From Quid Pro Quo to Quid Pro Bono: Reshaping the Influence of Industry on Health Care Epidemiologists

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Recent scrutiny of relationships between medical professionals and the pharmaceutical and medical device industries has highlighted many opportunities for conflicts of interest and has prompted calls for reforms in the way we conduct such business. This article reviews ways in which industry influences health care epidemiologists and considers a range of strategies that might be considered for reshaping these influences to preserve the benefits while eliminating the conflicts of interest.

Pharmaceutical and medical device companies invest an estimated $57 billion each year in marketing expenditures, directing the majority toward physicians [1]. Although some of this marketing investment, such as detailing by sales representatives, is easily recognizable, much of it takes subtler forms, resulting in industry influence on many aspects of health care ranging from education to research to guideline development and even to regulatory efforts. Recent articles cite evidence of negative consequences of conflicts of interest between health care professionals and their organizations and pharmaceutical and device industries, and these articles call for better control of these conflicts [2–9].

What are the underlying conflicts of interest for industry and medical professionals? To what extent might industry seek to influence health care epidemiologists (HEs), and how might we recognize potential conflicts before they are consummated? Are there changes we might make to the way we do business that would eliminate undue influence by industry but preserve the potential benefit of appropriate relationships? In this article, I consider these questions and a range of proposed mitigation strategies, writing from the perspective that change is needed.

SIMILAR GOALS, DIFFERENT RESPONSIBILITIES

The work of the medical profession and of the pharmaceutical and device industries is often aligned, as both have the capacity to improve the health and well-being of patients. Similarly, both physicians and those who work in industry are bound to ethical standards that demand that self-interest be subordinated to the interests of others. Here is where the two begin to part ways, however. As professionals, physicians’ ultimate fiduciary responsibility is to their patients, while for-profit companies are responsible to their shareholders. For this reason, even when both physicians and those who work in industry are acting “ethically,” their interests may be fundamentally in conflict.

HEs are responsible for preventing infection and creating a safer health care environment. Part of industry’s work is to convince HEs, who often advise their health care facilities about purchasing products, that a specific product is necessary to prevent infection or to improve infection surveillance capabilities. Once convinced, especially if perceived by peers as an “expert,” an HE has the potential to influence others outside his institution to adopt the same product. Ultimately, an expert HE’s participation in industry-sponsored continuing medical education (CME) sessions, annual meeting presentations, guideline development committees, or even congressional hearings might result in that product becoming a recommended or even mandatory part of standard practice. Somewhere along this continuum, the HE may unwittingly become part of the successful marketing of a product. If the HE receives direct benefits or if patients could be harmed in some way as a result of the HE’s participation in this process, conflicts of interest are said to exist.
BASIC INFLUENCE: THE FREE LUNCH

The most easily recognizable form of marketing to medical professionals is the industry-sponsored lunch, during which sales representatives or in some cases physicians paid to serve on a company’s speakers’ bureau [10] educate doctors and other medical staff about the benefits of their product. Sales representatives use these opportunities to gain access to and build familiarity with physicians or their office staff, often studying the physicians they detail ahead of time, to establish more personal relationships [11].

OPPORTUNITIES FOR INFLUENCE AT ANNUAL MEETINGS

The exhibit hall at professional society annual meetings, where companies buy space for elaborate promotional displays staffed by sales representatives, has been criticized for its “circus-like atmosphere” [4, p. 15]; the sight of professionals loading free stuff into bags labeled with company logos can be unseemly. However, these displays are easily recognizable as advertising and can easily be kept separate from scholarly presentations.

Like many professional societies, the Society for Healthcare Epidemiology of America (SHEA) allows drug, medical device, and medical product companies to sponsor its annual meetings. “Platinum Sponsors” at the 2009 meeting paid $40,000 and received formal recognition, 4 conference registrations, and complimentary registrant mailing labels. Nonsponsoring companies could purchase a postconference marketing list for just $1200. Through transactions such as these, professional societies sell unlimited access to society members.

