The University as Corporate Handmaiden: Who’re ya gonna trust?

“Data is not information; information is not knowledge; knowledge is not wisdom.” – Frank Zappa

Prologue: anatomy of twin scandals

I begin this essay by anatomizing a pair of research scandals whose aetiology can, in significant ways, be traced to the new entrepreneurial spirit prevailing in our universities. Later, I will argue that, with the ever-growing importance of university-corporate “partnerships”, scandals involving the integrity of university research may be expected to multiply in Canada, as they have elsewhere. The resulting loss of public trust is likely to be devastating to our universities and to the wider community which they serve.

In this context, either the Apotex-Olivieri scandal or the Prozac-Healy scandal would have been entirely apposite as illustrative examples. In both the Olivieri and the Healy cases, the University of Toronto failed miserably to defend the academic freedom of researchers – Nancy Olivieri and David Healy, respectively - who spoke publicly about dangers associated with drugs they were investigating. In both cases, there were wealthy and powerful drug companies hovering in the background: Apotex, in the case of Olivieri; Eli Lilly, in the case of Healy. But, having written previously about both of these shameful episodes in the history of Canada’s largest research university, I have instead chosen the more recent Vioxx and Celebrex scandals to illustrate the ways in which the integrity of university research is threatened by the entrepreneurial university and the new class of entrepreneurial academics who labour in its laboratories and teaching hospitals. I am packaging together the Vioxx and Celebrex cases because they nicely illustrate the perils that may befall university research when it is funded by for-profit corporations. Sadly, there is no shortage of other examples one could have chosen instead.
The Celebrex scandal involved a drug trial with sixteen authors, eight of them employees of the drug company Pharmacia [later purchased by Pfizer, the world’s largest drug company]. The other authors were from eight different American universities. All sixteen, however, were paid consultants to the company. The Vioxx scandal encompassed the world’s third largest drug company, Merck, and the world’s most high-impact medical journal, the New England Journal of Medicine as well as its editor, Dr. Jeffrey Drazen. It also involved, in the role of first author, a Canadian scientist, Dr. Caroline Bombardier, from the University of Toronto’s faculty of medicine. Since this is the same faculty and the same university which were earlier implicated in the Olivieri and Healy scandals, mentioned above, some readers may infer that the research environment at the U of T is ethically tainted to a degree greater than that which might be found elsewhere in Canada. Whether or not this conclusion is sustainable, it is certainly true that when it comes to attracting massive corporate funding, the U of T is far and away the most successful university in Canada. I shall argue that corporate funding of university research is at or close to the very heart of all these scandals.

In November of 2000, the New England Journal of Medicine published the VIGOR (Vioxx gastrointestinal outcomes research) trial. The trial appeared to demonstrate that those patients who were randomized to Vioxx experienced fewer stomach bleeds than those who received an older and much cheaper drug called naproxen. Publication of the VIGOR trial in the prestigious New England Journal launched Vioxx on its career as a blockbuster arthritis drug, with annual sales exceeding a billion dollars. The University of Toronto was very proud of the fact that Dr. Bombardier was the lead author of this article.

A few months earlier, The Journal of the American Medical Association had published the CLASS [Celecoxib Long-term Arthritis Safety Study] trial, which purported to show that Pharmacia’s drug, Celebrex, competitor of Vioxx, was associated with lower rates of stomach and intestinal ulcers when compared to two older and much less expensive drugs. Based largely on this publication, again in a highly prestigious journal, Celebrex, like Vioxx, instantly became a blockbuster arthritis drug.
Vioxx [rofecoxib] and Celebrex [celecoxib], belong to a class of drugs known as Cox-2 inhibitors. They are used for the treatment of arthritic pain. When these drugs were first introduced to the marketplace they were heavily promoted by their respective companies and were widely hailed by the mass media as “miracle aspirin”. The miracle was alleged to be the comparative absence of serious adverse effects. Promotional advertising for each drug - aimed directly at both doctors and potential consumers - ran to well over a hundred million dollars annually.

Vioxx was not finally withdrawn from the market until September of 2004, when a second clinical trial, the ADVANTAGE (Assessment of Differences between Vioxx and Naproxen to Ascertain Gastrointestinal Tolerability and Effectiveness) trial, provided damaging evidence of the cardiac risks posed to patients taking the drug. Tens of millions of Americans and millions of Canadians took Vioxx and Celebrex before both the VIGOR and the CLASS trials were exposed as being scientifically and ethically suspect. Vioxx was withdrawn from the market in 2004. Celebrex was allowed to stay on the market, but was required to carry a “Black Box warning” on its label.

The withdrawal of Vioxx from the marketplace occurred because the drug was shown to carry unacceptable risks of heart attacks and strokes. The cardio-vascular risks of Celebrex were comparable to those of Vioxx, and many critics thought that it, too, should have been withdrawn because of an unfavourable risk-benefit ratio.

The miasma of scandal which surrounds both of these drugs does not arise simply because they were found to be much more dangerous than first advertised. Rather, the scandal arises because the university (and company) researchers responsible for the conduct and publication of these two trials were discovered to have interpreted their data in an insupportable manner and, worse, to have suppressed vital data that would, if disclosed, have enabled doctors and patients to make a better informed choice about whether to recommend or use the drugs.

The Celebrex authors submitted data (for publication in *JAMA*) from the first six months of the CLASS trial. Based on these data, Celebrex appeared to be associated with lower rates of stomach and intestinal ulcers than the comparator drugs, ibuprofen and diclofenac. Significantly, however, but unknown to the editors of *JAMA*, the researchers, at the time they submitted their article, possessed evidence for a full year. Equally or more significant,
almost all of the ulcer complications occurred in Celebrex patients during the second six months of the trial. When the full year’s data were considered, the apparent safety advantage of Celebrex disappeared. In other words, the millions of patients who took Celebrex experienced no fewer GI complications than those who took ibuprofen. Indeed, when one looks at the overall incidence of adverse side effects one discovers that the people who took Celebrex experienced 11% more serious complications than those taking the older and much less expensive drugs. The safety advantage claimed by Pharmacia/Pfizer was illusory.\textsuperscript{viii}

Dr. Michael Wolfe, the Boston University gastroenterologist who wrote a favourable editorial to accompany the \textit{JAMA} Celebrex article, was upset when he discovered that the authors had suppressed half the data. “We were flabbergasted”, he said. “I am furious…. I wrote the editorial. I looked like a fool … But all I had available to me was the data presented in the article.”\textsuperscript{ix}

The editor of \textit{JAMA}, Dr. Catherine De Angelis, commented: “I am disheartened to hear that they had those data at the time that they submitted to us. …We are functioning on a level of trust that was, perhaps, broken.”\textsuperscript{x}

After reviewing the full year’s data, the U.S. Food and Drug Authority’s arthritis advisory committee concluded that Celebrex offers no proven safety advantage over the two older [and much less expensive] drugs.\textsuperscript{xii} Pharmacia/Pfizer unsuccessfully disputed this conclusion.

