Commercialism, Loss of Professionalism, and the Effect on Journals

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Immanuel Kant stated, “Everything has either a price, or it possesses dignity.”1(p53) Downie further elaborated that professionals should be “independent of the state or commerce.”2 Medicine is the prototype profession, incorporating a specific body of knowledge; a demonstrated competence in defining problems and solutions; a commitment to self-improvement, self-monitoring, and self-regulation; a system of admission and monitoring new members; and an ethical responsibility to use the unique knowledge and competence for the best interests of patients (ie, to resolve conflicts of interest in our patients’ favor).3 In recognition of certain conduct, society confers professional status to physicians, but this privilege must be repeatedly earned for the status to be preserved. In this article, I delineate the specific challenges peer-reviewed medical journals face in this age of commercialism within the medical profession.

THREATS TO MEDICAL PROFESSIONALISM

Commercialism is such a threat to the professional ethics of individual physicians that Angell4 concludes that commercialism is incompatible with medical professionalism. Personal financial choices by physicians at times violate professional responsibilities and the fundamental ethical pact with society.3 The conflict between commercialism and professionalism is precisely about the appropriate and inappropriate (not legal vs illegal) ways that physicians should make money and contribute to society.5 If medicine loses professionalism or the public perceives that physicians are not behaving as professionals, it is no wonder that medicine will surrender its influence and status in society. Can the medical profession and, specifically, peer-reviewed literature survive the challenges posed by the secular culture of commercialism and at the same time maintain the public trust?5-7

In 1980, the Bayh-Dole Act launched the biotech industry and permitted universities to commercialize products and inventions (“technology transfer”) without losing federal research funding. The influence of the health care industry on medical science has resulted in many advances in the care of patients, but the profession and its members must seek to preserve the benefits of this collaboration. At the same time, it must find ways to prevent industry marketing goals from dominating the scientific goals of commercially funded research.4 The Bayh-Dole Act fostered this intermingled relationship between the academics, on whom patients depend for unbiased medical information, and the health care industry, which comprises private companies whose main goal is a fiduciary responsibility to its shareholders. Three recent books by Marcia Angell, Howard Brody, and Jerome Kassirer, as well as an increasing number of books and articles in both peer-reviewed journals and the lay press, discuss the power of the pharmaceutical industry, the corrupting influence of commercialism in medicine, and the jeopardizing of public trust in medicine.6,8-10

THE COMMERCIALISM OF MEDICINE

For both academic institutions and individuals, receiving gifts, meals, books, or free continuing medical education creates the presumption of bias. The further acceptance of invitations to join speakers bureaus, to serve on boards, to consult on marketing issues, to receive payments for enrolling in clinical trials, and to participate in research studies with payment in stock pushes this presumption of bias into fact.3,11,12 Other enticements, sometimes for spouses, sometimes at the request of the physicians themselves, are im-

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moral, and some are illegal. Those who do not believe this bias exists are denying scientifically established patterns of human behavior and deceiving themselves. The “rule of reciprocation,” one of the strongest tenets of human social behavior, holds that we should try to repay what another person has provided to us. The ability of physicians to remain neutral under the present barrage of industry largesse is questionable.

In a 2007 article, it was shown that most physicians (94%) reported a relationship with the pharmaceutical industry, many of these relationships involving food received in the workplace (83%) or drug samples (78%); about 35% received reimbursement for costs associated with professional meetings or continuing medical education and 28% received payments for consulting, giving lectures, or enrolling patients in trials. Almost 60% of department chairs have some form of personal relationship with that industry.

There are 90 000 drug representatives providing these incentives, and by spending approximately $16 billion per year on marketing to physicians, the industry acknowledges that physicians can be influenced. Even the National Institutes of Health came under fire when it tried to prohibit outside consulting, indicating the depth of the “commercial spirit” in US medicine. It would appear that a good number of scientific experts on panels that advise a federal decision-making body have strong financial incentives to continue their relationships with outside commercial interests.

