmaceutical company its right to commercialise results of scientific research. But that issue is completely different from its "right" to block publication. *The Lancet* recently came under pressure to remove a sentence from the discussion of a research paper, which raised questions over the safety of a drug. The lead author had shown the report to the company after final journal pages were passed for publication. She was satisfied with the paper but the company was unhappy. The best way for the journal to support her was to promise to publish an editorial naming the company and describing its attempts to manipulate the study's conclusions, if the offending sentence was removed. The final report remained in its original form.

Efforts by drug companies to suppress, spin, and obfuscate findings that do not suit their commercial purposes were first revealed to their full, lethal extent during the thalidomide tragedy. Although government drug regulation schemes around the world are now in place, the insidious tactics of big pharma have changed little. For example, *JAMA* recently published a study whose dataset was incomplete because the sponsor refused to supply

necessary information to the research team. The issue at stake in all these cases is the relation between a company that is sponsoring a study in some way and the investigators. In protocols of trials that *The Lancet* is provisionally committed to publish, the sponsor's veto is occasionally made explicit, although there is usually no corresponding statement affirming the right of investigators to publish their results irrespective of the sponsor's views. In addition, the sponsor's role in interpreting data, writing the report, or publishing the paper is far from clear, leaving a damaging ambiguity over the entire research process.

The matter of malign commercial influence in research is complicated by investigators' own conflicts of interest. As research becomes driven by ever more costly technologies, so industry will intrude even further into the scientific process. If medicine wants a flourishing research culture, it will be hard to find ways to limit industry involvement in medical research without constraining that culture. But this position is weak and self-serving. Instead, doctors must look to existing institutions to challenge, on the public's behalf, forces of commercial bias that risk staining permanently the integrity of medicine.

Governments, nationally and regionally, have consistently failed to put their people before profit. By contrast, academic institutions could intervene to support scientists when financial conflicts threaten to do harm. But these institutions have become businesses in their own right, seeking to commercialise for themselves research discoveries rather than preserve their independent scholarly status.

Perhaps one last means of protection is the scientific journal. It is the editorially independent, peer-reviewed medical journal that remains a final common path by which investigators obtain justified credit for their work. Journal editors can do much to reinforce the integrity of the science they publish. For clinical trials, one important next step is to strengthen the latest revision of the CONSORT statement (see p 1191) to make explicit the role of the sponsor in data collection, analysis, and publication. Such rigour should apply to the oversight of all medical research.

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