Is There a Role for Industry-Sponsored Education in Cardiology?

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Education: “The process or art of imparting knowledge, skill and judgment; Facts, skills and ideas that have been learnt, either formally or informally.”

—Wikipedia 1

The term profession is applied to those persons who have specialized and technical skill or knowledge which they apply, for a fee, to certain tasks that ordinary and unqualified people cannot ordinarily undertake. The term derives from the Latin: “to swear (an oath) ...”.

—Wikipedia 2

Let’s consider how we as cardiovascular medicine specialists spend our days in the care of people with cardiovascular disease. In the office or making rounds in the hospital, we prescribe drugs and order diagnostic tests; in the noninvasive laboratory, we obtain and interpret images of the heart; in the electrophysiology and cardiac catheterization laboratories, we program and implant devices in patients. When antithrombotic and fibrinolytic drugs are administered, and primary percutaneous coronary intervention is done using balloon catheters and intracoronary stents, lives are saved among patients with acute myocardial infarction.

Response by Avorn and Choudhry see p 2227

The mortality risk from heart failure decreases and quality of life increases from the proper and appropriate use of angiotensin-converting enzyme inhibitors and β-blockers. Lipid lowering through the use of statin drugs saves lives and reduces serious cardiovascular complications such as myocardial infarction and stroke when properly prescribed to patients with a variety of manifestations of atherosclerotic vascular diseases. According to a recent publication by Ford and colleagues,3 deaths due to coronary heart disease in the United States declined substantially from 1980 to 2000, resulting in >340,000 fewer deaths in 2000. The authors attributed approximately half of this decline to changes in cardiac risk factors and half to the application of evidence-based therapies. An underlying theme in all of this is that the pharmaceutical, biotechnology, and device industries produce an enormous amount of public good through their investment in drug and device discovery, development, and research.

Likewise, education of the clinical practice community ensures that clinicians are familiar with the latest developments and advances in cardiac care so that they might be offered to our patients. Failure to implement evidence-based prescribing carries significant consequences for patients. Peterson and colleagues4 have shown that among patients with acute coronary syndromes, a 10% increase in guideline adherence translates to a corresponding decrease in in-hospital mortality. The mortality risk of patients with acute coronary syndromes has dropped by >30% in the past 15 years.5
Had this amazing application of technology to benefit people with cardiovascular disease been dependent on a medical products industry that operated in a vacuum, without facile interchange with medical practitioners, progress would have been much slower. The combination of the aggressive nature of an industry driven by a societal obligation to return value to its shareholders and the near abdication by academic medical centers of their responsibility for continuing education of medical practitioners has produced an imbalanced system that is in need of correction, but we should be wary of unintended consequences of well-intentioned reforms. The “elephant in the room” is a reimbursement policy that rewards doctors and hospitals for using expensive technology; this policy has resulted in a system that is facile in transferring knowledge about new technologies but profligate in applying those expensive technologies when simpler approaches would do as well or better.

Our principal thesis is that greater balance is needed than currently exists, and it must be achieved by constraining the role of industry funding, changing the payment system, and holding academic centers and professional societies accountable for educating physicians with appropriate independence. Recently, the Association of American Medical Colleges (AAMC) called for renewed attention and focus on the issues facing continuing medical education (CME). Although it is critical that medical schools reengage in this critical element of medical education, the draconian exclusion of industry from participation in the educational system is counterproductive, because it will deprive practitioners of ready access to critical knowledge about the proper use of medical products. Similarly, it will hamper the participation of American physicians in the development of new therapies by impeding much-needed communication between those who develop, manufacture, and distribute innovative new products and the practitioners who use them.

Framing the Debate

There are legitimate societal concerns that relationships between the medical products industry and the clinical delivery industry need to be carefully defined and governed by behavioral standards so that each group can best serve its mission, whether that means returning value to shareholders or providing health care to patients. Although the interests of the medical products industry should be aligned with those of the practice community, these interests should not be superimposable, because the care of patients requires consideration of many factors beyond a pure financial model based on return on investment.

The estimated economic costs for the care of heart disease and stroke in the United States exceed $300 billion annually. A recent article by Gawande in the New Yorker pointed out the societal harm that occurs when cardiovascular specialists, among others, turn a profession into a pure business model. Indeed, our current understanding of the effect of profit seeking by practitioners on our national economy raises the question of which is more of an “industry”: Those who make medical products or those who make money by applying those products to patients. Although we believe that reform of the CME system can be a vital part of reframing medicine as a profession rather than strictly as a business, we also believe that it is naïve to assume that we can completely separate economics and clinical care; we will argue that this is not even in the best interest of our patients.

