Regulation of Financial Conflicts of Interest in Medical Practice and Medical Research

a damaging solution in search of a problem

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ABSTRACT The free market, which includes most practicing physicians, publicly supported biomedical researchers, and private drug and device companies, has succeeded spectacularly in delivering new medical technologies to the public. Increased interactions between doctors (physicians and biomedical researchers), epitomized by the founding of the biotechnology revolution, have and can continue to accelerate this delivery. A powerful anti-commercial advocacy movement that has blossomed over the past 20 years threatens this momentum. This movement has succeeded in inverting reality by demonizing the market and by promoting distorted and damaging views of professionalism and of science. Most ominously, it has imposed onerous and counterproductive regulations on medical education and translational research.

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Then too, if a man gives the best possible advice but is under the slightest suspicion of being influenced by his own private profit, we are so embittered by the idea (a wholly unproved one) of this profit of his, that we do not allow the state to receive the certain benefit of his good advice. So a state of affairs has been reached where a good proposal honestly put forward is just as suspect as something thoroughly bad.

—Thucydides, *History of the Peloponnesian War*

MEDICINE AND THE MARKET

To a significant extent, medicine's amazing progress over the past 40 years is due to the market, defined by Friedrich Hayek (1974 Nobel Laureate in economics) as "the extended order." According to Hayek, the market consists of individuals operating "between instinct and reason," working in a network of human relationships that they did not create, cannot control, and cannot clearly perceive. With freedom under the rule of law, they produce goods and services and innovate to increase their productive efficiency, for which they acquire legally protected private property (Hayek 1988).

By this definition modern Western medicine is a market, albeit a complex one, in which patients more-or-less voluntarily contract with health providers for preventive and therapeutic services. Health care companies and doctors habituate the same economic system, and together they have created the miracle of technical progress in medical care. Market forces have resulted in highly variable remuneration for health care services, even in systems where the state makes the payments through tax revenues. Although people entrust their lives to bus drivers and airline pilots as well as to doctors, medicine differs from many trades by virtue of the education and training doctors undergo and because of its stated obligation to prevent and relieve human suffering. Medicine operates with the same moral principles as much of the market order in general—health care workers, like bus and airline companies, do not bargain with the safety of their customers (Novak 2000).

Among the most notable contributions of the market to the progress of medicine over the past 40 years have been the technologies developed by the private industries that service the medical profession. Although much of the research leading to product development takes place in government laboratories and academic institutions supported by tax revenues or philanthropic contributions, only for-profit companies actually translate this research into useful products. The taxpayers' and philanthropists' interests are primarily to obtain *results*, practical health-related deliverables, as evidenced by all biomedical research being explicitly justified sooner or later in terms of specific health benefits. The more private companies can access the broadest spectrum of research information, the better the chance that the promised products accrue to the public.

The growth in the number, size, and productivity of health-related companies delivering products to the medical market has promoted the diffusion of the most current and effective medical practices throughout developed countries,

thereby diminishing a performance gap that in earlier times differentiated medical activity between urban and rural, and between academic health centers and nonacademic practitioners. It has also increased opportunities for synergy between these companies and "doctors" (physicians and scientists not directly employed by industry). Some entrepreneurial doctors provide product candidates to companies at the "front end" of product development, while other doctors advise companies concerning unmet medical needs and scientific knowledge to address those needs—the "back end" of product development and dissemination. In return for such useful services, doctors appropriately receive fees and, in some cases, stock or stock options.

When doctors in either academic health centers or private practice participate in clinical trials of drugs and devices to assist companies developing products, they offer their patients the most advanced therapies. Interactions of doctors with industry also benefit medical education. Industry support of medical schools, professional societies, and physician opinion leaders can augment chronically limited funds available to support teaching medical students and to provide continuing medical education (CME) to practitioners. Another essential educational activity of doctors is to provide advice to financial analysts evaluating medical products for investment opportunities. These interactions between doctors and industry and the fundamentally commercial nature of medicine are highly beneficial but largely unheralded, misunderstood—and deeply maligned. The immense advances in technology based on entrepreneurship that have so improved medical care today compared to 40 years ago have appeared slowly and incrementally. As a result, taking them for granted and dismissing the efforts of the commercial contributions that provided them are all too easy. It is equally tempting to disparage the frustrating limitations of incremental products and to blame marginal improvements in efficacy or insufficient safety guarantees as deliberate concessions to greed. I know, because I have been there and done it.