At the time, the mass media virtually ignored the story. In consequence, most patients remained in the dark as to the true state of the evidence. Surprisingly, the medical profession seemed scarcely more attuned to the significance of what had transpired – possibly because much of the “education” doctors receive about drugs comes from representatives of the drug companies and from eminent medical colleagues who are paid-consultants of these same companies. At all events, the public revelation of data suppression exerted no discernable restraining influence on the frequency with which doctors wrote prescriptions for Celebrex. The newly available data might show that it was very far from being “miracle aspirin” but these data had little impact on sales and profitability.

It is perhaps worth remarking that it was a Canadian clinical pharmacologist and drug evaluator, from the University of British Columbia, Dr. James Wright, who first discovered the differences between the data presented in the \textit{JAMA} article and the data presented by the company to the FDA.\textsuperscript{xiii} Dr. Wright is completely independent of the pharmaceutical industry.
Returning now to the VIGOR trial, it is important to note that, as reported by Dr. Bombardier and her colleagues, the research subjects who took 50 mg of Vioxx per day developed significantly more serious cardiovascular complications than those taking naproxen. The VIGOR trial itself showed a 400% greater risk of experiencing heart attacks, strokes and blood clots for subjects who were randomized to Vioxx, compared to those in the naproxen arm of the trial. The study’s authors explained, or perhaps one should say “explained away” this elevated risk by claiming that Vioxx was not responsible for the surplus of heart attacks and strokes. Instead, they claimed, naproxen was protective. They also claimed that the serious heart and stroke complications occurred exclusively in patients with a history of cardiovascular disease. If true, this would suggest that Vioxx might have a favourable risk-benefit ratio for patients having no previous history of cardiovascular disease.

Given the importance of the issue one would have expected the VIGOR authors to provide some evidence to support their hypothesis that naproxen was protective against heart attacks and strokes. In February of 2001 the FDA cast serious doubt on the claim that naproxen had been protective, which leads one, inexorably, to the conclusion that Vioxx was harming many patients. Curiously (and embarrassingly) the editors of the *NEJM*, when they were refereeing the article prior to publication, somehow failed to challenge the VIGOR authors to justify their sanguine hypothesis. Nor did the editors invite a more sceptical interpretation of the data from independent scientists.

Fortunately, rescue from company “spin” was at hand. Some alert scientists discovered that the VIGOR authors had failed to report several heart attack deaths in their *NEJM* publication even though they had supplied the correct data to the FDA. [As we will see later, it was a similar case of data suppression, in the ADVANTAGE trial, discussed below, that proved to be the final straw for Vioxx.] These additional data showed that patients taking Vioxx were 5 times more likely to suffer from heart attacks and strokes than patients taking naproxen. Even worse from the company’s point of view, the Vioxx deaths which had been suppressed from the *NEJM* article were deaths which occurred in patients with no history of heart disease. This fact kicked the legs out from under the company’s specious claim that only those with a history of heart disease were at elevated risk from taking Vioxx.
The investigators did not correct the scientific record. Their failure to do so was compounded when Dr. Jeffrey Drazen, esteemed editor of the *NEJM*, declined an opportunity to publish a letter submitted to the journal by independent scientists which would have alerted readers to the misleading nature of the data originally published. Years later, when the full extent of the harm done to tens of thousands of patients became undeniably clear, Drazen and his fellow editors at the *NEJM* justified their refusal to publish a timely correction with the intellectually (and morally) feeble excuse that it is the responsibility of authors, not journal editors, to correct data. It must be conceded that the correct data were available on the FDA website; but the impact of the *NEJM* in promoting sales of Vioxx was incomparably more significant than the impact of data available on the FDA website.

Overall, if one considers serious complications, defining “serious complications” as those which lead to hospitalization, permanent disability or death, the subjects who were given Vioxx had 21% more serious complications (of all kinds, gastrointestinal, cardiovascular and other) than did those who were given naproxen. Tens of thousands of patients died unnecessarily because this salient fact was not adequately publicized; well over a hundred thousand suffered heart attacks and strokes.

In sum, if all the data from the VIGOR study had been properly disclosed and properly analysed, the publication of the trial in *The New England Journal* would in all likelihood have dealt a death blow to the marketing and sale of Vioxx. Instead, the death blow came several years later with the publication of a second Merck sponsored Vioxx clinical trial, known as ADVANTAGE. The ADVANTAGE study displayed some of the same ethically dubious features as the VIGOR study, but is worth considering separately, partly because it helps to establish and reinforce the pattern of unethical behaviour in university-industry research partnerships and partly because it introduces some new and disturbing wrinkles to the already toxic mix.