Speaker disclosures required by most professional societies reveal a more subtle influence by industry. At the 2009 SHEA annual meeting, for instance, 33 (43%) of 77 invited speakers disclosed a median of 4 (range, 1–19) potential conflicts of interest involving a total of 63 companies [12]. Potential conflicts most often involved receiving research support (reported by 22 [67%] of 33 speakers who reported industry relationships) or serving as consultants (reported by 19 [58%]) or on speakers’ bureaus (reported by 12 [36%]), but they also included large gifts, stock options, and holding “positions of influence” [12]. It can be challenging to find speakers who have no potential conflicts. As noted by the Washington Legal Foundation, which provides legal counsel to the pharmaceutical industry, “It is widely acknowledged that virtually all of the top speakers on medical topics are employed in some capacity by one or more of the country’s pharmaceutical companies” [13].

CME

Orbiting at the edges of many annual meetings are industry-sponsored “satellite symposia” that often feature speakers who present similar topics at the formal meeting. These symposia are usually accredited for CME, are held in interesting venues, and include meals. Attendees pay nothing. Invited speakers receive honoraria paid sometimes directly by industry and sometimes by intermediary “medical education and communication companies” that serve as liaisons between industry and content experts. Similar programs are offered through webinars as well as compact discs and digital video recordings that are often mailed unsolicited to society members.

Because of their timing and speaker expertise, satellite symposia can exert a powerful influence on the thinking and practice of physicians. Although presentations are usually not blatantly biased, a tendency toward overemphasis of new therapies, even those that have been disappointing in clinical trials, and underemphasis of non–industry-associated therapies can be subtly misleading. The relative time devoted to discussion of fecal bacteriotherapy versus pharmacological therapy as treatment options for recurrent Clostridium difficile infection [14] may be an example of such an imbalance.

In the past decade, CME has become an increasingly profitable business. In 2006, CME providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) had income of $2.38 billion, generating a profit margin of 31%. From 1998 to 2006, commercial support for ACCME providers increased from $3 million to $1.2 billion [15]. Such a large investment of resources by industry would not be justified if the returns were not favorable.

RESEARCH RELATIONSHIPS

Collaboration between HEs and industry on research to develop and test products designed to benefit patients is an opportunity for mutual influence. During the past several decades, industry’s investment in biomedical research has almost doubled, now accounting for more than half of research funding [16, 17]. In health care epidemiology, much of the research done on molecular diagnostic strategies for MRSA and on treatment and prevention of C. difficile infection has been industry-sponsored; many of the leading voices on these topics have relationships with sponsoring companies.

Although there is unquestionable benefit to collaboration among scientists, concerns have been raised regarding the potential dangers of having industry serve as the predominant funding source for academic researchers. In a 2003 meta-analysis that included 1140 original studies, Bekelman and colleagues [17] demonstrated a strong association between industry sponsorship and a study outcome that favored the industry, raising concern about undue industry influence on aspects of research design or publication decisions. Other concerns include undue influence on the research agenda and on decisions about which devices ultimately get to market [17, 18].

Although the involvement of medical professionals in guid-
ing research and development efforts by industry can be beneficial [19, 20], most companies’ marketing expenditures (including billions of dollars directed at physicians) continue to outpace company investments in research and development by almost 2:1 [1]. “Research” sponsored by marketing departments is unlikely to yield innovative products, such as new antibiotic classes—and such offers of funding should be viewed warily if HEs are to maintain academic independence and professional focus.

**INDUSTRY RELATIONSHIPS WITH JOURNALS**

Publication of favorable research findings benefits many, including the company that makes the successful product, the investigator seeking to advance academically, the patient who needs the product, and the editor seeking to publish important work. The pressure to achieve these benefits can lead to episodes of poor judgment by all parties, making everyone look bad and potentially undermining the credibility of scientific investigation.

