

# Privatization of Knowledge and the Creation of Biomedical Conflicts of Interest

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## ABSTRACT

Scientific and ethical misconduct have increased at an alarming rate as a result of the privatization of knowledge. What began as an effort to stimulate entrepreneurship and increase discovery in biomedical research by strengthening the ties between industry and academics has led to an erosion of confidence in the reporting of research results. Inherent tensions between profit-directed inquiry and knowledge-directed inquiry are instantiated in psychopharmacology, especially in the co-optation of academic activity to corporate objectives. The effects of these tensions are visible in research agendas, publication practices, postgraduate education, academic-industry partnerships and product promotion.

**Key Words:** conflicts of interest, ethics, intellectual property law, key opinion leaders, knowledge-directed inquiry, pharmaceutical industry, privatization, profit-directed inquiry

## Introduction

There are many pressures that potentially undermine the disinterested status of an academic scientist. None are free of bias. We carry pre-conceptions and expectations into research yet rely on research methodology to counter these effects. Most at risk are those who fail to acknowledge bias. In disciplines where research involves measurement, we rely on developing objective measures so that outcomes are less susceptible to researchers' judgments. Medical scientists are doubly vulnerable and may need a greater level of protection from bias than many other academics. They are also likely to be influenced by their idiosyncratic experience with their own patients.

Psychiatry may be the branch of medicine that is most vulnerable to influence. Diagnoses are difficult to define let alone to measure. Given the ascendancy of what Ziliak and McCloskey call the "cult of statistical significance," researchers turn to what is measurable

rather than to what is meaningful, so that findings that are likely to be clinical and meaningful are rejected because they fail to reach statistical significance whereas others that appear clinically trivial are accepted (Ziliak and McCloskey, 2007). The disenchantment with the psychoanalytic paradigm of psychiatry led to a massive investment in psychopharmacology and other physical interventions. A concession now to the limited benefit that psychopharmacology offers would come at great cost to the profession. A vested interest in protecting the new paradigm of neurological models of psychiatric disorders reaches beyond the quest for a secure scientific foundation.

To the vulnerability created by personal bias and questionable methodology we must add the dangers of pervasive financial conflicts of interest, of which we investigate the root cause in this paper. With the privatization of knowledge comes a heavy burden of untangling the motives of profit from the motives of scientific objectivity. Conflict of interest has created an epistemological morass and a serious problem of credibility for the profession of medicine. The bias created from researchers' interests and ambitions pales in comparison to bias due to the now pervasive influence of industry.

## Profit-Directed Inquiry vs. Knowledge-Directed Inquiry

It is in industry's interests to be competitive, protect discoveries and strategies as trade secrets, demand product loyalty, and suppress criticism, all to the end of gaining market share and maximizing profit. As such, inquiry is profit directed. By contrast, academe is a cooperative enterprise, characterized by free, open critical inquiry and disinterest in the results of research in the pursuit of truth and discovery of error. Richard Horton citing the American historian Steven Shapin, contends that the two cultures of the scientific and trading classes, or what we identify as the knowledge vs. profit inquiry, were kept separate, to protect the integrity and virtues of the former from the vices of the latter. Scientists were, and are still meant to be, trusted to produce a reliable body of knowledge, while no such requirement is supposed from those who seek private advantage (Horton, 2004, 7).

A marriage of these two very different cultures or motives has produced a situation in which the profit motive threatens the ideal of intellectual inquiry. Addressing the most important needs of humanity becomes subservient to the pursuit of significant revenue. But more importantly for our present concern, profit inquiry instantiated in the corporate model of the academy has resulted in an alarming increase in scientific and ethical misconduct, especially in biomedical research. This is not to say that the industry-academe dichotomy has been sharply drawn and immune from contamination until recently, but in our view what might have been well-intentioned legislation to spur entrepreneurship in the commercial development of research has accelerated the conflicts of interest and the resulting misconduct with virtually no regulatory oversight. In fact, the political motives that created the acceleration of conflicts of interest are the very same ones that have considerably weakened regulation—all as a result of pro-industry legislation. The marketplace, we are assured by apologists, will correct product defects and expose corruption. Yet the harm to public health that has resulted from distortion in clinical research and the use of that research in drug promotion has made it clear that the marketplace is too slow or inept when it comes to medicine (Topol, 2004).

