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Financial conflicts in biomedical research

The *New England Journal of Medicine* recently made headline news by admitting violations of its own policy on conflict of interest. The journal requires authors of research articles to disclose any financial conflicts to the editors, and it also has an absolute prohibition—which it now admits was repeatedly ignored—on opinion pieces by authors with financial interests in the work they are discussing. The fact that this story was so widely reported reflects a general concern about the extent to which biomedical research in academic institutions is being affected—some say corrupted—by commercial interests[1].

The distinction between academic and for-profit research has become increasingly blurred over the last few years, particularly in the United States. The change stems largely from the Bayh-Dole act of 1980, which allowed US universities to seek patent rights on their discoveries. The result has been a massive increase in the number of patent applications from universities (from around 250 per year before Bayh-Dole to over 4800 in 1998)[2], with a corresponding proliferation of licensing agreements, start-up companies based on university inventions (more than 2500 since 1980), and consulting opportunities for faculty members. The closer relationship with industry has led to a large increase in overall corporate support for academic research, particularly at major research universities; at MIT, for example, industry now funds about 25% of total research expenditure[3].

The benefits of this trend are obvious and substantial, but the increasingly commercial outlook of many universities also raises new concerns. It is no longer realistic to assume that academic researchers are motivated by purely scholarly considerations; a survey[4] of biomedical papers appearing in 1992 found that for more than a third of the cases, one or more author had a financial stake in the research.

Why does it matter? Decisions about what to study may be affected by financial considerations (this is true of both faculty members and their students). Professors who invest time and energy in business ventures inevitably have less to spare for academic duties such as mentoring students. Commercial considerations may also lead to a culture of secrecy, including delays in publication while patents are filed[5], and if some faculty members become well funded and personally wealthy through their business ties, this can lead to divisions and bitterness within the academic environment.

The most serious concern, however (at least for journal editors), is that conflicts of interest may affect what gets published. Blatant fraud is probably rare, but more subtle effects have been documented, mainly from the clinical literature. One survey found that drug studies sponsored by the manufacturer are more likely to report favorable outcomes than studies without such sponsorship[6]. Others found that authors who favored the use of calcium-channel antagonists to treat hypertension were much more likely to have received support from the pharmaceutical industry than those who were neutral or negative[7], and that studies of cancer treatments that had been funded by the industry were eight times less likely to reach a negative conclusion about the treatment's cost-effectiveness than studies without such funding[8]. Comparable data from the basic science literature are hard to come by, but these findings should give pause to anyone who doubts that financial conflicts of interest can affect scientific judgment.

It would seem unrealistic to ban academic researchers from commercial activities altogether, and it also seems excessively stringent to ban authors from writing about any subject in which they have a financial interest—as one editor pointed out, the *NEJM* policy would have prevented Thomas Edison from writing about the future of electricity. This leaves disclosure as the main option, but to whom should one's interests be disclosed, and what should they do about it? Many universities have an internal disclosure policy, but it may be difficult for (say) a departmental chairman to penalize a faculty member who is highly productive and brings in large amounts of sponsorship money, absent clear evidence that the competing interests have led to actual negative consequences. Similarly, some journals require authors to disclose potential conflicts to the editors, but it is not clear how useful this is, because in most cases there is little that editors (or referees) can do with the information except block publication, which would obviously be unfair.

The only practical option is to make the information public, so that scientific peers can judge for themselves how to interpret it. For a research paper, it can be regarded as a source of potential bias that readers should be allowed to evaluate along with other methodological details. Some clinical journals publish disclosures routinely, but this practice is not yet widespread in the basic sciences. The main counter-argument is that it is intrusive and unfair to authors to force an admission that their work might somehow be tainted. More selfishly, journals may worry about deterring submissions from the best-funded and most productive authors. But if every author were to make disclosures routinely, commercial interests would cease to have such negative overtones, and vague suspicions would give way to a more informed assessment of their effects. The *Nature* titles, including *Nature Neuroscience*, do not currently require disclosure by authors. We are, however, reviewing our policies, with a view to deciding how best to balance the interests of our authors with those of our readers and of the larger scientific community. Meanwhile, we welcome your opinions, which can be e-mailed to the editors at neurosci@natureny.com.

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