The first point to note is that the ADVANTAGE trial was not a genuine scientific study. Under the guise of science, the marketing department of Merck set up this “study” with the prime purpose of inducing an additional 600 doctors to prescribe the drug to their patients. In other words, the study was really marketing dressed up as science. Ironically, however, ADVANTAGE indicated - what the company had been denying strenuously since its earlier VIGOR trial – that Vioxx carried significant heart attack
risks: five ADVANTAGE research subjects taking Vioxx experienced heart attacks, compared with only one in the naproxen arm of the study. Second, although Merck insisted that this number of heart attack deaths did not reach a level of statistical significance, the number of reported deaths was discovered to have been understated. In an instance of unethical data suppression comparable to that which occurred when the VIGOR study was first published, the ADVANTAGE study did not reveal that two additional Vioxx patients died from heart attack. Worse, the number of unreported heart attack deaths was likely three rather than two. Internal company records reveal that Merck’s top scientist, Dr. Edward Scolnick, pressured a colleague to change his views about the cause of one patient’s death, which was subsequently recorded as “unknown” rather than cardiac. When all these additional Vioxx cardiac deaths are included in the study’s total, they undermine the company’s claim that there was no statistical significance to the number of deaths. As if these ethical breaches were not enough, it should also be noted that the lead author of the ADVANTAGE trial, Dr. Jeffrey R. Lisse, an academic rheumatologist from the University of Arizona, later admitted that he was little more than a ghost author: “Merck designed the trial, paid for the trial, ran the trial”, Lisse admitted to a New York Times reporter. “Merck came to me after the study was completed and said, ‘We want your help to work on the paper’."

When university students put their names to work that they have not done themselves they are failed for plagiarism. However, a surprising number of university scientists seems comfortably to accept drug company money in exchange for putting their names to studies which have been designed and carried out by drug company employees. Prominent academics thus pad their resumes at the same time as they pad their wallets and, in the process, lend their scholarly prestige to the company’s products. Frequently, these academic “lead authors” have not even had access to the raw data on which the study’s conclusions are based. As a result of the Vioxx scandal and a host of others, many medical journals now require that the lead author take explicit responsibility for the data presented.

In sum, almost no one emerges with much credit from the saga of the Cox-2 inhibitors. The drug companies which massively marketed the drugs, both to doctors and directly to consumers, made billions of dollars; but, when the facts eventually emerged, the companies experienced a serious loss of public trust. Merck, in particular, is now facing a staggering number of expensive law suits. The company continues to insist that it took all reasonable
measures to determine whether Vioxx carried undue cardio-vascular risks and is defending its conduct in all of these law suits. Medical journals and their editors, in particular the *NEJM* and its editor Dr. Jeffrey Drazen, were seen by some critics as being incompetent at best and collusive at worst in what turned out to be a terrible human tragedy. The medical community allowed itself to be “sold” on these miraculous new drugs, often persuaded of their merits over fine dinners at luxury resorts. The after-dinner talk would generally be delivered by a respected colleague who was also a highly paid consultant to the companies. In consequence of such “education”, doctors wrote millions of prescriptions and their unwitting patients paid a fortune of money for drugs that claimed to have a superior safety profile but which were, in fact, inferior to older and much cheaper pain control drugs.

None of this is likely to have enhanced public trust in “evidence based medicine” or the medical profession which claims to practice it. When the evidence on which evidence-based medicine relies has been massaged or otherwise tainted then it scarcely provides a reliable tool for medical decision making. In the interests of truth-in-advertising, perhaps the medicine practiced in this era of corporate-university partnerships should be referred to as “pseudo-evidence based medicine”.

Finally, and from our point of view most significantly: University scientists, who are professionally obligated to pursue and to publish the truth, however embarrassing that truth might be to the corporate bottom line, were instead responsible for withholding data which were unfavourable to the products of their commercial sponsors. They withheld data and they also misinterpreted the data which they chose to disclose, spinning that data in such a way as to give the impression that their sponsors’ drugs had a safety profile superior to older and cheaper drugs. The opposite was true.

Although I have been focusing attention on one class of drugs, the Cox-2 inhibitors, there is ample evidence that similar problems are to be found with respect to many different drugs and classes of drugs. York University drug researcher Joel Lexchin and colleagues have done a comprehensive meta-analysis of the tendency of drug company sponsorship to produce biased research results. They conclude that “there is some kind of systematic bias to the outcome of published research funded by the pharmaceutical industry”.


Canadian universities, like their American counterparts, tend to measure their success by the extent of the corporate financial support which their researchers attract. Our universities and hospitals aspire to be world-class research institutions and, in pursuit of this objective, they vigorously solicit money (in support of research but also for new buildings and laboratories) from the world’s wealthiest and most powerful drug companies. The pharmaceutical industry has come to be accepted by our research universities as a vital “partner”. Handsome new buildings mushroom on campuses across the country, built with funds donated by these companies. However, when one discovers the cost to research integrity which seems to be an inescapable risk of such partnerships, the bargain may come to seem Faustian, with a terrible quid pro quo: the loss of research integrity and, eventually, the loss of public trust.

*What are universities for?*

I have been discussing some of the ethically dubious practices in which university scientists have engaged under the aegis of drug industry sponsorship. Now let’s go back to basics for a moment to ask: What are universities for?

Universities are places where scholars pursue *knowledge for its own sake*. Hence, the venerable metaphor of the “ivory tower”. University research is (primarily) curiosity-driven. Indeed, the intellectual vitality of universities derives from the fact that scholars are largely autonomous: beholden to no one, least of all the wealthy and powerful elites of society. The knowledge gained by university research is then freely disseminated to colleagues, students and the wider community. For this reason, universities are a vital source of critical perspective on many of the issues that matter most to society. This critical perspective is possible only because universities and the scholars who work in them are fearlessly independent of governmental, church or corporate control.

Well, this is the story we tell ourselves; or it’s the story we used to tell ourselves. The paradigm of the university as a place of independent scholarship derives in some measure from the Enlightenment. We know, of course that the Enlightenment ideal of the university as a centre for pure scholarship, untainted by the pursuit of wealth, power and status, was never entirely true. How could it have been true? As Immanuel Kant famously
observed, “Out of the crooked timber of humanity, no straight thing was ever made.”xxiv Given our imperfections, it would be naïve to deny that among the motives which inspire university research are to be found some which are less than estimable. Career advancement, for example, would often be part of the motivational mix, along with competition for status and even hope for glory. When Churches or other ruling elites/classes controlled universities and their finances, there was never a shortage of academics who sought promotion via scholarship which told power whatever power wanted to hear. La trahison des clérics was a phrase made popular by Julien Benda (in 1928) to describe the kind of betrayal committed by intellectuals who advance their self-interest (by providing legitimation to ruling elites) at the expense of the more dangerous enterprise of devoting one’s scholarly energies to the disinterested search for truth.xxv