Research and education make up 2 parts of the tripartite mission of the clinical cardiovascular professional. Innovation requires investment of time, energy, and financial resources. Major progress in the diagnostics and therapeutics of modern medicine has been driven by the market-based reality of a financial return. The continued advancement of cardiovascular care and science depends, in part, on defining a legitimate and appropriate working relationship between clinicians and the industry. Thus, to develop new, effective therapies, the profit motive is needed, but to translate the therapies into better health, equilibrium is needed; the system should balance education about the intricacies of applying medical technologies with education about when to apply medical technologies in the best interest of the patient or the healthcare delivery system. In fact, the medical errors literature now refers to 2 distinct types of errors: Errors in the application of the correct plan and errors in the plan itself. The former error (application) is very much in the domain of the medical products industry (imagine defibrillator use without qualified industry consultants), but the latter error (formulating the plan) is much more common and should be off-limits to the medical products industry, because it clearly falls within the purview of the profession and its key knowledge repositories, professional societies and academic medical centers/health systems.

Medical Education: Learning About Medical Diagnostics and Therapeutics

Traditional medical education, including cardiovascular specialty education, can be thought about in 3 broad categories: Undergraduate, graduate, and postgraduate. During medical school, the undergraduate category, students are typically not exposed to the complexities of drug and device development. Much of the first 2 years of medical school in most curricula focuses on understanding the basic sciences and the underlying pathophysiology of diseases. Little attention is paid to the realities and challenges of how medical products are actually developed and evaluated in a highly regulated environment. Nor, with the exception of an introduction to basic statistics, are most medical students exposed to a detailed, quantitative approach to evidence that allows them to critically assess new information that arises from clinical investigation or to concepts of probabilistic reasoning and decision making that are so critical to proper application of therapies in practice. During the apprenticeship part of medical school, students spend time in the clinical care setting, where they are expected to apply their understanding of science to the care of
patients. During these 2 years, the emphasis is on learning how to take a medical history, perform a physical examination, interpret basic laboratory findings, and arrive at a diagnostic and therapeutic plan. It is during these years that students need to begin to understand and appreciate the development and application of medical products. Unfortunately, few if any medical schools and training programs approach this part of medical education in a systematic way, educating their students on sales and marketing theory and techniques or on how sales representatives are trained to interact with physicians. Considering that most students will spend the majority of their future professional lives ordering, prescribing, and implanting products, it is remarkable that so little attention is paid to this aspect of education. A critical element of system reform will require an overhaul of our outdated undergraduate medical education system.

During the residency and fellowship years (the graduate medical education years), there is again little to no systematic or organized attention paid to understanding how drugs and devices are developed, studied, approved, and entered into the medical marketplace. Yet it is during these years of clinical training that new physicians have extensive exposure to both the good and the bad of industry-supported education. In most cardiovascular training programs in the United States, many conferences are supported directly or indirectly by the medical products industry. Some of these conferences grant CME credit and so fall under the rules/regulations of the Accreditation Council for CME (ACCME). We will discuss these in more detail. Other conferences are more informal, do not grant CME credit, and vary greatly in their quality, including their bias. At their best, these conferences can serve as a vehicle to transmit timely information, including new research, on medical products. At their worst, they are marketing events with little emphasis on objective science. It is a mistake to assume that all industry-supported conferences are of poor quality, and such an assumption can deprive trainees of valuable learning opportunities.

The Medical Products Industry in US Society
The development of medical products in the United States is a highly regulated activity for drugs, biologics, and devices (diagnostic and therapeutic). The Federal Food, Drug, and Cosmetic Act outlines the laws that the US Food and Drug Administration is expected to enforce. Medical products are expected to be “safe and effective” before being approved for use. Federal law requires the medical products industry to abide by Food and Drug Administration regulations in developing new diagnostic and therapeutic products. Regulations and guidance documents govern all aspects of product development, research, reporting of results, marketing of products, dissemination of information to consumers and healthcare providers, and interactions among company representatives (many of whom are physicians) and healthcare professionals. The specifics of the regulations differ between drugs and devices, but general principles apply to both. Essentially, medical product companies (“sponsors”) become repositories of an enormous amount of data about their products. Although the manufacturing of the product is a critical skill, it is the knowledge of the product that confers its economic value, and attempts to apply a technology without access to this knowledge would be foolish. This has been referred to as being part of a “knowledge-based” industry/economy. Indeed, the medical products industry has a legal obligation to ensure that those who use its products have adequate knowledge to use them appropriately, and the industry is at substantial risk of product liability if this does not happen.