Discovering the Market: A Case Study of Academic Myopia and Its Cure

During my career, I have run a laboratory research program encompassing cell biology, biochemistry and molecular genetics. I have also led a clinical hematology program in major teaching hospitals, edited professional journals, and have had leadership positions in professional medical organizations. Yet for half of this career, I was unaware of the market. I believed that as a physician-scientist funded by grants from the National Institutes of Health (NIH) and other agencies, I was mining gold that companies might some day carry off to the bank. I thought that these companies should subsidize academic work with no strings attached. When prominent researchers began to establish or consult for fledgling biotechnology companies, instantly undermining the prevalent perception that applied research was inferior to basic research, I envied them. I resonated with the concerns

voiced by some regarding the theoretical dangers of this commercial activity to the university (Kenney 1986; Stossel 1987).

My resentments dissipated in 1987, when I joined the Scientific Advisory Board of the then decade-old pioneering biotechnology company Biogen. The opportunity to interact with the eminent investigators, including Nobel laureates, who founded the company—and to be paid to do so—was exciting. The scientific knowledge I gained and the contacts I made helped my research. I learned that business people were as (if not more) honorable and in touch with their motives than many of my academic colleagues. I also became aware of the immense difficulties impeding product development, including many issues that I never considered in my small-scale research, such as ascertaining in detail the composition of materials being used in experiments, scaling up processes, and addressing mind-numbing toxicity evaluations that no academic investigator could stomach. Furthermore, I learned that the documentation of procedures has to be far more meticulous than in academic research. I learned that the further the development effort proceeded, the greater the financial risk, and that unpredictable failures loomed at every step. Decisions concerning what products to develop were excruciating. Finally, and most importantly, I developed the desire to translate my basic research into product opportunities, thereby emulating the successes of some of Biogen's scientific founders, whose discoveries now impact favorably on millions of lives. Some of these giants also achieved great wealth (as did their academic institutions), but the value of their work to society was incalculably greater. To be sure, projects failed, and investors had to gain more sophistication in their ability to discern reasonably high-risk choices from ridiculous ones. Some researchers and investors made money on projects that had no ultimate value, while others gained nothing or lost out. Such is the nature of risk and rewards in the free market—but on balance it delivers results.

My experiences attempting research translation taught me how difficult it is, and that the pathway to success—which may never happen—is impossible to plan. Only a passion to persevere through many setbacks keeps the process alive. This experience convinced me that we must make this translation work better. Companies, especially large ones, have in common with academic institutions bureaucratic impediments to product discovery and development. By necessity, they employ as many or more people whose primary interests are to maintain the infrastructure of the organizations, an activity that in the short term does not necessarily create new knowledge or develop products. Employees supposedly fostering interactions between universities and companies—technology transfer offices on the university side, and business development personnel on the company side—are often understaffed, saddled with conflicting agendas, and inadequately trained or knowledgeable to identify opportunities for cooperation. Doctors lack the understanding of how their work might fit into what markets and over what time period. Venture capitalists make uninformed investment decisions with spotty due diligence.

However, with the right application of energy and imagination, these impediments are addressable. Instead, many influential medical academics and anti-business activists have focused energy and imagination in a different direction, one that denies the fundamentally commercial nature of medicine and medical research. The academic obsession with financial conflicts of interest not only endangers medical progress but also the very fundamentals that drive that progress.

The Rise of the Conflict of Interest Movement

In 1988, about the same time I joined the Biogen scientific advisory board, the *Boston Globe* reported that a research trainee at the Harvard-affiliated Massachusetts Eye and Ear Infirmary allegedly violated regulations protecting human subjects and engaged in insider stock trading in a clinical trial for a company in which he had equity. In response, the Dean of the Harvard Medical School convened a committee that drafted the first university rules intended to prevent such behavior, defined as financial conflict of interest, and ushered in a new movement. A *PubMed* search reveals almost no publications on this topic prior to 1987; thereafter, the number of papers on the subject rose annually at an exponential rate.