Companies target academic “key opinion leaders” (a marketing term) to populate scientific advisory committees, join speakers bureaus that sometimes aggressively promote drugs or devices, and participate on manuscript writing committees that support industry marketing themes. Although key opinion leaders seem convinced of their own impartiality, Carl Elliott, a moral philosopher at the University of Minnesota and author of Better Than Well: American Medicine Meets the American Dream, strongly disagrees with them, as do their own colleagues. The practice of key opinion leaders consulting with multiple companies to present the appearance of objectivity is even more misleading. Industry is acutely aware of the conflict between patient vulnerability and profit incentives, in spite of which it continues to orchestrate these unprofessional relationships.

Pharmaceutical firms have voluntarily begun to regulate themselves more rigorously and their effort is laudable, but some physicians’ behavior remains egregious. In many instances, physicians have allowed the pharmaceutical and biotech industries to insinuate and manipulate medical science through financial relationships, abrogating their responsibility to advance true or important science. Many key opinion leaders make unjustifiable requests to their “handlers” for perks (oral communication with pharmaceutical company marketers, September 2007). Sometimes authors in peer-reviewed literature are not even cognizant of the implications of their obvious financial ties and have to be publicly reprimanded and reminded to disclose.

NEW GENERATION MAY NOT VALUE PROFESSIONALISM

A generation of new physicians has grown up with the mistaken belief that professional values can be replaced with marketplace values and that medical care is just another economic service. Financial success has become the dominant standard of measurement or value even for most academic medical centers. Young professionals are reminded that these commercial activities were previously considered unprofessional. So the lingering question is, should the profession try to uphold traditional principles or alter the concept of “professional” within the contemporary medical practice and research environment? Tinkering with the tenets of professionalism risks the loss of society’s trust. Therefore, professionalism needs to be reasserted over commercialism while the profession seeks to preserve autonomy, exhibit discretionary decision making, and control selection, training, credentialing, and recredentialing of the new professionals.

Attempts by professional societies and pharmaceutical or device companies to curtail unprofessional activities with various decrees have been largely ignored by individuals or given only lip service. A new proposal by Brennan et al encourages academic medical centers to place a ban on all gift giving from pharmaceutical and medical device makers to physicians and prohibit faculty from participating in speakers bureaus; this movement seems to be gaining momentum. As Brennan et al assert, physicians should recommit to altruism and professionalism, putting the interests of patients first, maintaining scientific integrity in speaking and publishing, and eliminating bias in medical decision making, especially with regard to conflicts emanating from relationships between physicians and pharmaceutical companies and medical device manufacturers. The truth, however, is that universities and physicians have become so dependent on industry largesse they cannot even imagine disentangling themselves.

There is tremendous value in the cooperation between academia and industry, but the engagement should be at a distance, with both sides maintaining their own standards and ethical norms. Although academic medicine and the health care industry seem intertwined at present, the profession needs to be reminded that the goals of the medical profession are very different from the goals of the commercial industry. We must seek ways to disentangle the two and not just use “disclosure” as the mechanism to cleanse the system; “reader or buyer beware” should not be the mantra of a profession.

EFFECTS OF COMMERCIALISM ON JOURNAL CONTENT

Editors of peer-reviewed clinical medical journals accept articles on the basis of their capacity to improve patient care; at the same time, editors must preserve the integrity of their journals as disseminators of accurate, unbiased scientific information. The production of useful medical products is the essential scientific goal of the medical profession but just one of the goals of industry. One of the means that industry has of enhancing its value to shareholders is in funding research and subsequently influencing the peer-reviewed literature. The concern for journals is that the marketing goal of a company has the potential to domi-
nate the supposedly scientific aspect of company-funded research. Health care companies have an unprecedented influence and ability to "spin" the message about how patients and physicians should interpret a study in an industry that involves the consumption of $160 billion worth of pharmaceuticals in the United States each year.  