## The Privatization of Knowledge and Conflict of Interest

Conflict of interest is defined as a problem of competing motives. A conflict of interest exists when one in a position of trust has competing professional or personal interests which make it difficult to fulfill his or her duties impartially. We take as a case study the United States pharmaceutical industry (by far the world's biggest), and its relationship with Key Opinion Leaders (KOLs), particularly psychiatrists who are amongst those most generously supported by pharma (Sorrell, 2008). In medicine, the phenomenon of the KOL is a result of the industry-academic partnership that has become virtually synonymous with financial conflict of interest. KOLs are individuals who act as consultants, researchers and teachers for drug companies. The relationship is mutually beneficial to the KOLs and the companies but not necessarily to patients. For the company, it provides an apparently independent expert to publish and speak on behalf of its products. For the academic, it offers kudos, research income, publications (including invitations to co-author influential papers that are largely ghost-written) and a profile at major congresses. It also offers great financial benefit. As the inquiries of US Senator Charles Grassley have revealed, senior KOLs have failed to disclose the extent of their financial entanglements with industry (Grassley, 2008). We can only guess at the degree of influence this undeclared income has had on their practice, but even absent any financial irregularities, KOLs are subject to influence through the benefit to their academic careers.

Pharmaceutical companies take considerable effort in recruiting KOLs they identify as malleable to their purpose by carefully monitoring a potential KOLs' prescribing and research. A young academic might be supported in research or asked to teach. If the company likes what it hears, its investment in the KOL will increase. The KOLs need never feel that they are being influenced by the company's generosity. The company will shape and influence existing conducive attitudes rather than attempt to change the

opinions of someone who is not sympathetic to its product. Few physicians and psychiatrists can resist the lure of fame and fortune offered by industry, but the primary motive of ethical duties to patients is compromised by profitable drug and medical device promotion; marketing directives threaten the accuracy of research results and university professors become what David Healy calls "ornamental additions to business" (Healy, 2004, xv).

The rise of the KOL and academic entrepreneur coincides with what is arguably one of the most influential pieces of legislation to impact the field of intellectual property law—the Bayh-Dole Act of 1980. Such legislation was explicitly designed for the privatization of knowledge during Reagan Revolution in the United States, and resulted from a shift in the philosophy of government from creating public wealth and safety nets for the less fortunate to maximizing private, for-profit sections (Krimsky, 2004, 108).

The Bayh-Dole Act created a uniform patent policy that allowed universities to retain ownership to inventions made under federally-funded research. Previously the federal government assumed ownership of the research it funded but it did not have the resources to expedite transfer of technology for commercial development. Moreover, when the government granted non-exclusive licenses to businesses, competitors could acquire the same licenses and thus there was little incentive to enter into such arrangements. The motivation behind Bayh-Dole was to speed up the commercialization process of federally-funded research, create new industries and open new markets from the university-patented inventions. Robert Kelch reports that: "since 1980, at least 2900 companies have been formed that were built around an innovation licensed by researchers at an academic institution" (Kelch, 2002, 285).

The growth of university patents and the commercialization of research that followed Bayh-Dole at first seemed to have nothing but positive effects, such as the innovations in the development of biotechnology and rapid development of pharmaceuticals, but it soon became clear that the legislation had opened a Pandora's Box. Universities that were losing government funding found the new source of revenue in the technology transfer to industry, but at the price of a proliferation of conflicts of interest. It increased consulting arrangements with greater emphasis on intellectual property (Krimsky, 2006, 22) and created a culture of secrecy that "may actually have slowed the sharing of scientific information and the exploration of new scientific leads" (Angell, 2004, 203). The most disturbing aspect of these arrangements, however, is the manipulation of research results in favor of the sponsor company's products.