Although initially focused on doctor-industry research relationships, concerns about conflict of interest have permeated every aspect of medicine and medical science. Only the imagination limits the extent of corruption now ascribed to financial conflict of interest:

> Financial conflicts of interest threaten patient care, taint medical information, and raise costs. They create deception, impair physicians' judgment, and reduce their willingness to be their patients' advocates. They reduce professional dignity and integrity, denigrate the profession and erode trust in the profession's practitioners, researchers and institutions. (Kassirer 2004, p. 192)

Corporate support of basic research, clinical research, CME, clinical practice (through gifting and sampling by drug companies), practice guidelines, Food and Drug Administration (FDA) advisory committees, and drug formularies are all now examples of unacceptable financial conflicts of interest. Previously routine practices, such as the use of "ghostwriters" in the preparation of research or educational articles, or the matching of medical opinion leaders with medical audiences through "speaker's bureaus," have received special criticism (Moffatt and Elliott 2007).

The dictionary defines a *conflict* as a clash of competing interests or, more narrowly, as "the circumstances of a public officeholder, whose personal interests might benefit from his or her official actions or influence." Conflict of interest advocates have expanded this definition and transformed it to "a set of conditions in which professional judgment concerning a primary interest (such as a

patient's welfare or validity of research) may be unduly influenced by a secondary interest such as financial gain" (Bekelman, Li, and Gross 2003; Thompson 1993); or, "When physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements for the physician's roles are or will be compromised" (Brennan et al. 2006). In other words, a conflict is no longer simply a conflict—it has undergone definition creep into a situation likely to "influence unduly," or, more ominously, anything a "reasonable" person questions.

In response to this perceived conflict of interest pandemic, research institutions, biomedical journals, medical and scientific professional societies, and medical and educational accrediting bodies have followed Harvard's lead and established elaborate requirements for the disclosure of financial conflicts of interest and for regulating or eliminating such conflicts.

Disclosure

Research presentations and publications have always included acknowledgments of financial support, intended to give credit to the patrons of the research. Now, increasingly, information concerning commercial support serves not to honor but rather to flag it as a reason to discount the validity of the research, the credibility of the practitioner, researcher, or educator, or to reveal venal motivations of advisors to regulatory guideline or policy bodies. The level of detail demanded for these disclosures has increased so much that the space devoted to them makes up a large amount of publications and other communications.

In order for organizations to obtain approval to provide CME, CME lecturers must reveal their (and their spouses') financial relationships with commercial entities producing health care products or services and "attest" to a long list of stipulations intended to assure independence from any commercial promotions (Accreditation Council 2006). The minute level of detail in the attestations is so dense that anyone intent on challenging a teacher's lack of independence could easily dredge up an example. In some cases, presentations must be submitted far in advance for "peer review" of conflict of interest. This ritual is not really about protecting CME students from biased information but about satisfying the bureaucratic requirements of the American Council for Continuing Medical Education that accredits educational programs, enabling the CME-sponsoring institution to charge the students for an accredited course.

Furthermore, conflict of interest activists are not satisfied with this detailed disclosure but want to see the dollar amounts compiled. The intense focus on disclosure has created an informant culture. Conflict of interest vigilantes search for evidence that doctors have failed to disclose corporate connections in publications or in presentations. The reasons for such failure are unclear, but that they arise from deliberate intent to deceive is highly improbable. It is more likely that they result from a discrepancy between the reasonable assumption by researchers

and educators that they should only disclose *relevant* commercial relationships—concerning products they are investigating or lecturing about—and the assumption of conflict of interest activists that *all* commercial relationships should be disclosed (*New York Times* 2006).

REGULATIONS

The Harvard regulations concerning academic-industry research relationships and similar ones from other institutions represent prophylactic law, absolutely prohibiting certain types of doctor-industry interactions ("red-light rules"). For example, since manipulation of stock was supposedly a centerpiece of the inciting event, the Harvard regulations forbid researchers performing any type of company-sponsored research, basic or clinical, from holding more than token ownership in that company. They thereby cut off rewards for work that had generated some of the most beneficial products of the early biotechnology revolution. Red-light regulation is also now rampant in medical communication. For example, scholars who disclose receiving more than *de minimis* consulting fees or having equity in a company cannot write review articles or editorials concerning topics related to the consulting relationships for many journals. Under these regulations, a 1981 *New England Journal of Medicine* editorial that was influential in the development of statins for hypercholesterolemia would not have been permissible, because the authors, future Nobel Laureates Michael Brown and Joseph Goldstein, were consultants to a statin manufacturer at the time.