Up until the 1980s, independent clinical researchers and academic medical centers usually designed the protocols, analyzed the results, and produced the peer-reviewed scientific literature. With the decrease in public funding, drug companies have over-filled the void, especially with the advent of the Bayh-Dole Act. Now about 70% of therapeutic trials are funded by an industry that might produce the protocols, analyze the data in-house, write up the articles using communications agencies, and sometimes attach prestigious authors to a manuscript, with the attribution possibly being in name only. Annual revenues for contract research organizations have increased from about $7 billion in 2001 to an estimated $17.8 billion in 2007.  

Peer-reviewed journals seek articles that are valid, credible, and unfettered by financial bias. Editors are frequently at a disadvantage and usually must simply trust that authors have used an appropriate scientific skepticism when viewing their own data and that the results and the discussion are presented in an objective, believable, scientific fashion that can be duplicated. Editors and peer reviewers can usually detect faulty reasoning and logic, judge how the study was designed and executed, and determine if appropriate statistics were applied. Beyond this, peer reviewers must simply trust that authors have appropriately resisted introducing commercial biases.  

There are serious questions about the reliability of some of the commercially funded trials, raising very significant moral and ethical questions for some physicians and a dilemma for journals. As revealed by Bodenheimer, there is now considerable evidence from at least 8 studies that researchers with ties to drug companies are indeed more likely to report results that are favorable to the products of those companies than researchers without such ties (eg, a nonprofit entity or the federal government). In reality, it is the physicians who have permitted the pharmaceutical and biotech industries to manipulate medical science through these financial relationships.  

There is a laundry list of irregularities committed by for-profit companies, and indeed the system has permitted a new art form of manipulating studies to produce a desired result. There is always the possibility of fraud and dishonesty or of falsifying data, but other more subtle forms of bias demonstrate a lack of scientific rigor, which is the antithesis of good science and an issue that is being increasingly identified and critiqued in many peer-reviewed articles and in the lay press. Some of these exposed techniques in commercial studies include altering the design of studies to create positive results; canceling or seriously delaying reports of studies; burying unfavorable results, adverse effects, or negative findings; incomplete reporting of serious adverse events; refusing to provide all study data to the principal investigator and study team; reporting only short-term data when longer-term data are both available and established as the primary outcome; influencing study data and statistical analysis; failing to provide data for independent statisticians to confirm; ghostwriting by marketing departments; contracting with researchers to prohibit the publication of negative results without the permission of industry; permitting industry rather than the researchers to decide about publication; making exaggerated claims in advertisements; submitting to multiple publications without disclosing such; and publishing and reporting data selectively.  

Sponsor control over academic randomized trials is frequently overbearing without the transparency needed to ensure research integrity. Again, sponsors are not solely to blame because the present state of affairs could not exist without the collaboration, or acquiescence, of the academic researchers.  

Many researchers have delayed publication of their results by several months to allow for patent application, to protect their scientific lead, or to slow the dissemination of results that would hurt sales of their sponsor's product, and in some instances scientists at top research universities have completely refused to share results with their colleagues. The reporting of trial outcomes is also sometimes incomplete, biased, and inconsistent with protocols. Published articles, as well as reviews that incorporate them, may therefore be unreliable and overestimate the benefits of an intervention; meta-analysis simply amplifies erroneous results and is much less powerful or valuable than assumed. To ensure transparency and avoid the overbearing of commercial industry, planned clinical trials must be registered and protocols should be made publicly available prior to trial completion. Many major journals will not permit submission of clinical studies that have not been registered.  

There are also concerns about potentially unethical financial influence by reviewers or editors. Any individual in the peer review process can be influenced by commercialism to the extent that he or she provides negative peer reviews of others' submitted but yet-to-be published manuscripts because these reviewers do not want to be "scooped." Similarly, an overlooked opportunity cost to the public is that many important questions are not being answered in medicine because some of the best researchers are using their resources to answer industry's marketing queries, which of have has until use other than providing fodder for ads. In the process, faculty members are also distracted from their teaching duties. Many times these marketing research projects lead to secrecy in research and to the subsequent privatization of medical knowledge, to the detriment of society.  