The secrecy involved in privatization created another obstacle to scientific progress since a significant portion of industry misconduct in clinical research is protected under the intellectual property law called "the Uniform Trade Secrets Act." This legislation prevents release of important information on the basis of the alleged necessity of protecting commercial interests that would be of value to competitors.

Pharmaceutical companies under challenge by legal proceedings to release information to the public routinely claim protection under the aegis of trade secrets. While some documents are unsealed and released to the public because they are already in the hands of

a third party such as a peer-reviewed journal or a Public Relations agency, the majority of critical documents remain unknown to the medical community and the public. These include documents that reveal exploitation of academics or physicians for marketing and promotion purposes, budgets that include payments to KOLs and medical communication companies that have produced ghostwritten publications, advisory board and speakers' symposia members, marketing agendas that describe manipulation of the peer-reviewed medical journals, programs designed to increase patient compliance, secret liaisons with patient support groups, disease mongering, and the results of negative clinical trials. Only occasionally does anything of this sort see the light of day and only because of attorneys' errors in submitting documents to the court or because an industry insider has smuggled documents and revealed them to the media. There are, of course, legitimate uses of the Trade Secrets Act such as protecting discoveries of new molecular entities from industrial espionage, but the abuse of the Act in order to protect companies from discovery of misconduct and fraud only adds to the general problem that privatization has created for the attempt at reliable science.

## The Consequences of Privatization in Medical Research

Sheldon Krimsky has documented well the misconduct that has resulted from the academic-industry alliance that makes knowledge the property of for-profit companies (Krimsky, 2003). We wish to expand Krimsky's thesis with further evidence of the destructive consequences of ownership of data and industry research agendas.

As mentioned above, the most serious consequence of the privatization of knowledge concerns the reporting of results from industry-sponsored clinical trials. When academic investigators enter into a contact with a pharmaceutical company, they will sign a confidentiality agreement that makes it clear from the outset that the data produced in the trial is the property of the sponsor company and that any publication of results must be approved by company. In fact, before any publication appears the company signs off on release of the results to the named lead author thereby transferring ownership of the paper. Physician-investigators who have signed such contacts and then discovered in the course of the trial that the drug they were testing presented a serious danger to public health have found themselves in an ethical dilemma: either remain silent and violate the primary obligation to patients' health, or reveal the danger, face legal action and the destruction of their careers. The cases of Nancy Olivieri, Betty Dong, Aubrey Blumsohn and John Buse are particularly noteworthy in this connection because in their choice to reveal the danger, the sponsor companies sought retaliation. (Schafer, 2004, Krimsky, 2004, Baty, 2005, Committee on Finance, 2007)

In 2006 we were asked by the Baum-Hedlund law firm to do an independent analysis of study 329, sponsored by GlaxoSmithKline, on paroxetine (Paxil, Seroxat) use in adolescents. While it might seem hasty to extrapolate from this one trial, similar trials conducted on rofecoxib (Vioxx) and gabapentin (Neurontin) have shown a pattern whereby the sponsor companies working with medical communication companies have spun positive results

from negative trials (Ross et al, 2008, Steinman et al, 2006). Others such as drotrecogin alfa (Xigris) and aprotinin (Trasylol) reveal further instances of manipulation of data and marketing hype (Singh and Singh, 2007a, 2007b). Indeed as Krimsky reports, this is just the proverbial tip of the iceberg since the majority of cases remain undisclosed (Krimsky, 2004, 9). Industry-sponsored trials conducted by academic investigators are prime examples of the harm done to the reputation of clinical research in the wake of Bayh-Dole. The paper that reported study 329, for example, claimed that: "paroxetine is generally well tolerated and effective for major depression in adolescents" (Keller et al, 2001). Yet documents obtained during litigation reveal that study 329 was negative for efficacy on all eight protocol specified outcomes and positive for harm. The incorrect claim for efficacy was supported by removing four of the eight negative outcome measures specified in the protocol and replacing them in the published paper with positive ones (two of which were introduced after breaking the blind), and by conflating measures to give the false impression that one of the primary outcomes was positive (Jureidini et al, 2008). Harms were either not reported or glossed over.