Not all institutions have defaulted to red-light regulation. Some (Boston, Duke, New York, and Stanford Universities, and the Scripps Research Institute, for example) only require disclosures of doctor-industry interactions and determine the risk-benefit aspects of these relationships on a case-by-case basis. The practical outcome of such "yellow-light regulation," of course, depends upon the attitudes of individuals deciding on the merits of specific instances.

A small number of adverse incidents publicized by the media as examples of conflict of interest have stimulated this rule making. A decade after the first conflict of interest regulations at Harvard Medical School, a committee was prepared after long deliberation to recommend loosening some of the rules from red-light to yellow-light status. But publicity surrounding the death of a subject in a research experiment at the University of Pennsylvania, which was partially funded by a company, led the Harvard dean to shelve the recommendations and make its rules even more severe. By the same token, congressional investigations in response to sensational media reports alleging violations of industry consulting rules by researchers at the NIH resulted in the NIH's administration forbidding all industry consulting by its researchers and threatening to force all NIH employees to sell any stock they held in health care industries. The NIH eventually withdrew the stock divestiture requirement, but the total consulting ban remains in force (NIH 2005), despite the fact that the actual number of viola-

tions was eventually revealed to be small and no material damages based on these infractions were demonstrable.

Even in the absence of specific incidents, research institutions have piled on conflict of interest rules. Harvard Medical School gratuitously added more red-light regulations in 2004. One prevents inventors from receiving licensing fees or milestone payments for their technologies prior to marketing. Since the vast majority of inventions never reach the market, this regulation is confiscatory. Another rule precludes authorship on a company-sponsored clinical study of an inventor's technology (Harvard Medical School 2004). Both of these regulations assume that at least some investigators may perpetrate misconduct in the interest of financial gain. Such stringent institutional rules invade private property and individual freedom, thereby violating both utilitarian and classical liberal principles of jurisprudence (Bentham 1781; Hayek 1966; Mill 1959). They are equivalent to forbidding people from owning fast cars instead of penalizing them for speeding in them. The tolerance by academic faculties of this extremity of martial law requires explanation. One explanation, that financial conflicts of interest impose sufficiently great damage on medical practice and medical research to justify such severity, does not stand up to scrutiny.

OBJECTIVE RISK-BENEFIT ANALYSIS OF CONFLICTS OF INTEREST

I have elsewhere summarized that facts do not justify the puritanical attitudes or prophylactic rules concerning conflicts of interest. The allegations that financial conflicts of interest have compromised research behavior, quality, openness, or objectivity are untrue (Stossel 2005). Moreover, taken in context of positive outcomes from doctor-industry interactions, they distort what is in the public interest. My analysis revealed that the case for damages from financial conflicts of interest, far more than financial conflicts of interest per se, violates standards of scientific rigor. Conjecture and anecdotes form the basis for the allegations of harm. Appropriate controls (evidence that the presence of commercial influence causes more adverse outcomes than in its absence) are nonexistent. No evidence indicates that institutions with more lenient (yellow-light) conflict of interest regulations have more adverse outcomes than those with severe (red-light) policies.

Conversely, the total ban on consulting by NIH researchers has by definition interfered with research translation, because companies who previously obtained advice from NIH scholars no longer do. Venture capitalists, university technology transfer managers, and my own experience confirm that many technology licensing arrangements remain unconsummated because conflict of interest regulations that limit the use of equity to incentivize and involve technology inventors are deemed too risky by investors, and because universities demand upfront cash instead. When investors default to other, more flexible opportunities, the medical technology that fails to enter the development pipeline will never ben-

efit patients. The most extreme conflict of interest opponents believe that having government impose restrictions on and manipulate the development and marketing strategies of companies will lead to more innovation. If the track record of innovation in socialist countries is an accurate indicator of the result of such practices, we will have fewer new drugs and devices. If companies cannot profit sufficiently by making drugs and devices, they will make and sell other products such as dog food.

If *any* risk from conflicts of interest is deemed unacceptable, then the preponderance of objective evidence in a risk-benefit analysis is of no importance. This arbitrary stance derives from consideration of self-interest and from ideology, both of which drive attitudes and responses to financial conflicts of interest in medicine and medical research.