Granting this point and thereby conceding that there may not have existed, at some indeterminate point in the past, a “golden age” of scholarly purity, one might nevertheless insist that there was a time when the percentage of dross mixed in with the gold was less prominent than it is today. It is impossible to deny the claim - and many, within and without the university, want to trumpet rather than to deny it - that we are now living in an era when universities are regarded, perhaps first and foremost, as engines of economic prosperity. We constitute an important part of national “manpower policy”. Our graduates, many of them, end up working in the corporate trenches. Our intellectual patents generate wealth for the biotech companies we have formed or with which we have struck up commercial alliances. Universities themselves often demand and receive an ownership share of these companies, from which arrangement they hope to receive substantial profits. It is now expected, indeed it is demanded, that university research findings should move rapidly from the academic laboratory or teaching hospital to the real world of bottom-line corporate profitability. Arguably, the modern university, in its role as corporate handmaiden, has acted in a way that restricts rather than expands the scope of researchers to engage in disinterested or critical scholarship.

Scientific research in Canadian universities is extensively funded by industry. This proposition is generally true, but it is especially true for pharmacological research, which attracts strikingly large sums of money from the pharmaceutical industry. As explained in the brief historical section which follows, it’s important to remind ourselves that these university-corporate partnerships are a comparatively recent phenomenon. Thirty or
forty years ago, most research funds came from governments and from quasi-governmental funding bodies (known as granting agencies). Today, although governments continue to invest large sums of money in scientific research (albeit a much smaller percentage of the total than in the past), the marked trend is towards private funding. Moreover, the importance of private funding is enhanced by deliberate government policies, which give strong funding preference to scientists and scientific projects which have also succeeded in attracting corporate sponsors. Often university researchers are not allowed to apply for public funds in support of their investigations unless they can recruit a private partner.

To put the point bluntly, this means that academics who seek to pursue a career doing scientific research at a Canadian university had better ensure that they and their projects will be attractive to potential corporate sponsors. University careers depend heavily upon the ability to bring in a continuous stream of research dollars. Pity the naive researcher who adopts as her research project a cancer treatment that depends on eating broccoli sprinkled with lemon juice. Which pharmaceutical corporation would fund such a profit-threatening idea? Which university would give tenure or promotion to a researcher who could not attract corporate funding, however brilliant and socially beneficial her research project might be? Which government agency would support such research in the absence of a legitimating corporate partner? It may be an exaggeration to say that universities have transmogrified into the R&D departments of economically powerful corporations but the exaggeration, if any, is mild. In other words, the kind of research that is undertaken at our universities must nowadays be designed to please potential corporate sponsors by promising to produce results which will satisfy the profit-maximizing expectations of a lean, mean, competitive economy.

The gravamen of my argument, in what follows, is this. We have made a Faustian bargain. With the best of intentions, we have sold our souls for company gold and, in the process, have put the integrity of our research and the credibility of our universities into serious question. Data are fast accumulating which demonstrate that when corporations fund research the results of that research are powerfully biased by the corporate agenda. A worrying series of academic scandals, two of which (the Vioxx and Celebrex sagas) have been discussed in some detail above, shows that when universities become closely allied with the marketplace their vigilance in the promotion and protection of research integrity may be less than stellar. In
other words, when the search for truth turns into the pursuit of profits the end result is often very far from beneficial to society.

A Brief Historical Perspective

The widespread public attention generated by the Olivieri and Healy scandals at the University of Toronto sharply focused public attention on the dangers posed by corporate sponsorship of universities and university research. Public concern about the growing commercialization of university research is heightened, almost on a weekly basis, by publicity given to the kind of data suppression engaged in by drug companies and their university collaborators. The Vioxx scandal received more media attention than most, partly because of the very large number of unnecessary deaths and illnesses that were associated with Vioxx use; but equally shocking revelations seem to hit the mass media almost on a weekly basis. One thinks here, for example, about the way in which drug companies suppressed vital evidence concerning the safety and efficacy of the SSRI anti-depressant drugs, as David Healy has carefully detailed.\textsuperscript{xxvi}

A growing number of scholars and some thoughtful citizens as well are already persuaded that the commercialization of university research threatens to corrode if not entirely to undermine research integrity at our universities. But even among those who harbour such fears, a majority appears to hold the TINA view, popularized by former British Prime Minister Margaret Thatcher: There Is No Alternative. And if it’s true that there is no alternative to the new entrepreneurial university, then the best we can do is to introduce reforms which will restrain, even though they cannot altogether eliminate, the malign potential effects of the unholy alliance between universities and the commercial marketplace.

In this section I sketch briefly the history of corporate involvement as “partner” to university research.\textsuperscript{xxvii} Only when we understand how we got to where we are at present will we have an opportunity properly to consider whether there might, \textit{pace} Margaret Thatcher, be an alternative.

Because the pharmaceutical industry has been in the vanguard of the movement to commercialize research at our universities, I am focusing my discussion on the so-called partnership between Big Pharma, as the pharmaceutical industry has become known, on the one hand, and
universities, on the other. It should be noted, however, that university agricultural research has been captured (primarily by the petro-chemical industry) to an extent scarcely less worrying than university medical research.\textsuperscript{xviii} And what is true for university medical and agricultural research is also true, to a greater or lesser extent, for university research in such disparate fields as climate change (funded by the fossil fuel industry) and foods and nutrition (funded by multi-national food corporations).\textsuperscript{xxix} Even such ostensibly humanistic disciplines as “Strategic Studies”, nestled typically under the departmental aegis of “Political Studies”, are often funded significantly by the military and by allied defence industries, on condition that they produce research results which are pleasing to their military sponsors.\textsuperscript{xxx} Those old enough to remember U.S. President Dwight Eisenhower’s warning, issued in 1961, of the dangers posed to American society by the rise of the “military/industrial complex”, will now, almost half a century later, have a renewed appreciation of just how prescient Eisenhower was.