When the Keller et al paper was published, paroxetine was vigorously promoted to SKB/GSK sales representatives as demonstrating "REMARKABLE Efficacy and Safety in the treatment of adolescent depression" (Hawkins, 2001), and the same message was delivered to the psychiatric community by KOLs, who frequently did not disclose the results for the primary outcomes and serious adverse events (see, for example, Keller 1998, Berard et al, 1998, Wagner et al, 1998, Gagiono, 1999, Wagner, 2003). Reprints of the Keller et al paper were distributed by GSK with Med Query Letters to physicians.

A whole industry has developed as a result of privatization called "medical communications." At last count, there were close to 200 such companies in the United States alone (Golden et al, 2002). These firms have been identified as a major source of facilitating misrepresentation in journal publications and in conference posters which they prepare for industry. For a modest fee, the drug company can retain control of the message via the medical communication company it hires, reward KOLs with publication and thereby ensure that there is little risk that the named authors will take control of the message communicated through the paper. Study 329 was first drafted and then revised by a medical communications company, and there were very few meaningful changes (and therefore little scope for contribution by the named authors) from that first draft to the published paper (McHenry and Jureidini, 2008).

Commercialization of science results in distorted priorities in research. Rush to blockbuster status for relatively trivial medical problems or disease-mongered creations for consumers in first-world countries dominate the research agenda rather than the development of medicines for more serious problems throughout the world. Of 1393 new chemical entities marketed between 1975 and 1999, only 16 were for tropical diseases and tuberculosis (Trouiller et al, 2002). Marcia Angell exposes the main business of the pharmaceutical industry as the development of "me-too" drugs, namely, minor changes in the molecule of a blockbuster drug that is just different enough to qualify for a new patient (Angell, 2004, 76). So, drugs that treat heartburn, obesity, hair loss, toenail fungus, sexual performance, depression, allergies,

high cholesterol, and the like will have a high priority in the company while other important drugs that are less profitable will not be developed or will be discontinued. Examples of this latter group include certain anesthetics, antivenins, antidotes for drug overdoses, anticlotting drugs, antibiotics, and vaccines against flu and pneumonia, many of which are lifesaving treatments, but which have lesser appeal to industry because they are short-term rather than life-long treatments, or they treat diseases of the poor. An investigation into the development of HIV/AIDS drugs reveals that the real source of success was not profit-inquiry via KOL development, but rather liaisons between government, universities and other non-profit research before the compounds were shifted to private drug companies for further development, manufacture and distribution (Angell, 2004, 25-27, 67-68).

The industry-academe alliance has stifled academic freedom and critical inquiry. As Fava has made the point: "Investigators who swim against the tide of corporate-driven research strategies may indeed have difficulty in publishing their findings and observations" (Fava, 2004, 2). Commercial interests have come to dominate the content of academic medical journals. Advertising and reprint revenue alone raise serious questions about the degree to which such journals can claim to be neutral arbiters in the attempt to produce a reliable body of knowledge (Lexchin and Light, 2006). What has become known as "commercially valuable content," allegedly good news about medical breakthroughs in pharmaceuticals and medical devices much to the advantage of the industry, has higher priority over bad news resulting from critical studies about manipulated results or ineffective and unsafe medicine. No advertising contracts or profitable reprint orders follow the publication of a study that demonstrates the failure of clinical trial. Few journal editors seem to realize the degree to which they have been infiltrated by pharmaceutical marketing and the strategy of the latter to use the journals as vehicles of promotion. Richard Horton, in this connection argues that: "Medical journals have become an important but underrecognized obstacle to scientific truth" since they "have devolved into information laundering operations for the pharmaceutical industry" (Horton, 2004, 9 also see, Smith, 2007).