Self-Interest

Administrative Employment Insurance

Scandals involving financial conflict of interest represent employment risks for academic administrators. A theoretical insurance policy against such risks is regulation. Although no evidence indicates that such regulation prevents scandals, an administration can point to the rules as their effort to maintain academic sanitation. To be fair to administrators, large university or government research institutions require constant financial feeding, and conflict of interest issues pale before these nutritional demands. As a result, administrators do not have time to think deeply about conflict of interest and are therefore easy prey to prevailing propaganda about it. Controversies also interfere with the institutional feeding process, and even the most open-minded and thick-skinned administrators cannot survive if subjected to continuous assault from one-sided advocates, especially if credible members of the organization with different viewpoints do not speak out. Such has been the case in the conflict of interest era.

Apathy, Envy, and Political Correctness

At face value, those unaffected directly by conflict of interest activism have little reason to oppose it. Most doctors have no front-end interactions with companies, and the financial conflict of interest regulations relating to these interactions do not affect them. Certainly, some may resent and envy academics who enjoy corporate largesse, and the fact that medical training fails to educate doctors about where new technologies arise, with what difficulties, and at what cost may foster such attitudes (Shaywitz 2005). However, many doctors who interact with companies do so in a manner that even the most stringent academic conflict of regulations accommodate—they receive fees and stock for directorships or for serving on advisory boards, or they receive grants for performing labora-

tory research or clinical trials. They have little reason to complain and may take the attitude that if the system works for them, it works for everyone. When the NIH administration backed off of the requirement that employees sell health care stock, an imposition on many, opposition to the consulting ban, which affected relatively few NIH researchers, effectively ceased.

In addressing the conflict of interest movement, the pharmaceutical industry has emphasized accommodation over rebuttal. It labors under the delusion that if it embraces conflict of interest activists and engages in conversations about "integrity" and "trust," industry bashing will cease. However, the default to political correctness, which does not assuage the conflict of interest movement or fool the public, may well abet the plummeting status of drug companies in public opinion polls. If the influence of the conflict of interest movement persists, future doctors will know even less about these companies and how they develop products than they do now.

IDEOLOGY

While understandable, the pragmatic support of excessive attention to financial conflicts of interest could not sustain itself without powerful ideological influences. The most recent and revealing ideological manifesto of the conflict of interest movement emerged as an article entitled "Health Industry Practices That Create Conflict of Interest" in the high-profile *Journal of the American Medical Association* (Brennan et al. 2006). Its authors included individuals with major administrative positions in American medicine, which afforded the article authority and wide media attention. The article appeared four months after my risk-benefit analysis (Stossel 2005) but did not refer to it or address any of its arguments. Rather, the *JAMA* manifesto restated the firm warnings that conflicts of interest are rampant, citing the usual anecdotal evidence. As with most such literature, the only research cited concerned studies claiming to show that marketing promotes prescribing of marketed products and that commercial sponsorship tends to result in outcomes favoring the intervention sponsored by the company. That advertising works , that positive outcomes also dominate studies sponsored by nonprofit entities (Ridker and Torres 2006), and that these outcomes may actually be appropriate are not considered. The paper also contains a major factual error—the ascription of negative clinical outcomes to industry influence in academic health centers—although the citation to support that claim explicitly disclaims any such conclusion (Wazana 2000).

Like most conflict of interest discussions and the current definitions of conflict of interest, the document demands avoiding even the *appearance* of conflict of interest. This attitude, which elevates medicine and medical research to the status of government or religion, purports to defend "public trust." This elevation appoints medical leaders and especially journal editors as guardians of mor-

ality rather than as facilitators of the interests of the medical and medical research marketplace. Accordingly, as in government and religion, they justify an appearance standard (Stark 2000).