To pick any date as “the turning point” - the point at which university research became a predominantly entrepreneurial activity – would be somewhat arbitrary. There is widespread consensus, however, that a confluence of developments in the 1980s best qualifies as such an historic turning point.\textsuperscript{xxxi} This was the decade when the norms of science, as adumbrated by Robert Merton in his classic book, \textit{The Sociology of Science},\textsuperscript{xxxii} began to undergo a radical transformation.

The paradigm of scientific culture, as described by Merton, may be encapsulated as follows: the soundness of scientific research should be judged by impersonal criteria; research findings should be treated as open and shared rather than in a proprietary or secretive fashion; researchers should be motivated primarily by the desire to advance knowledge rather than by financial or careerist considerations; and research findings should be tested to death. That is, the scientific community should accept research claims only when they have been rigorously tested by disinterested scientists. Investigators can be counted on to communicate their results freely with each other because they share the same professional canon: a primary commitment to the advancement of knowledge.

These norms of scientific research were offered by Merton partly as descriptive of how scientists generally conducted themselves and partly as prescriptive of how they ought to behave \textit{qua} professional scientists.
Mertonian norms were still widely accepted at the mid-point of the 20th century. It was this point, however, that things began to change.

Much to the delight of the scientific community, the funding of scientific research became a top national priority in the U.S.A. during and after WWII. Prominent among the reasons for this development was the conviction that the advancement of scientific knowledge, via massive government research spending, was necessary for America’s health, prosperity and, most important, security. In consequence, the fifties and sixties in America were a golden age for government funding of basic science. During this period, less than five per cent of university research funding came from private industry. Direct interaction between academic scientists and for-profit corporations, was quite limited.

By the late seventies, however, university research came to be regarded as the means whereby America could achieve and maintain global industrial and military dominance. University science was now assigned the role of serving the nation as a potent commercial weapon in a highly competitive world economy. Passage in 1980 of the Bayh-Dole Act enabled universities and their researchers to patent discoveries resulting from federally-funded research. As a result of these and other developments, corporate support for academic biomedical research escalated from less than five million dollars (1974) to hundreds of millions of dollars (1989).xxxi

By the standards of history, this transformation occurred in the twinkling of an eye. The entrepreneurial scientist working in the entrepreneurial university moved, almost in one fell swoop, from being an oxymoron to being the way science was done and, or so it seemed, must forever be done. Within a mere few decades, the pharmaceutical industry became the major funder of clinical drug trials and, a major financial contributor to medical schools and universities, via donations of buildings and equipment.

Critics warned that these dramatically increased levels of corporate funding could produce, as an unintended side-effect, a serious erosion of the norms of scientific research. What the Vioxx and Celebrex scandals, discussed above, are meant to illustrate, is that the critics knew whereof they spoke. Biomedical research at our universities has been absorbed, to an alarming extent, by the profit-seeking ethos of the marketplace. The norms of commerce are now threatening to swamp the traditional norms of science. As Lexchin and others are demonstrating with persuasive empirical data,xxxiv
when the disinterested pursuit of knowledge gives way to the entrepreneurial pursuit of financial self-interest the result is a body of scientific evidence which is skewed towards the interests of the sponsoring corporation. It’s as simple as the old folk wisdom: He who pays the piper calls the tune.

The history of medical research in Canada followed a trajectory similar to that in the USA, though with about a ten year time lag. In Canada, it wasn’t until the late eighties that the federal government came to view the drug companies as a key to economic growth and moved to extend patent protection for drugs. By the 1990s, Canadian governments were either freezing or cutting funds for medical research under the rubric of fiscal responsibility. Caught in a squeeze between shrinking government funding and escalating research costs, Canadian medical researchers sought salvation in the welcoming embrace of the pharmaceutical industry. For many university presidents and medical faculty deans, commercializing university research by marketing universities to wealthy corporations was a realistic way, perhaps the only realistic way, to obtain the research funding necessary to compete on the international stage. Under the banner of “pursuing excellence” in research, universities became supplicants of the very corporations whose products and practices they had, in previous times, subjected to critical scrutiny.

At the outset of this chapter two case studies were analysed [the Vioxx and the Celebrex scandals] to illustrate the way in which powerful drug companies were able, via their funding of university research, successfully to develop and market drugs for which the risk-benefit ratio was known from the outset to be dubious at best. Investigators whose careers depended on drug company sponsorship seem to be producing research which often has greater affinities with marketing than with the pursuit of scientific truth. To understand how and why this problem arose it will now be necessary to explore the key concept of “conflict of interest”

Conflicts of interest

The best short definition of “conflict of interest” defines the concept as follows:

A person is in a conflict of interest situation if she is in a relationship with another in which she has a moral obligation to exercise her
judgment in that other’s service and, at the same time, she has an interest tending to interfere with the proper exercise of judgment in that relationship.\textsuperscript{xxxv}

My argument is that when university researchers accept corporate funding for their research projects they put themselves in a conflict of interest situation. The same would be true of universities or hospitals which accept corporate donations and thereby allow themselves to become beholden to those corporations.

Drug researchers, for example, have an ethical obligation to put the interests of truth (and patient safety) ahead of the interests of the corporations which are funding their projects. When, however, the researcher’s career depends upon the direction of her findings then there is a worrying danger that the objectivity of the researcher may be biased or skewed. Thus, if a researcher stands to gain monetary and/or career success by demonstrating the safety and efficacy of a sponsor’s new drug, but stands to lose research funding and perhaps her job if she finds that the new drug is unsafe or ineffective, then she is in a conflict of interest situation.

The suggestion here is not that researchers who have a conflict of interest will necessarily behave in a (consciously) corrupt fashion. Only a small minority of investigators is likely to be guilty of deliberately skewing their investigations so as to produce dishonest results which will be pleasing to their corporate sponsors. The real danger is that the unconscious effect of financial benefit or career self-interest has a marked tendency to generate biased research findings. There is a deal of social science evidence which demonstrates that “even when individuals try to be objective, their judgments are subject to an unconscious and unintentional self-serving bias.”\textsuperscript{xxxvi} [Emphasis mine.] Moreover, we now have a substantial body of empirical evidence which confirms that when it comes to biomedical research, financial conflicts of interest are associated with significant effects.