Finally, instead of following the results of peer review, there is much evidence that the final decision to publish is made by legal counsel to the journals. Papers that expose the extent of scientific misconduct and manipulation of trial results in industry-sponsored studies are routinely rejected due to fear of legal action brought by the companies (Healy, 2008). Our papers on study 329 (Jureidini et al, 2008; McHenry and Jureidini, 2008) began life as an invited contribution by the editor of the *British Medical Journal*. Amongst the reasons for her rejection was a "combination of editorial and legal concerns that we feel are unlikely to be resolved even with a great deal of further work on your part and on the part of the journal." This raises an important question about academic freedom when our journals routinely publish ghostwritten articles from industry-sponsored clinical research, but then reject critical studies of those same publications on the basis that legal counsel to the journals has advised of potential libel actions brought by the pharmaceutical and medical device industries (McHenry, 2008). Industry influence on the medical journals has thus led to a form of censorship forced on editors. Under the business model, criticism of products or processes is regarded as little more than competitors' vying for market share and a hostile threat to the company's well

being, while in academe it serves a vital function in the pursuit of truth. Pharmaceutical marketing objectives identify academic physicians as hostile adversaries of their drugs and seek strategies to 'neutralize' their criticism. One manner of accomplishing this objective is by alleging that doctors with concerns about efficacy and safety are secretly promoting competitors' drugs (Coynne, 2005). Another is the co-option of KOLs to sign on to ghostwritten letters to the editors that defend the drugs against criticism. This tactic creates the appearance of academic discourse, but in reality is nothing more than exploitation of the medical journals by pharmaceutical marketing (McHenry, 2005).

All of the above has led to an erosion of confidence both in the wider medical community for the integrity of medical research and reporting of such research and in the public perception of the profession.

## Conclusion

The profit vs. knowledge-directed inquiry distinction can be a false dichotomy if indeed profit and knowledge motivations merge to produce excellent scientific results and much needed innovations. The evidence of the past twenty-eight years since Bayh-Dole in the United States, however, suggests otherwise. While the short-term stimulus to biomedical research has been much celebrated, the unintended, long-term consequences for medicine have been severe. Scientific progress is thwarted by the ownership of knowledge, especially in clinical medicine where the adverse impact has reached an unprecedented crisis point (Fava, 2006). When the profit motive dominates research agendas, there is relatively little confidence in the results. The level of cynicism in the medical community was summed up in a response to Angell's editorial in *The New England Journal of Medicine*, "Is Academic Medicine for Sale?" with the quip, "No. The current owner is very happy with it" (Ruane, 2000). Competition in industry prevents cooperative research and open, critical evaluation essential to the long-term advance of knowledge. This is not to say that privatization of knowledge is the only source of conflict of interest in medicine, but there is little doubt that it has accelerated such conflicts since the 1980s. When knowledge, and especially that of critical concern to public health, becomes the private property of industry and academics are co-opted for the purpose of advancing this interest, the society that enables such activity has lost all claims to participate in the advance of science.

It may be impossible for medicine to sever its relations to its pharmaceutical and medical device industries. There is nonetheless little doubt that restoring confidence in the profession requires active protection of its autonomy and integrity. Since it seems highly unlikely that there will be any reversal of legislation that led to the problem or competent government regulation, it is the moral imperative of individual practitioners to eliminate conflict of interest. This demands first of all a unified effort of psychiatrists and other physicians to resist the relationships with industry that have distorted results of clinical research and led to habits of overprescription. Second, the profession must regulate itself by moral censure of practices that are profit-oriented and ostracize rather than lionize KOLs. Third, no investigator who has signed a confidentiality agreement with a sponsor company can claim

scientific status for the results of the trial. As Wagner and Steinzor make the point: "Science demands that, to the maximum extent possible, scientists have no stake in the outcome of the research" (Wagner and Steinzor, 2006, 6). Rigorous science can only exist when there is a genuine, risky test that could prove the hypothesis or theory false (Popper, 1959). This demands skepticism towards the outcome of experiments whether those outcomes are welcome or not (Ziman, 2000). As we have seen above, industry-sponsored research seldom if ever meets these criteria.

As for Robert Kelch's dilemma of "how to strike a balance between the need for investigators to act in the best interest of patients and their desire to serve the interests of the product they are developing" we agree that there is no choice to make (Kelch, 2002, 285). Physicians have a primary ethical duty to patients, not to products of industry. The doctor-patient covenant is violated once the physician enters into an agreement that gives industry ownership of the data.

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