As emphasized above, however, medicine and medical research that are not directly pertinent to government prerogatives such as military medicine or public health emergency work are *commercial* activities, and federal regulations addressing appearances of conflict of interest do not apply to them:

> A public health officer or military doctor is in the service of the state, a guardian. He doesn't depend on voluntary mutual agreement; he can call upon prowess if necessary to put people in quarantine, to make them accept mandated vaccinations, to close contaminated wells or beaches.
>
> Not so with a physician in private practice, even if a state medical care system is paying the bills. Now voluntary agreement on the part of the patient—the doctor's customer—takes over. (Jacobs 1992, p. 112)

I pointed out in my risk-benefit analysis that the subjectivity unleashed by an open-ended mandate to regulate appearances of conflict of interest means that any doctor making money from interactions with industry is potentially in unacceptable conflict (Stossel 2005). Informed by conflict of interest critics, the news media has exploited the open-ended opportunity afforded by the appearance standard to embarrass conflicted doctors. For example, the *Los Angeles Times* (2005) publicly excoriated leading investigators at NIH who have made enormous contributions to public health for receiving consulting fees that were not only legal but also mostly trivial. Hyperbolic adjectives, such as "egregious," "outrageous," involving "lucrative" or "lavish" financial trappings from "cozy relationships with industry," "endangering the public health," embellish the media accounts. The events described in these accounts, moreover, are rarely what the media accounts make them out to be. For example, conflict of interest activists and the press held up the University of Toronto's Dr. Nancy Olivieri as a martyr to the sellout of academic freedom to industry. A more thorough follow-up investigation by an initially duped reporter, however, documented interpersonal difficulties, not company-imposed coercion, as the source of Dr. Olivieri's problems at the University (Shuchman 2005).

That conflicts of interest compromise (or will compromise) public trust is, according to the *JAMA* paper, a self-evident truth (Brennan et al. 2006). But again, the justification of an appearance standard on the basis that financial conflicts erode public trust in medicine and medical research has no factual support. A 2004 poll of the American public performed by the nonprofit NIH advocacy group Research!America—hardly a reactionary organization—revealed that public esteem for physicians and researchers is high. Nevertheless, nearly 70% of respondents had no objection to researchers profiting from their discoveries. Subsequently, a poll of 250 patients enrolled in cancer treatment trials found that

an even higher proportion (over 80%) were not concerned about the investigators having financial ties to the companies sponsoring the trials (personal communication from Dr. Ezekiel Emmanuel, Department of Clinical Ethics, NIH).

The *JAMA* paper's call to action, based on flawed arguments, is to remove all commercial marketing and gifting from academic health centers and to collectivize commercial research and education support. Companies are to donate unrestricted funds to academic health centers for administrators to dole out to researchers and educators unfettered by any specific commercial agenda. In making these recommendations, the authors reveal that, without seeming to be as extreme as those who aver that industry is fundamentally anti-innovative and predatory and should be managed like a public utility (Angell 2004), they are not far from this persuasion. Furthermore, they question industry's objectivity (adherence to an "evidence-base") and propose to ward it off from the "professionalism" and "science" allegedly manifest in noncommercial medicine and commercially uncontaminated medical research. The *JAMA* article's recommendation is to buttress that wall.

Three conceits underlie this artificial segregation between production (science) and promotion (remuneration, or profit). One is that academic science or medical practice are not highly "promotional." Researchers routinely put their findings in the most positive light. Hospitals and medical practices advertise. Are the *US News & World Report* rankings touted by academic health centers "evidence-based?" The second is a failure to appreciate that "profit" is essential in order to invest in technological advances. This dismal reality applies to medical practice and academic health centers, as well as to private companies. The third is to claim that this mythical separation of production and promotion existed in the past, and that a commercial conspiracy is ending it. This ignores the fact that there was so much less to commercialize in the past that opportunities to do so—and to improve medical care—did not exist. Today's increased commercial opportunities represent an evolutionary adaptation to favorable circumstances.

The following quotations epitomize these three conceits:

> The . . . good work, together with the relatively low levels of faculty compensation, the disdain toward commercialism, the prevalent attitudes toward commercial patents, and adherence to high standards of intellectual honesty, reinforced public notions that medical schools were dedicated servants of society. (Ludmerer 1999, p. 341)

> Putting "business strategies" on a high pedestal (has) encouraged many in medicine to ignore a long-held principle that the patient comes first. (Kassirer 2004, p. 187)

> When a great profession and the forces of capitalism interact, drama is likely to result. On display . . . are the grandeur and weakness of the medical profession and . . . the power, social contributions, and occasional venality of a very prof-

> itable industry . . . that sometimes employs methods that are . . . even criminal. (Blumenthal 2004)