The study which first drew wide attention to the issue of how research objectivity might be eroded by drug industry sponsorship was published in 1998 by Stelfox and colleagues.\textsuperscript{xxxvii} Their goal was to investigate the issue of whether (and if so, to what extent) industry sponsorship of biomedical research might influence the outcome of that research. To answer this question they studied published articles on the safety of calcium channel blockers – a class of drugs used to treat high blood pressure. Stelfox and
colleagues first divided authors according to their financial relationship with pharmaceutical companies and then, separately, classified (as “supportive”, “critical” or “neutral”) their research findings on the issue of whether these drugs were safe. What they found was that “96 per cent of supportive authors had financial relationships with the manufacturers of calcium channel antagonists, as compared with 60 per cent of neutral authors and 37 per cent of critical authors.” In other words, there was a striking association between the conclusions reached by investigators (with respect to the safety of calcium channel blockers) and the financial relationship of those investigators with pharmaceutical manufacturers.

The Stelfox study was unable to determine conclusively whether corporate funding came to the authors before or after they reached favourable conclusions about these drugs. However, more recent studies have repeatedly demonstrated that industry sponsored studies are significantly more likely to reach conclusions which favour their sponsors’ products than studies which are independently funded. To cite Lexchin again:

Research sponsored by the drug industry was more likely to produce results favouring the product made by the company sponsoring the research than studies funded by other sources. The results apply across a wide range of disease states, drugs and drug classes, over at least two decades and regardless of the type of research being assessed – pharmacoeconomic studies, clinical trials, or meta-analyses of clinical trials.

The proliferation of studies pointing to the important impact of funding source on the results of biomedical research should be of serious concern to those who support industry-university partnerships.

It might be helpful to reflect that in fields far removed from biomedical research there is a sharp awareness of the dangers posed by conflicts of interest. Referees are not permitted to accept benefits or gifts from team owners; police are not allowed to accept benefits or gifts from crime suspects; judges are not permitted to accept benefits or gifts from litigants; professors are not allowed to accept benefits or gifts from students. That’s because referees, police officers, judges and professors are obligated to exercise their judgement impartially according to professional standards. When we hope for future benefits our self-interest may skew our professional judgement. Moreover, gifts and benefits make the recipient
beholden to the gift-giver. The well-established anthropological phenomenon of reciprocity operates powerfully, though (again) often not in a conscious, deliberate manner, to motivate us to return kindness for kindness, gift for gift.

Although most people recognize that the powerful combination of self-interest and reciprocity can bias the judgement of others, often in ways of which the recipient of is scarcely aware, few of us are willing to acknowledge that we could ourselves be “bought” in this way. I have lectured on biomedical conflicts of interest at universities in Canada, the USA, and Great Britain but I have only once encountered a researcher who was willing to acknowledge that he had been biased by drug company funding. The vehemence with which most researchers deny that they could have been biased by the acceptance of drug company funding or other financial benefits from these companies, such as consulting fees and stock options reflects a common misunderstanding. Researchers become understandably indignant when they believe someone is accusing them of deliberate corruption. What many seem not to recognize, however, is that when one allows oneself to be placed in a conflict of interest situation, that is, when one has a vested interest (usually financial) in reaching a particular conclusion, one tends almost automatically, at a subconscious level, to weigh arguments and evidence in a biased fashion. xl

Pseudo-Evidence-based decision making

We pride ourselves on being a society in which important decisions of public policy are based upon (mostly) reliable scientific evidence. Across many domains, governments depend upon the research done at our leading universities, research institutes and academic hospitals to guide policy. With respect to areas of great social concern, such as public health and safety, nutrition, environmental sustainability, employment, housing, foreign policy and much else besides, governmental deliberations are framed and shaped by the work of university scholars.

What is true for us as a society is also true for (most of) us as individuals. When we must reach a decision about such matters as whether to take medicine for a health problem and, if so, which medicine would be (comparatively) safe and effective, most of us rely upon the expertise of university researchers and the research findings they have published in
scholarly journals. Some of us consult these research findings directly, but many learn of them and their significance indirectly both from the doctors and other professionals whose expertise we regularly consult and from popular reports in the mass media. When professionals dispense advice to us they are meant to base that advice on research findings published in peer-reviewed scholarly journals by their academic colleagues.

We are similarly reliant upon university-based research when we deliberate about such disparate questions as which foods are nutritious, whether genetically modified crops pose an unacceptable threat to us or to the environment, and whether to have our children vaccinated against measles, mumps and rubella. The list of personal decisions we make in reliance upon university expertise could be expanded almost indefinitely.

This is not to deny that we are also, most of us, influenced in our personal decision-making by epistemologically less reputable factors, such as celebrity product endorsements. For reasons best explored by social psychologists, we are more likely to buy life insurance from Company X or cough syrup from Company Y when a hockey super-star has lent his name and image to the brand. Still, all but the most naïve of us understand that the celebrity in question very likely does not possess expertise in the relevant domain. Wayne Gretsky may be just the person to consult when buying a hockey stick; but life insurance? We understand, also, that he is being heavily remunerated for lending the star-power of his name and image to the products whose virtues he publicly extols. We would not be shocked to learn that he has never actually used these products himself (except, perhaps, when he they are given to him as free samples). So, we buy the stuff he endorses but, if questioned, we would readily admit that it is emotion of one sort or another (fear of this, hope for that), often below the level of full consciousness, which impelled our purchase.

Clearly, it would be foolish to deny that there is a deal of credulity among the general public. Ordinary folks seem prepared on occasion to believe in and/or act upon the most implausible propositions. Nor are elites immune from foolish irrationalities. University graduates can be every bit as credulous as *hoi poloi* when it comes to consulting the “expertise” of the astrologer, the medium or the Tarot Card reader. It’s sad to reflect, for example, that astrologers find a market among every stratum of society for the hokum they peddle.
Government policy-making

Governments, too, have been known to base their policy-decisions on factors other than scholarly evidence relating to “best overall net benefit”. Nor is this aberration necessarily the result of an ignorant reliance upon superstition or other forms of irrationality.