Industry and Cardiovascular Clinician Relations
Let’s now return to our opening example of how cardiovascular clinicians spend their day in the care of patients with cardiovascular disease. If much of what will transpire over the course of a day involves the use of various medical products, then what is needed are methods by which there can be a knowledge transfer (education) between the industry and cardiovascular clinicians. Although there are academics who have been involved with a product’s development and a broader group of clinicians who have been intimately engaged in the research evaluating a product, there is no denying that industry scientists are very knowledgeable about the product and its uses. The challenge, as well as the opportunity, in the development of educational materials about a medical product is how best to tap into industry experts while appropriately limiting their inherent bias and focus on their own product engendered by both financial conflict and employee loyalty.

This tension is not new. Podolsky and Greene reviewed the historical issues in a 2008 perspective published in JAMA, noting that “…the history of industry involvement in medical education involved tensions between promotion and education dating back to the origins of the wonder drugs, from antibiotics to antipsychotics.” They pointed out that prominent physicians in the 1950s worried whether the profession was capable of regulating its own education. The worry centered on the industry’s very clever use of marketing disguised as education. The authors pointed out that formal CME grew out of these concerns as a way of regulating professionalism and providing some control over the content of postgraduate medical education. In fact, Podolsky and Greene noted that “arguments from academia, industry and organized medicine articulated in 1958 persist in almost untouched form in 2008.”

The themes of freedom from bias, independent selection of content, and a separation of marketing from education have been present in this debate for almost 50 years. In 1960, the Pharmaceutical Manufacturers Association and the Association of American Medical Colleges issued “Guides for Medical Education Efforts by the Drug Industry,” supporting the notion that industry-supported education was to be free of commercial influence, insisting that “the final choice of
individual speakers should be made by the medical school concerned, in the interest of providing the best possible source of information on a specific subject.14

Although the intention to separate commercial influence from the education of physicians has a long track record, we are obviously still debating the topic 5 decades later. The Food and Drug Administration provided a draft guidance document on the subject of “Industry-Supported Scientific and Educational Activities” in 1997,15 and more recently, both the AAMC and the Institute of Medicine issued position papers on the topic.16,17 The American Medical Student Association supports a campaign known as PharmFree, which “promotes the conscientious, explicit and judicious use of the current best evidence in clinical care. Information used by physicians in making clinical decisions should be comprehensive, transparent in its methodology and results, and independent from institutions and individuals with a financial interest in physician prescribing. Physicians should not seek education from industry marketing efforts, whether they are in the form of advertisements, sales pitches from representatives, or sponsored lectures by paid physicians.”18

There is no question that egregious behavior has occurred in the relationships between clinicians, both academic and private practice–based, and the medical products industry.19,20 Speakers bureaus, although potentially a useful educational activity and source of up-to-date medical information, have evolved to a largely commercial activity with carefully prepared slide sets and messages to be delivered that are crafted in company-led speaker training sessions. Part of this is due to Food and Drug Administration requirements that company-sponsored speakers bureau slides be consistent with product labeling, but much of it is due to the sponsors’ desire to ensure consistency in product messages. Such activities are not consistent with the educational goals/missions of the cardiovascular profession and should not be supported outside the realm of independent CME activities (more on this below).

Some physicians derive a substantial part of their income by making dinner presentations, most often outside the realm of regulated CME. Although there is undoubtedly some benefit to meeting informally with colleagues and exchanging ideas and information over a meal, many of these activities are little more than marketing exercises. For decades, conferences in major academic centers or smaller community hospitals were accompanied by breakfast or lunch provided by an industry sponsor. Did that make the education bad? Or did it send inappropriate messages of influence on the part of the sponsoring organization? “Ghost and guest” authorship continues to be a byproduct of commercial support for medical education and remains inappropriate in all forms.21,22

There are important themes and lessons to be learned here. All of these modes of knowledge exchange are potentially both useful and appropriate. The intention to deliver new product information via academic and clinical peers is a critical part of professional education and should be supported appropriately by the medical products industry. But given the enormous financial stakes in our current healthcare system and the emphasis on the sales-trained and sales-oriented pharmaceutical/device representative as the key interface between prescribing clinicians and the company, the relationships have become distorted, with the lines between advertising and education blurred and indistinguishable. Let’s talk specifically about postgraduate professional education or CME.