The last quotation, contrasting doctors and business, is particularly telling. Why is the medical profession "great" and capitalism something less? I do not deny that industry is profitable, occasionally venal, or sometimes even criminal, but to imply that doctors lack these characteristics is blatantly unfair. Moreover, the assertion that the ethical standards of today's physicians and researchers are degraded compared to the past is unfounded. The inaccuracy of this idea is readily discernible in George Bernard Shaw's 1913 play, *The Doctor's Dilemma*, in Sinclair Lewis's 1925 novel *Arrowsmith*, and in scholarly accounts of the history of medicine (see, for example, Starr 1982). The myth of professional degeneration gratuitously insults contemporary physicians and researchers who, in my experience, have as much if not more integrity and compassion than their technically far less competent (and far less demographically diverse) forebears.

Implicit in the conflict of interest movement's definition of professionalism is a logically inconsistent ascetic imperative: commercialism is about money, and medical professionals, like feudal aristocrats, should eschew it. Strangely, the movement has no problem with the fees—sometimes large—that physicians routinely earn from their clinical encounters with patients, and these doctor-patient financial transactions are also exempt from CME conflict of interest disclosure representations. The most plausible reason for the glaring disparity between the suspicion of corporate consulting income and tolerance of fees for clinical services is that conflict of interest activists, like the *JAMA* paper's authors, pick their enemies carefully. A frontal assault on practicing physicians would most likely threaten these activists' leadership positions in medical organizations dedicated to the interests of medical practitioners or of medical journals sponsored by these organizations. And it is worth noting that many of these conflict of interest activists are among the highest-paid doctors in American medicine.

Another inaccurate charge is that conflict of interest impairs scientific objectivity. Conflict of interest activists, many who are not working researchers, adhere to a discredited doctrine known as positivism. Positivism, or scientism, is the concept that humans are capable in time of accruing sufficient knowledge to achieve full "objective" understanding of nature. In the absence of evidence for it, the conviction that conflict of interest diminishes public trust is simply an example of scientism:

> The scientificality of totalitarian propaganda is characterized by its almost exclusive insistence on scientific prophecy. . . . Nowhere does the ideological origin, of socialism in one instance and racism in the other, show more clearly than when their spokesmen pretend that they have discovered the hidden forces that will bring them good fortune in the chain of fatality. (Arendt 1968, p. 345)

Philosophers of science have long rejected positivism and retreated to a humbler conception of human knowledge (Fleck 1979; Kuhn 1970; Polanyi 1958; Popper 1996). Although researchers use precise measurements to generate and test theories and accrue information that seems to build on itself, in reality they advance knowledge in a random and nonlinear manner, often against fierce resistance. They may exhibit a wide range of personal behaviors, ranging from generous to proprietary, but, as well codified by sociologists, researchers ritualistically feign "disinterested" objectivity while passionately promoting their self-interest by competing vigorously for attention and for limited resources (Gilbert and Mulkay 1984; Merton 1973; Sindermann 1982). Objectivity in facing and adapting to obstacles and contradictions to favored hypotheses keeps science advancing, but subjective passions are necessary to fuel that adaptive spirit. As Polanyi (1958) put it: "A scientist must commit himself in respect to any important claim put forward within his field of knowledge. He can be strictly agnostic only on subjects of which he knows little and cares nothing" (p. 276). Hence, no serious analysis of science supports the demand by conflict of interest activists such as the *JAMA* paper authors for a cadre of professionals free of commercial or any other biases to be the decision makers and educators, helping us navigate the nuanced and often nearly impenetrable pathways at the boundaries of our knowledge.

REMEDIES: RESTORING BALANCE

The free market may be the best arrangement for the good of human society, but it must cope with the inevitable bad luck, error, and corruption of the real world. The conflict of interest movement has blamed all these ills on private business and, together with the media, has so hounded industry and the doctors who work with it, that constructive dialogue is practically impossible. By exaggerating the risks without balancing them with benefits, the movement diverts attention from real problems to imaginary ones. The conflict of interest movement has taken control of academic institutions, government research programs, and professional organizations, and has hampered private industry—and hence medical progress. Only by challenging and discrediting the ideological underpinnings of the conflict of interest movement will it be possible to break away from the sanctimony, onerous regulations, and waste of time incurred by the institutional preoccupation with financial conflicts.

