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'Why drug-industry funding of university research should be banned

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(A controversial article by Professor Arthur Schaffer, Director of the Centre for Professional and Applied Ethics at the University of Manitoba, drew national media coverage last week for its criticism of medical research funded by Canada's drug companies.

This is the second in a two-part adaptation of that article. The full paper, "Biomedical conflicts of interest: a defence of the sequestration thesis," appeared in the Journal of Medical Ethics and is available on-line at: <http://jme.bmjournals.com/misc/advanced.shtml>.)

The evidence now seems very strong, indeed: When medical research is sponsored by drug companies, it tends to be biased in favour of the companies' products. And given the industry's major role in funding research, it is not altogether surprising that published drug studies are often of poor quality.

Data showing that a new drug may be dangerous for patients is sometimes "lost" or "re-interpreted" or simply not submitted for publication. Scientists who try to warn patients about potentially serious drug side-effects sometimes find that their university or hospital appointment has been terminated. This happened to Dr. David Healy at the University of Toronto after he issued public warnings about his concern that Prozac was being over-prescribed. Healy was not intimidated, but many researchers are understandably concerned to protect their future funding and their jobs.

Since doctors rely on published studies when deciding the best treatment for their patients, anything which threatens the objectivity of medical research is bad news for patients. There is also an issue of economics, as well as patient safety. New drugs, which are vastly more expensive than older drugs but often no more effective, sometimes achieve enormous popularity based on flawed research.

Celebrex, for example, became a "blockbuster" drug for the treatment of arthritic pain, largely based upon a now-notorious study appearing in *The Journal of the American Medical Association* (JAMA) in the summer of 2000. The published data, covering six months, indicated that the new drug was associated with lower rates of stomach and intestinal ulcers than two older drugs. Only after publication was it revealed that the full year's data -- which had not been disclosed -- did not support the claim that Celebrex was safer than its generic competitors.

Although the company, Pharmacia, continues to claim that Celebrex has a superior safety profile, the U.S. Government Food and Drug Administration's arthritis advisory committee concluded, based upon the full year's data, that Celebrex offers no proven safety advantage in reducing the risk of ulcer complications. JAMA's editor laments: "I am disheartened to hear that they had those data at the time they submitted (the manuscript) to us."

Half of the Celebrex study's 16 authors were medical faculty at eight different universities, acting as paid consultants of the company. The other eight were company employees.

In such an environment, can the public trust in the objectivity of university research?

Cases such as this one have generated a powerful reform movement within the medical research community. In an article published recently in *The Canadian Medical Association Journal*, the acceptance of drug-company funding by university researchers is compared to "dancing with the porcupine". Those who wish to dance with porcupines must exercise great care if they are to avoid painful skin punctures. By analogy, it's okay for scientists to partner with industry, so long as precautions are taken. What kind of precautions?

The general public would likely be amazed to learn that, until very recently, researchers were not required publicly to disclose who was funding their research. Worse, it was -- and still is -- common for medical researchers to attach their names to scholarly articles that they have neither designed nor written. That is, the experiments are designed by the drug companies and ghost-written by company employees, but appear under the names of prominent doctors (who duly reap status from their colleagues and cold cash from the company).

Important reforms, adopted in recent years by many universities, have included the requirement that investigators disclose the sources of their funding, that they take responsibility for the design of their experiments and the interpretation of data, and that they (not the companies) have the final say as to whether to publish.

Disappointingly, however, a recent (2002) survey shows that these reforms are routinely ignored by academic institutions. Universities and researchers appear to be competing so fiercely for drug-industry funding that the reforms have been sidelined in a race to the ethical bottom.

Is it likely that any reformist approach will succeed in restoring integrity to medical research? Keep in mind that the fundamental duty of universities is "to seek truth". By contrast, the duty of pharmaceutical companies is "to make money for their shareholders". Thus, from the university's perspective, "partnership" with the drug industry may be characterized as "an unholy alliance", more akin to swimming with sharks than to dancing with porcupines. To avoid becoming shark bait, universities might be wise to decline the swimming invitation altogether.

Universities and university researchers have, as their prime duty, the obligation to put the health and safety of the public above all else. When they accept drug-company donations and funding, they are beholden to the companies. Disclosing this conflict of interest is scarcely an adequate solution to the problem. Would we permit our judges to own shares in for-profit prisons on condition that they disclose their investment? Would we allow judges to accept payment from some of their corporate litigants? The answer is obvious. Our judicial system would lose all credibility if such practices were permitted, even with full disclosure.

Analogously, if biomedical researchers and their universities are to retain public trust, then they should simply not be permitted to put themselves into situations of financial conflict of interest. If the community values public science in the public interest, then it will have to be paid for by public tax dollars.

This does not mean that university-originated discoveries should never be commercialized. In western marketplace societies, many discoveries from fundamental research will be developed and marketed commercially. But it should become the job of governments to develop new mechanisms so that a fair share of the resulting profits are captured for the benefit of universities and hospitals. There is no need for our researchers to become handmaidens of business, nor is it desirable for universities to become adjuncts of large corporations. University research and university researchers must be sequestered from the process of commercialization if we want to avoid the kinds of damaging conflicts of interest described earlier.

How might such a sequestration be achieved? One practical possibility might be to require of any drug company which desires to bring a new drug to market that it provide to an independent institute all the funding necessary for the design and performance of a clinical trial of its drug. The institute would then allocate to qualified university and hospital researchers the task of conducting the necessary trials. The independence and objectivity of clinical research would thereby be protected.

Another promising solution might lie in changes to the tax system. If industry profitably exploits the public's investment in scientific research, it could not legitimately complain when a fair share of its profits from such research is recaptured through special taxation. The government could then provide research support through special taxes raised from corporations which make use of discoveries originating from university science.

Moreover, if drug research were publicly funded there might actually be a net saving, because drug costs would be significantly lower. We now waste fortunes on ineffective or positively harmful treatments, not to mention the cost of lives lost or blighted.

The stakes are certainly high. To continue on our present course is to risk losing the one commodity which, for physicians, universities and hospitals, should be viewed as beyond price: the public trust.

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