The publication of articles under the names of academic investigators when they have actually been “ghostwritten” by professional writers paid by industry is an obvious example of such poor judgment [21]. Other examples can be more nuanced. For instance, once published, an article with positive findings can be a very effective marketing tool [22], prompting some companies to spend thousands of dollars purchasing article reprints for mass mailings to physicians. A former *BMJ* editor points out the potential conflict of interest that can arise when journal editors know that substantial reprint revenues depend on their decision to accept or reject a manuscript [23]. He also describes efforts on the part of industry to influence journal content through the manipulation of advertising revenue and the difficulty of finding scientists without industry-related conflicts of interest to write editorials to accompany published research [23], an issue also noted by Kassirer [5]. Given that journals are often associated with specialty societies and that both editorial and society boards often include content experts who have relationships with industry, the potential for unrecognized influence to occur in the process of review and publication of papers is real.

**INDUSTRY INFLUENCE ON CLINICAL GUIDELINES**

Several recent studies and surveys reveal considerable evidence of connections between physicians who participate in guideline development and pharmaceutical and medical device manufacturers [24–27]. For HEs, this is an area of particular concern. Although guidelines have long been useful to practicing clinicians and HEs, they have taken on additional weight in recent years, because regulatory agencies that wish to increase safety and to ensure that “best practices” reach all patient care settings are seeking to adapt guidelines for use in a regulatory capacity [28]. Significantly, the Joint Commission, an accrediting organization, was represented among the authors of the 2009 Compendium of Strategies for Preventing Healthcare-Associated Infections SHEA/IDSA Compendium [29]. For companies whose devices or diagnostic tests are recommended in national guidelines, the potential benefits are obvious, exceeded only by the opportunity to have the use of their products mandated by law, as in the case of several states that now require screening of patients for MRSA colonization. Guidelines often rely heavily on the opinion of experts. Given often incomplete and evolving evidence and the awareness of the importance of local context, legitimate differences of opinion among experts often emerge. It is critical that these experts are not unduly influenced by industry relationships.

The missteps of other professional societies offer ample lessons. As noted by Steinbrook [30], a number of guidelines in other fields have been compromised because of real or perceived conflicts of interest of the guideline writers. Of the 25 authors of the recent SHEA/IDSA Compendium, 16 (64%) reported ≥1 potential conflict of interest, involving a total of 24 different companies. In guideline writing the potential for undue influence is great, and the potential for harm, including loss of professional credibility, is even greater. Other studies have called for reform of the clinical guideline development process [5, 7, 9, 30, 31]. For health care epidemiology, as for other specialties, the time is now.

**WHERE COULD WE GO FROM HERE? A RANGE OF SOLUTIONS**

Conflicts of interest exert their effects in complex ways; managing them is not simply a matter of transparency and choice. In their review of social science research relevant to conflict of interest, Dana and Loewenstein [32] note that individual physicians tend to believe that professionals with high ethical standards can simply choose not to allow their decision making to be compromised by potential conflicts of interest. The authors illustrate the fallacy in this thinking, drawing on social science experiments to demonstrate that “self-serving bias” is both unintentional and unconscious and that individuals cannot remain objective even when they are motivated to do so. Moreover, people tend both to deny bias and succumb to it, even when they are explicitly instructed about its existence. Thus, neither awareness nor disclosure is adequate to negate the potential influences of relationships between individuals with conflicting interests [32].

Although disclosure alone is unlikely to resolve conflicts of interest, most experts agree that it is a necessary first step when such relationships do exist. Yet, current rules about disclosure are inconsistent, unreliably implemented, and often left to the discretion of the individual. Audiences faced with a list of com-
panies to which a speaker has ties often lack sufficient knowledge to assess potential biases. Despite the inadequacies of the current system, many professional societies, guideline committees, and annual meeting planning committees continue to rely on self-disclosure to mitigate the conflict of interest problem. Similarly, there are national efforts to force disclosure of pharmaceutical payments to physicians [33]; it is unlikely that such laws alone will achieve the desired effect.