Continuing Medical Education

Much of the debate over the appropriate role (if any) for industry support of medical education centers around the industry’s heavy financial support for CME activities. As noted in the AAMC’s report on industry funding of medical education, “An effective and principled partnership between academic medical centers and various health industries is critical in order to realize fully the benefits of biomedical research.”16 The majority of states require CME for physician licensing. In 2007, more than 1 million hours of CME were offered through accredited providers.23 That same year, industry grants provided almost half the $2.5 billion generated through accredited CME programs. There is little question that CME is big business, with universities, professional societies, and for-profit medical education companies all competing for these educational funds. The problem is not industry support of education per se but the manner in which it has evolved, steeped in the methods of advertising and product placement.

The ACCME oversees the delivery of CME in the United States and, as such, provides guidance for the role of industry support of CME.24 These standards are designed to ensure that CME activities (identification of needs, design and delivery, selection of faculty, resolution of conflicts of interest) are free of commercial bias. The recently issued AAMC statement addresses the role of academic medical centers and faculty in the CME process.16 In that document, the AAMC acknowledges the legitimacy of industry support of postgraduate medical education and of the ACCME as the regulating entity overseeing these activities in the United States. The AAMC report clearly stresses that academic medical centers need to conduct postgraduate medical education in accordance with ACCME policies and standards. It also clearly states that industry-supported education for physicians should be conducted under the auspices of the CME regulations. Some academic medical centers have adopted new policies to more appropriately create firewalls between faculty and industry influences. Some of these were addressed in a recent American Medical Association report on financial relationships with industry in CME.25 One notable example in all of this is the Memorial Sloan-Kettering Cancer Center’s decision to forego all industry support for its CME programs.26 More experience and research are needed on all of these changes to better understand the overall impact on the quality of CME.
As with many other organized professional medical associations or public interest groups, the American College of Cardiology and the American Heart Association offer an extensive set of educational activities to members and other interested cardiovascular professionals. These offerings include live meetings, World Wide Web–based education, self-assessment programs, journal articles, and audio learning. Some of this is made possible through industry grants. Both the American College of Cardiology and American Heart Association have extensive guidelines about the use of industry funding for CME activities that are consistent with both organizations being accredited CME providers through the ACCME.27,28

Some authors have recently called for a severe limitation on industry funding for professional society educational efforts in an attempt to better manage “real and perceived” conflicts of interest.29 Whether or not this is feasible in the current economic environment is unclear, but it is also highly dependent on what members desire from their professional organizations. In his presidential address to the American College of Rheumatology in October 2004, Wofsy noted that “since 1998, our annual budget has increased by 75%, while dues have increased only 6%. The expanded programs include, for example, enhanced educational offerings at the annual meeting and elsewhere, practice management seminars, scholarships for trainees to attend our meetings, and major new initiatives to provide assistance to rheumatologists at the local level.”30 Likewise, industry funding to support education within the American College of Cardiology and American Heart Association has resulted in a markedly expanded set of learning opportunities that would be unlikely to be developed without those funds. Given the investment of time, energy, and resources to bring a therapy to market, it is a reasonable societal expectation that the industry that will bring those products into its pricing model, as does every other industry.

Professional societies are heavily dependent on industry money for educational activities, and more balance is needed, particularly in the specialties in which the financial stakes are high, such as cardiovascular medicine. The American College of Cardiology has recently taken important steps to limit even the appearance of bias in the manner in which funding for its annual meeting is used,34 and continued reform is under way. The engagement of the professional societies is highly preferable to a model of for-profit CME. Academic medical centers have simply chosen to focus their available dollars on other issues, particularly basic biomedical sciences, and have put little genuine, dedicated effort into CME, even for those who practice at their own hospitals and clinics. At our own university, the total support of the CME office is less than the cost of several transgenic mouse cages per year, and yet our health system includes more than 2600 doctors, not to mention numerous other medical professionals.