The history of research misconduct provides an instructive practical approach to problems with doctor-industry interactions. Notorious scientific misconduct incidents involving fabrication, falsification of research data, or plagiarism received widespread media attention in the 1970s and 1980s (Broad and Wade 1982). The furor appropriately encouraged research institutions to tighten up oversight of research activities and to establish mechanisms for investigating mis-

conduct allegations, mimicking standing procedures for dealing with clinical misconduct or impaired physicians. The NIH, as the major public sponsor of academic biomedical research, set up an Office of Research Integrity to receive and process misconduct claims and to direct research institutions receiving NIH grants in providing instruction to researchers concerning proper research conduct. Whether the enforced ethics training has impacted upon research behavior is unknown, and misconduct cases continue to arise sporadically. However, no misconduct cases reported to the Office of Research Integrity have involved financial incentives associated with commercial interactions (Stossel 2005).

Academic researchers historically have enjoyed a freedom of operation unencumbered by the detailed audits of data characteristic of the world of business and finance or of the FDA reviews of corporate product development. Sociologists of science believe that the incidence of misconduct in science is low because of the premium scientists put on the ability of other researchers to replicate their findings (Merton 1942). This low frequency of malfeasance derives in part from a narrow definition of scientific misconduct, namely fabrication, falsification, or plagiarism (FFP). The definition of misconduct therefore tolerates a wide range of research behaviors that some or even most might deem objectionable, relegating to research laboratories and clinics rather than to regulatory agencies the burden of addressing disputes. While not always pleasant or obviously fair, this freedom-maximizing system arguably best facilitates research progress.

However, ethicists, academicians with grievances, attorneys specializing in whistleblower cases, and members of Congress eager for grandstanding opportunities all call for expanded regulation of research conduct. Their claim that research malfeasance is inherently worse than misconduct in other arenas, because it breaches public trust presaged and paralleled that of the financial conflict of interest campaign. Dismissing the notion that research misconduct is an uncommon aberration, they instead claim that the publicly known cases are merely the tip of an iceberg, and that when whistleblowers expose them, senior scientists and their institutions cover them up. They propose a broad expansion of the definition of misconduct to include "other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing conducting or reporting research" (Martinson, Anderson, and de Vries 2005; Ryan 1995).

The Federation of American Societies for Experimental Biology has resisted both the adoption of an expanded definition of research misconduct and the extension of more protection to whistleblowers than is afforded to researchers accused of misconduct (FASEB 1995). However, the success of activists in imposing prophylactic regulations concerning financial conflict of interest has effected an end run around the narrow (FFP) misconduct definitions, and this success has far more coercively influenced doctors' conduct than the expanded misconduct definitions possibly could.

Recognizing this irony, academic health centers, professional organizations and journals should apply the current operational misconduct model, one that emphasizes treatment over prophylaxis of adverse outcomes involving doctors' commercial activities. Academic institutions, the Office of Research Integrity, the FDA, the courts, and adverse publicity already punish companies and doctors who misbehave. Rather than arbitrarily smearing "ghostwriters" of corporate-sponsored research articles, why not focus on what the ghosts *write*? Rather than shaming opinion leaders who work through "speakers bureaus," why not pay attention to what the presenters *say*? To accuse an "opinion leader" of being "a corporate minion" is self-contradictory: how can anyone who is uncritically beholden to a sponsor be a leader? Furthermore, why should the second-best and the less-than-brightest be entrusted with medical education or sought out to advise the FDA and other agencies? Why should journal editors be incapable of assuring balance in review articles and editorials?

The time to regain balance has come. This imbalance has not arisen from factually or logically justifiable reasons, but from ideology and the lack of articulated opposition. Doctors on the ground who treat patients and who perform basic and clinical medical research are as capable of discerning right from wrong as unconflicted critics. They are not morally inferior if they accept gifts of any kind from the companies that provide their patients with the best gifts of all—improved quantity and quality of life. These doctors have far more credibility than the unengaged authorities or ambitious critics, and the media will inevitably recognize who is truly credible. Most Americans base trust on competence, track record, and reliability, not who pays whom or how much. Resistance can work, common sense can prevail, and perfection need not be the enemy of the good. It is imperative to act, so that physicians 40 years from now can look back and be thankful for as much progress in medicine as I can.

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