The desire to obtain or to retain donations from wealthy individuals and corporations has been known to induce governments to massage the available scholarly evidence or even to ignore or suppress it entirely when that evidence points to inconvenient truths. One does not need to be an inveterate cynic to recognize that manipulated data and consciously biased interpretations often form the basis of decision-making. This is especially so when governments seek to placate major party political donors or to curry favour with influential segments of the electorate.

In short, whether we are speaking of individuals or governments, one must concede that the decision-making process on important issues is not always fully rational. Nevertheless, at both the social and the personal level, it seems reasonable to believe that our lives are likely to go better if we have access to accurate, reliable, honest and disinterested information from experts whose commitment is to the truth rather than to their own financial or career self-interest.

Thus, when one thinks about how we, both as individuals and as collectivities, reach important decisions one is confronted with a contradictory pattern of decision-making. Sometimes we seek out the best available evidence and weigh it carefully; sometimes we follow our gut feelings or irrational prejudices (which, not infrequently, coincide). As well, our thinking is often distorted by self-interest, including especially financial self-interest, in ways of which we may be only imperfectly aware.

Information and advice offered by the scholarly professions is generally accorded considerable weight. But it must also be acknowledged that not all professional advice is accorded equal respect. Advice from the medical profession is generally though not always, thought to be trustworthy. By contrast, advice offered by lawyers is often greeted with cynical derision. Advice which is professionally mandated may nevertheless be seen as suspect when the profession in question does not enjoy a high reputation for
honesty and integrity. Widespread public cynicism about the legal profession often expresses itself in the corrosive form of anti-lawyer jokes; nor are other professions, including accountancy and (even) medicine, immune from the perception that the professional advice they offer may be self-serving (and therefore unreliable) rather than public-spirited.

As an illustrative example of the potentially malign effect of such widespread public cynicism, consider the current widespread rejection of the MMR vaccine. Many parents, especially in Europe, refuse to allow their children to be vaccinated against potentially deadly childhood diseases, such as measles, mumps and rubella. They refuse because they disbelieve the reassurances offered by prominent medical scientists.

Scientifically unsubstantiated rumours abound to the effect that the MMR vaccine is responsible for an alleged increase of autism rates among children. The scientific community has strong evidence which points to the vaccine’s having no such adverse side effect; but notwithstanding the fact that the British Government has paraded a troupe of leading scientists before the media, in an effort to reassure the public, the public remains sceptical. The public remains sceptical in large part because it has become known that virtually all of the vaccine experts have had their research funded by the companies manufacturing the MMR vaccine and are themselves the recipients of substantial consulting fees from these same companies. The scientists in question are persuaded of their own rectitude but, understandably, the public questions whether their scientific conclusions may not have been shaped by some combination of career advancement and personal financial self-interest.

University researchers and conflict of interest

At present, the public appears not fully to appreciate that such financial and career conflicts of interest have become the norm for university researchers in many different fields, including but not limited to such fields as academic medicine, agriculture and climate change. Not only is it the case that most of our leading university scientific researchers benefit from sponsorship by industry; the universities and teaching hospitals in which these scientists work also accept very substantial amounts of money from the same corporate sources, usually in the form of “charitable donations”. Indeed, it is these corporate donations which make possible the proliferation of many
fine new research buildings on Canadian university campuses. They also fund the expensive equipment and technical staff without which the buildings would be empty shells.

This connubial relationship between universities and the world of business is seen by many, including a significant portion of university administrators and governing boards, as something to be welcomed and fostered. Revenue generated by such partnerships (in the form of royalties on joint ventures, funds for salaries, equipment and support staff and the aforementioned donations for buildings) is seen as providing the leverage which universities and teaching hospitals need in order to achieve “excellence” or, even better, to become “world-class”. The alternative to such university-industry partnerships is seen as mediocrity and stagnation. University administrators are persuaded that if they do not aggressively pursue corporate research funds and corporate donations for their own institutions then their competitor universities/hospitals, both nationally and internationally, will win the race for gold and glory.

This way of putting the case for university-corporate partnerships is misleading and incomplete, however, since it portrays the institutional imperative of the university as focused solely on growth for the sake of growth, or growth for the sake of status, fame and fortune. Critics of the corporate university should, in fairness, acknowledge that university administrators typically see themselves as committed to the advancement of socially vital knowledge, both scientific and humanistic. This altruistic self-image should not be entirely dismissed. Human motivation is almost always complex, multiple and ambiguous. Doubtless, university administrators generally do believe, sincerely, that their strenuous efforts to harness corporate wealth, on behalf of university expansion, make an important contribution to the promotion of the university’s fundamental objective: the benefit of humankind through the advancement and dissemination of useful knowledge. It’s also true, however, that in their ceaseless quest to raise money university administrators may occasionally lose sight of the proper goals of a university. Means and ends are easily confused, with the means (rapid growth) coming to displace the end they were meant to promote (the advancement of knowledge); but that’s not to say that administrators don’t sleep soundly at night, comfortable in their conviction that their corporate fund-raising efforts are aimed towards a noble cause.
Conclusions

Many members of the biomedical research community are persuaded that in this era of rapidly escalating costs, industrial sponsorship of university research is the best (and perhaps the only viable) path towards the advancement of science. They see or claim to see a synergy between the expansion of corporate profits and the flourishing of scientific creativity. The creation of beneficial new drugs is often cited as evidence to demonstrate that the commercialization of university research is a highly positive development for society as well as for science.

Critics tend to be less sanguine than university administrators about the outcome of increasingly close ties between universities and corporations. They argue that it was government funding rather than corporate funding which promoted innovative and socially beneficial research. Corporate funding of university research has instead led us to a point where many of the new drugs coming to market are nothing more than “me-too” drugs: invariably more expensive than their predecessors (which have come off patent) but no more efficacious and often more dangerous. Despite the very considerable sums of money invested by pharmaceutical corporations in university research, the U.S. Food and Drug Administration reports that this money is producing fewer and fewer “new molecular entities”. In short, the number of golden eggs produced by the corporate goose is disappointingly exiguous. Even more worrying, adverse effects from prescription drugs now occupy the number four place on the list of leading causes of death in the USA.