If one accepts that knowledge transfer must occur between medical products companies and the practitioners who use those products, then it stands to reason that the industry should build the cost of education about the use of its products into its pricing model, as does every other industry. But this contribution should be more than matched by out-of-pocket support for CME by practitioners, by health systems in which practitioners practice, and by payers who count on informed practitioners for their clients’ well-being. It is time for medical schools and academic health centers to correct their educational portfolio imbalances and embrace their societal responsibility to provide high-quality ongoing education for the practitioners whom they both train and employ as members of their faculty and medical staffs.

Two individuals from the Office of the Inspector General recently presented their view of the role of industry support for CME.35 They described the federal government’s concern about industry influence and what it may mean for the delivery of quality care. They also described the challenges of a system that depends on industry funding for CME and offered several alternative models for consideration. Although these are not novel suggestions, the notions of pooled
funding support, enhanced professional society oversight, and accreditation of individual activities all have merit and deserve consideration.

**Recommendations for Appropriate Engagement With Industry Over Medical Education**

We recommend the following:

1. Medical education, undergraduate through postgraduate, should be treated as a social benefit, with the expectation that key stakeholders invest in it. All groups who benefit from a well-educated healthcare community, including medical professionals, the medical products industry, the government, private foundations, academic medical centers, and the insurance industry, should contribute to the funding of medical education.

2. Medical schools, health systems, hospitals, and medical practices should establish rules of behavior for interacting with industry for their faculty, staff, and students; this includes methods for accepting funds for educational support that are highly transparent and free from commercial control, influence, and bias.

3. Appropriate firewalls should be put in place to ensure independence of content development, faculty selection, and delivery methods when academic medical centers receive industry funds for CME programs.

4. Conferences held in a training environment (students, residents, fellows, etc) should follow a standard set of rules regardless of whether or not these are formal CME events.

5. Beginning with undergraduate medical education, practitioners should learn much more about the key issues in decision making when considering technology applications, especially knowledge of our regulatory system, understanding of clinical research, and use of quantitative, probabilistic reasoning.

6. Professional medical associations should meet their obligation to provide high-quality education and training about new knowledge to their members and other interested professionals, and academic medical centers should create and invest in first-rate CME offices. This should be explicitly stated in the mission statements/goals of these organizations. Educational activities should be overseen by a group of professional staff and member volunteers with expertise in the therapeutic area of interest, methods of adult learning, and knowledge of appropriate ACCME regulations. There needs to be explicit guidance for transparency of funding, selection of topics, faculty, and methods of delivery. The professional medical associations should have clearly defined methods of disclosing relationships with industry and managing conflicts.

7. Additional formal research on optimal CME models (i.e., funding, content development, delivery mechanisms, and assessment methods) is needed and should be coordinated through academic medical centers with support/collaboration from the professional medical associations.

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**References**


Response to Harrington and Califf

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Harrington and Califf raise several concerns with which we enthusiastically agree: Our failure to provide medical students with adequate training in the quantitative assessment of risks and benefits of treatments, or in critical evaluation of evidence; the continuation of this inadequacy in postgraduate training years; and the “near abdication by academic medical centers of their responsibility for continuing education of medical practitioners.” These educational deficiencies underlie many of our healthcare system’s current problems of quality assurance and affordability. However, we differ on how to address the problem. We do not agree that curtailing industrial involvement in education would “deprive practitioners of ready access to critical knowledge about the proper use of medical products.” Presenting evidence to medical trainees and practitioners should be the responsibility (and the domain) of medical educators and the learners themselves, not of manufacturers. Although it is tempting to fund these activities through support from interested corporations, this economic dependence inherently comes with influences that can (and demonstrably do) shape their content. Healthy skepticism is a key perspective for the scientist and the astute clinician alike; it does not coexist well with commercial boosterism. Harrington and Califf acknowledge that the mission of medical products companies is “returning value to shareholders.” The missions of educators and most caregivers are quite different. Educational programs that present appropriately critical views of therapy in cardiology or other medical specialties will be most effective if they do not depend for their support on funders with missions that, however legitimate, must answer to a different set of imperatives.
Is There a Role for Industry-Sponsored Education in Cardiology?