Much has been written about limiting the value of gifts from industry to physicians [32, 34], and indeed several recent guidelines specify the types and sizes of gifts that are unacceptable, although the range of acceptability is wide. At the stricter end of the spectrum are the recent Association of American Medical Colleges recommendations [6]. Building on social science research that suggests that even small gifts generate a sense of reciprocal obligation [32, 34], they prohibit all gifts from industry, including food. At the other end of the spectrum, and of relevance to HEs, is the Biotechnology Industry Organization, which has no formal guidelines at all governing relationships with health care professionals. The Pharmaceutical Research and Manufacturers of America’s voluntary code [35] and the American Medical Association’s Code of Ethics [36] fall somewhere in between.

SHEA’s conflict of interest policy requires board members to disclose financial interests of $5000 or more.

Unless it is part of more comprehensive change, the elimination of gifts from industry to physicians would be likely to result in a shifting of industry’s huge investment in marketing to less regulated areas. From the perspective of shareholder value and profit margin, such investment yields a high return, and as long as there are opportunities for physician-industry relationships to occur, it will be in the interest of industry to cultivate them. Several recent position papers have called for major changes to the ways that academic medical centers [2] and professional medical associations [8] relate with industry. The latter recommendations call for broad reforms, including the elimination of conflicts of interest among society board members and increased independence from industry influence in a range of activities: the planning and conducting of national and regional meetings, the development of guidelines and performance measures, and the funding of research and training programs.

Some have argued that such stringent standards have too many potential negative consequences [20, 37], depriving industry and society of valuable expertise in the development of new medical products. But it is the quid pro quo that creates the conflict of interest. If physicians are willing to forego personal gains, including monetary ones, that often accompany such activities, there may be ways to preserve the components of these activities that are consistent with our professional ethics.

Industry could continue to benefit from expert input if centralized industry-independent advisory boards were created by professional societies to develop and communicate key priorities for research and development. Such a shift would allow alignment of priorities around the consensus positions of a broader group of experts. Moreover, it would eliminate the individual financial incentives that create conflicts of interest in the current system and also would establish new incentives for professionals to avoid potentially compromising relationships with industry.

A similar redirection of industry support for research and education could be considered. A shift from the current practice of awards made directly to individuals or organizations by industry (and often by marketing, not research departments) to one in which monies go to centralized repositories and are awarded by industry-independent panels, may bring about greater alignment of research priorities and more evenly distributed support of education. The details of these changes would need careful attention to avoid redirecting inappropriate influences from society membership to its society leadership.

Moving from our current situation, in which the influences of industry are myriad, complex, and largely left to the discretion of individuals, to one in which conflicts of interest that have the potential to undermine professional credibility and fiduciary responsibilities do not exist, will involve changing the way we do business. SHEA policy states a commitment to ensuring the absence of genuine or perceived conflicts of interest among SHEA members. To achieve this goal, SHEA should consider taking several actions.

First, it should develop standards discouraging members from serving as paid consultants or on speakers’ bureaus for companies that might benefit from their perceived endorsement. Such standards would have a broad impact in reducing industry influence across many different activities. Second, SHEA should begin to reform its guideline development process by creating a panel of reviewers without industry affiliations to review guidelines before they are endorsed by SHEA, with the goal of identifying and mitigating potential conflicts of interest. Ultimately, guideline development committees should include only industry-independent individuals, which would stand as an acknowledgment of the importance of these committees in influencing both practice and national policies. Finally, SHEA should consider changes to its annual meeting, including the elimination of formal sponsorship opportunities, the sale of member mailing lists, and satellite symposia. If IDSA took similar steps, these sister societies could lead other professional organizations in reaffirming our professional values.

Making such changes will require us to think creatively about alternative sources of revenue and research funding, because industry partners may prove less generous when their opportunities to buy influence are reduced. The transition is likely
to be painful, particularly for those who have reaped rewards from the current system, and it will take time. Ultimately, however, assertion of our independence as professionals will benefit patients and society and is likely to make our own work more rewarding and focused as well.

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References

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