They, the critics, worry about the marked divergence between the fundamental raison d’etre of industry, on the one hand, and universities, on the other. If we ask “What are corporations for?” the simple answer is that corporations are for the maximization of shareholder profits. By contrast, although today’s multiversity may aspire to be all things to all people it nevertheless continues to be the case that the “bottom line” for any university worthy of being so called must continue to be the pursuit of truth.

Corporations owe a fiduciary duty to their shareholders. That duty is to maximize profitability. Realistically, given the competitive global economy in which most corporations now operate, it is short- rather than long-term profitability which often dominates the thinking of corporate officials, If
quarterly profits don’t satisfy market expectations then stock values will decrease, sometimes precipitously, and heads may roll. The fundamental commitment of the university, by contrast, is to seek truth even when that truth may have an adverse effect upon the corporate bottom line.\textsuperscript{xlv}

Once it is recognized that our current way of funding biomedical research is both vastly expensive but sadly unproductive of beneficial new molecules and also demonstrably undermining the integrity of both our researchers and our research institutions, then it becomes a matter of some urgency to contemplate alternative funding arrangements.

Since the fundamental problem arising from university-corporate partnerships is the problem of conflict of interest, and since many of the reforms suggested as tools for “managing” this conflict – reforms such as disclosure of the conflicts – have proven ineffectual, the most promising solution to the problem turns out also to be the most simple: an outright prohibition of corporate funding for university research. The sequestration thesis, which I defend, insists that university researchers must be entirely sequestered from the process of commercialization.

If we as a society want public science in the public interest it will have to be funded through public tax dollars.\textsuperscript{xlv} The “partnership” between universities and their researchers, on the one hand, and for-profit corporations, on the other, is almost pre-ordained to produce research findings that promote the interests of the corporations even when, as not infrequently happens, those interests clash with the best interests of both patients and the wider community.

Hitherto, the community of university researchers has been viewed by society at large as an invaluable source of independent information and critical analysis. University-industry partnerships, as we have seen, threaten seriously to corrode the independence of university research and thereby its integrity. Once the true nature and extent of corporate financial sponsorship becomes widely recognized and understood by the rest of society, the credibility of university research is likely to suffer irreparable harm. Loss of public trust is a heavy price to pay for the short-term benefits that come when universities float on a sea of corporate largesse.


v Lisse JR, Perlman M, Johansson G et al Gastrointestinal Tolerability and Effectiveness of Rofecoxib versus Naproxen in the Treatment of Osteoarthritis, the ADVANTAGE Study : A Randomized, Controlled Trial. Annals of Internal Medicine, 2003; 139:539-564.


At least 4,600 people or their survivors are suing Merck. These suits allege death and other damage from the drug. The company does not concede that its drug caused such harm and it has adopted the position of fighting every law suit. See: Berenson, op.cit.

The company applied to the U.S. Food and Drug Administration (FDA) for permission to change Celebrex’s label. It wanted to declare on the label that Celebrex was safer than other arthritis products. On 7th February 2001 the FDA review committee recommended that any labeling changes be denied. This did not stop the company from continuing to market its drug widely to doctors as having a superior safety profile. “The real drug pushers”, McLean C. Report Newsmagazine, March 19, 2001.


x Loc. Cit.


xii Loc.cit.


xiv See an excellent discussion of the cardiovascular risks posed by Vioxx in Chapter 3 of John Abramson, Overdosed America: The broken promise of American medicine. New York. Harper Collins, 2004. Abramson also points out that the subjects of the VIGOR trial were quite unrepresentative of the majority of people for whom doctors prescribed Vioxx. More than half of the subjects in the trial were on steroids. This little-noticed fact is of great importance because the study shows significant reductions in risk of serious GI complications only in those patients who were on steroids. For the others, i.e., most of the people who ended up taking Vioxx, there was no statistically significant reduction of GI complications.

Theoretically, the ADVANTAGE trial was meant to show that Vioxx caused fewer stomach problems than naproxen, but this had already been demonstrated by the VIGOR study, which had a much larger number of subjects. Dr. Edward M. Scolnick, top Merck scientist between 1985 and 2002, admitted as much in an internal company memo: “Small marketing studies which are intellectually redundant are extremely dangerous”, he wrote. See: Berenson, op. cit.

Merck bought 900,000 reprints of the article to use in marketing Vioxx, more than one for every doctor in America. The revenue to the NEJM is estimated to be in the range of ¾ million dollars. See Smith, op. cit.

If either the data suppression or the scientifically skewed interpretations were done deliberately, intentionally or knowingly, then the scientists involved could be seen as corrupt. If these problems arose because of an unconscious desire to please commercial sponsors then a charge of corruption might not stick. Instead, the researchers would be guilty of unprofessional conduct for allowing themselves to be in the kind of conflict of interest situation which tends to undermine research integrity. The conflicts of interest inherent in corporate sponsorship of academic research are now so pervasive that many now regard them as professionally acceptable because unavoidable and because “everyone is doing it”.


For a fuller discussion, see Schafer, op. cit.

E.g., much of the research being done on genetically modified crops is funded by petro-chemical companies such as Monsanto and Bayer. See: McIlroy A. “Under Siege in the Ivory Tower”. Globe and Mail. 8th September, 2001, for an interview with Professor Ann Clark of Guelph University. Clark describes how fearful her colleagues are, across Canada, when it comes to speaking publicly about genetically modified organisms (GMOs). What they fear, according to Clark, is that their research will lose its funding. In effect, that they will be blackballed by industry. Worse, says Clark, they also fear harassment from their own universities. Clark then describes her own experiences of serious harassment by Guelph University after she established a web site critical of GMOs.


See Krimsy, op. cit.; Schafer, op. cit.

Lexchin, op. cit., 1169.


Dana J, Lowenstein G. A social science perspective on gifts to physicians from industry. JAMA, 2003; 290, p. 252.


Lexchin, op. cit.
Dana and Lowenstein, op. cit.


Angell, op. cit.


For a range of possible answers to the question “From where will the vast sums of money needed to fund research” come?” see Schafer A, *Biomedical conflicts of interest. Op. cit.*, pp. 22-24.