Funding for Medical Education
Maintaining a Healthy Separation From Industry

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Attitudes and policies about conflict of interest in medical education have evolved rapidly in the last several years. Temporally and conceptually, these changes have paralleled the rise of the relatively new field of behavioral economics in explaining commercial relationships. The traditional view of economics holds that in any transaction, all inputs and outcomes are simply the result of decisions by rational participants making choices that optimize their goals; however, the past decades have seen a reassessment of this “expected utility theory” with the growing awareness that unconscious biases and emotional factors profoundly affect behavior.1 The same insight has begun to influence how we think about medical education and the messages that are sent by and received from industry-sponsored speakers and programs. Because cardiology addresses the most common illnesses in developed societies and employs the most widely used and costly drugs and devices, these issues have been especially acute in this field.

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Unquestionably, the drug and device industries make important contributions to the development of products that reduce the morbidity and mortality of cardiovascular disease. Industry is also a major source of both funding for and collaboration in cardiology research, and it provides substantial support for professional cardiology societies, topics that are beyond the scope of this report. But in the realm of teaching, whether of medical students, house officers, or practitioners, there is growing concern that educational activities should not be supported or influenced by companies whose profitability and very existence depend on the sales volume of the products they make.2

Our position that industry should not directly support educational programs is not ideologically driven. Rather, it is based on the expectation that medical knowledge can be transferred most efficiently and with the least distortion if those responsible for this activity have minimal commercial interest in the topic being presented. After all, this assumption is no different from that underlying well-accepted policies at many journals and in other sectors of society. A person employed or funded by the maker of a drug or device is not permitted to author review articles or editorials on that topic at several journals, not because of the presumption of deceitfulness, but because of the concern over possibly unconscious bias that such relationships might induce. Many judicial and regulatory proceedings similarly require a person with commercial ties to a product to recuse himself or herself from deliberations related to that product. Medical education is an outlier in the extent to which we have traditionally ignored such conflicts in making decisions about funding and decision-maker participation.
The Role of Industry-Funded Medical Education

Industry funding of medical education takes several forms, each of which in our view can pose important potential problems. The most direct form of industry-supported education is through funding for continuing medical education (CME) activities. Industry-funded CME providers include physician organizations, publication and education companies, medical schools, and hospitals, many of which derive substantial profit from these activities. According to the Accreditation Council for Continuing Medical Education, CME companies directly or jointly offered more than 100 000 CME activities accounting for more than 760 000 hours of education in 2008 alone. Support from pharmaceutical and medical device manufacturers for CME, which has quadrupled over the past decade, accounts for more than half of the $2.4 billion that is spent annually on CME. “Medical education companies” were established to act as intermediaries between physicians and industry, accepting funding from drug or device manufacturers and passing it along to physicians, medical schools, hospitals, or other organizations that offer lectures or educational programs. Although this arm’s-length “third-party” status is said to eliminate the manufacturer’s influence over the educational content of these programs, the fact that most medical education companies are heavily dependent on industry for their revenue raises questions about the adequacy of this separation. The world’s largest drug company, Pfizer, recently decided to stop funding educational programs through such intermediaries, recognizing that industry-supported programs should be labeled and acknowledged as such.

There are other equally important but less visible forms of industry-funded education. “Speakers’ bureaus,” in which prominent physicians are paid to lecture about a company’s products, constitute another common form of industry involvement in teaching. Manufacturers may exert substantial influence over the content of these lectures and frequently provide the slides to be used; some physicians earn more than $50 000 per year from these talks alone. Other “key opinion leaders” (known in industry marketing language as KOLs) can earn up to $10 000 from a corporate sponsor for chairing a single educational symposium. The sales representative, or “detailer,” is a major source of drug information for many physicians. This is especially true for new products, for which there may be little or no information available in the medical literature. On average, cardiologists meet with pharmaceutical sales representatives 9 times per month. Unfortunately, many of these salespeople may have limited scientific training and are paid on a commission basis, depending on how much of their company’s products are prescribed by the clinicians they target. There is also growing evidence of companies’ use of such communication to persuade physicians to prescribe products without a given Food and Drug Administration indication and, more importantly, without adequate evidence of efficacy or safety. Several of the nation’s largest drug companies have in recent years paid enormous sums in legal settlements mandated by state attorneys general for such off-label marketing of Neurontin (gabapentin, Pfizer: $430 million settlement), olanzapine (Zyprexa, Lilly: $1.3 billion settlement), and valdecoxib (Bextra, Pfizer: $2.3 billion settlement).