"Disclosure" is not the promised panacea. Readers, especially practicing physicians, are not usually able to assess an author's motives or judge whether his or her actions were appropriately influenced. Even experts in the field cannot always identify bias in how a study was constructed, reported, or discussed ("spun"). The need for financial disclosure only became evident as a consequence of the Bayh-Dole Act. As late as 1997, Krimsky surveyed 631 articles in some 181 journals and found that only 0.3% disclosed a conflict of interest related to the topic of the article, an impos-
sibly low number given the fact that a quarter of biomedical researchers at the time were receiving funding from the industry. Even in 2007, many faculty members were still not fully cognizant of the implications of financial ties to commercial industry, and individuals are only now being publicly reprimanded. 20

Journals at least try to ensure that readers are aware of the authors’ financial relationships and potential conflicts of interest. This “reader beware” warning fosters an unfounded assumption that disclosure in and of itself cleanses the issue; in fact, disclosure alone cannot resolve the problem. The only way to definitely resolve potential conflicts of interest is for the financial relationship between physicians and industry to disappear. Indeed, in 2000, Angell, the editor in chief of the New England Journal of Medicine at the time, wrote that disclosure was not sufficient to preserve the integrity of the science that appeared in her journal’s pages, and that a policy of “caveat emptor is not enough for readers who depend on the opinion of editorialists.” 18(p535) Certainly little has happened in the interim to refute her claim; it has become even more difficult to avoid financial conflicts in publishing. Between 1974 and 2000, no editors or statistical consultants at the New England Journal of Medicine were allowed to have financial arrangements. This goal is no longer attainable by any medical journal and is evidence of the pervasiveness of these conflicts.

Journals are hampered by this assault of commercialism on publishing. The only tools editors have in their efforts to enforce policies on full financial disclosure or to control excess commercialism and bias is the instigation of a full investigation following complaints by informed readers. When this happens, the journal is dedicated to clarifying the situation for the reader albeit indirectly, by involving the relevant institutional review board because journals do not have formal investigatory or enforcement functions.

## REVERSING THE COMMERCIALISM TREND

There is reason for hope, however, as resistance begins to mount against commercial influence in medicine, as evidenced by suggested changes in the relationship between academic medical centers and industry. 15-22,33 There are also new and influential parallel initiatives from academic medical centers themselves, from the Institute of Medicine, and from think tanks addressing continuing medical education (the education permissive in fostering biases than is publishing). 34-37 Time will tell whether professionalism will rein over commercialism in medicine.

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## REFERENCES

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pupil dilation. The weakness of this study is that it is a cross-sectional study, and other studies are needed to confirm these findings and examine the natural history of ITC.

This study shows that open or narrow angles may be closed in dark lighting conditions, leading to ITC. The risk of ITC depends on the height of the iris plane relative to the trabecular meshwork and the degree of physiological dilation of the pupil. Because ITC is commonly noted in the older age group and in patients with newly diagnosed OHT-GL, and can cause the IOP to fluctuate, gonioscopy should be performed to assess whether the angle is closed by looking for ITC. Thus, is ITC a risk factor for developing elevated IOP that can lead to glaucoma, or do patients with primary open- or narrow-angle glaucoma have primary angle-closure glaucoma? Long-term longitudinal studies are needed to examine this prospectively.

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Correction

Error in Text. In the Special Article titled “Commercialism, Loss of Professionalism, and the Effect on Journals” by Liesegang, published in the September issue of the Archives (2008;126[9]:1292-1295), an error occurred in the text on page 1293. The last sentence of the article should have read as follows: “Time will tell whether professionalism will reign over commercialism in medicine.”