The Impact of Industry-Funded Medical Education

These developments demonstrate that the lure of multibillion-dollar sales from blockbuster drugs and devices can distort the accuracy of information provided by manufacturers to physicians, even when no laws are broken. There is a growing literature in the social and behavioral sciences documenting how judgments and actions can be shaped by subtle factors; some of these findings as they relate to clinical information were presented in a 2007 publication of the Association of American Medical Colleges. Manufacturer-sponsored CME is associated with increases in prescription rates of the sponsor’s medication, perhaps because of the added attention paid to it during these sessions. In one study, the positive effects of the sponsor’s drug were mentioned 2.5 to 3 times more often than those of competitor’s drugs. Interactions with pharmaceutical representatives increase the likelihood that a physician requests to add the company’s drug to hospital formularies by more than 300%, and the receipt of honoraria to discuss a company’s new drug is associated with even larger effects on formulary requests. Interactions with detailers have been linked to more frequent prescribing of the marketed drug, as well as prescribing that is more expensive and less evidence-based.

Several specific cases highlight our concerns. Rofecoxib (Vioxx) was one of the most widely used drugs in the United States until its withdrawal. Its capacity to nearly double the risk of myocardial infarction and stroke made it one of the most important causes of iatrogenic cardiovascular disease in modern history. Newly available data and company documents discovered through litigation documented that its manufacturer (Merck) skewed the depiction of cardiac risk in its presentation of clinical trial data and deployed programs to train its sales representatives to avoid direct responses to physicians who asked about the drug’s potential for cardiac toxicity. Other reports have documented the efforts of GlaxoSmithKline, the manufacturer of rosiglitazone (Avandia), to minimize or suppress early information that the drug could cause congestive heart failure and myocardial infarction. Cardiovascular device makers, too, have been found to have performed poorly in uncovering and disseminating information about potentially dangerous adverse effects of their products. Accounts such as these, relating to information provided by large, well-known companies about their widely used products, support some measure of doubt about the advisability of having manufacturers participate, even indirectly, in the delivery of education about their products.
Other kinds of conflict of interest in medical education

Defenders of corporate sponsorship of medical education programs often object that numerous participants in education can have potential conflicts of various kinds. Many medical school faculty members may have strongly held beliefs about particular kinds of treatment. Some may receive partial salary support through their institutions from industry-funded grants for work on clinical trials or other research. Faculty members or their institutions, such as medical schools or teaching hospitals, may also hold shares of patents and thereby derive financial benefit from the use of particular drugs, devices, or tests. These issues warrant careful attention, but the focus of the present discussion is on a more direct kind of influence: The transmission of knowledge that is funded by companies whose business is based on sales of a product that is the subject of that communication.

The funding of an educational activity by a corporate entity whose primary goal, by definition, must be the promotion of its products appears alongside peer-reviewed articles. However, in most good journals, it is quite clear what is an advertisement and what is a scientific article, so that physicians can evaluate each kind of information in its own context. Relevant exceptions include the purchase of company-dominated sponsored “supplements” linked to otherwise peer-reviewed journals and the recent disclosure of the creation and control by 1 manufacturer of an entire journal.

Other kinds of conflict of interest in medical education

Other reasons for concern about industry involvement in education in cardiology and other areas of medicine are based on worries about the balance presented among competing therapeutic and diagnostic choices, beyond the accuracy of specific facts. For example, in the 1990s, when calcium channel blockers were among the best-selling drugs in the world, their manufacturers were unlikely to sponsor CME lectures or conferences highlighting the advantages of off-patent thiazides for the management of hypertension, even though this was the first-line treatment recommended by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure and it cost less than one twentieth the price of a brand-name calcium channel blocker. Currently, because individual branded statins (atorvastatin, Lipitor) and antiplatelet agents (clopidogrel, Plavix) are the first- and second-highest grossing drugs in the world, it is also unlikely that industry-sponsored talks would focus on the greater affordability of a generic statin or aspirin, respectively, even in patients for whom there is no trial-based evidence that the more costly drug is superior.

Some argue that industry-sponsored education is no worse than industry-sponsored medical journals, in which advertisements for products appear alongside peer-reviewed articles. However, in most good journals, it is quite clear what is an advertisement and what is a scientific article, so that physicians can evaluate each kind of information in its own context. Relevant exceptions include the purchase of company-dominated sponsored “supplements” linked to otherwise peer-reviewed journals and the recent disclosure of the creation and control by 1 manufacturer of an entire journal.

Sources of bias can be important. But in an appropriately structured university setting, they should be mediated by institutional policies and values that can serve as a check on undue influence. Although such mediation is sometimes deficient, these deficiencies do not justify the glib statement that “everyone has conflicts” as a reason to ignore the problems of direct industry support of education.

Spurred by student activism, our own institution, Harvard Medical School, in 2008 adopted a new policy that attempts to address some of these forms of potential conflict. In all presentations to students, faculty members are now required to disclose at the start of their lecture any commercial relationships that may have bearing on the topic about which they are teaching, so that trainees can be aware of relevant external relationships. This policy simply extends to pre-MD education the same arrangements that are becoming universal in CME.

Another aspect of the potentially blurred line between commercial and scientific communication is the relationship between industry influence and another aspect of physician education, the creation of clinical recommendations and practice guidelines. Several instances of preventable iatrogenic cardiovascular disease illustrate this problem. The use of postmenopausal estrogen therapy was widely believed to help prevent ischemic cardiovascular events, until well-controlled randomized trials revealed that such a protective effect did not occur in most patients and that estrogen-replacement regimens could in fact increase the risk of cardiovascular disease. Although the incorrect belief in a protective effect was due in part to observational studies that did not adequately control for important differences between estrogen users and nonusers, evidence revealed more recently in litigation makes it clear that the drugs’ manufacturers also aggressively shaped clinical and public opinion through programs of ghost writing in the medical literature and public relations campaigns.

Formal clinical practice guidelines represent a more concrete way in which improper influence by industry stakeholders can shape messages in ways that may not faithfully reflect the existing evidence base. Choudhry et al found that 59% of practice guideline developers had a financial relationship with a company that made a product addressed by those guidelines. This potential problem was identified as a major concern in 2 current reports from the Institute of Medicine and is also being addressed by a new committee formed by the Institute of Medicine in 2009.

Influence by commercial stakeholders can help determine the design of clinical trials that might help shape updated guidelines, as well as distort the way physicians practice. For example, in 2006, the National Kidney Foundation produced guidelines for anemia management in patients with renal disease; the manufacturer of erythropoietin was the principal sponsor of the guideline development process, and most of the participants and leaders of the initiative were consultants to that company, its competitor, or both. Those guidelines...
recommended use of erythropoietin at levels high enough to achieve hemoglobin goals in excess of those warranted by the available evidence. Later the same year, such aggressive use of erythropoietin was found in a randomized trial to significantly increase the risk of a composite outcome of death, myocardial infarction, congestive heart failure, and stroke. The Food and Drug Administration added a black-box warning to the drug’s label, and the National Kidney Foundation later modified its practice guideline.

Opinions From the Leaders of Medicine
Over the last 3 years, 3 influential mainstream organizations have issued major reports recommending the separation of industry from all forms of medical education. In 2007, the Macy Foundation, which has been a major force in medical education for decades, examined the role of industry support in CME activities. It concluded that “[p]harmaceutical and medical device companies and healthcare professionals have inherently conflicting interests in [CME]. Commercial entities have a legitimate obligation to enhance shareholder value by promoting sales of their products, whereas healthcare professionals have a moral obligation to improve patient/public health without concern for the sale of products.” The report noted that “[n]o amount of strengthening of the ‘firewall’ between commercial entities and the content and processes of [CME] can eliminate the potential for bias.” The Macy Foundation report concluded that accredited organizations providing CME “should not accept any commercial support from pharmaceutical or medical device companies” and that the “[f]aculty of academic health centers should not serve on speakers’ bureaus or as paid spokespersons for pharmaceutical or device manufacturers.”

In 2008, the Association of American Medical Colleges released its own report on industry funding of CME. The recommendations were formulated by a broad-based committee that, along with academics and consumers, included the chief executive officers of Pfizer, Eli Lilly & Company, Medtronic, and Amgen and was chaired by the former chief executive officer of Merck. It determined that the potential of commercial sources to influence the objectivity of academic teaching “engenders public skepticism, not only in the commitment of medical schools and teaching hospitals to their primary public purpose, but also in the commitment of academia and industry together to promote the public’s interest by fostering the most effective, evidence-based medical care possible.” On the basis of this finding, the Association of American Medical Colleges recommended that industry funds should not be provided directly to any CME course; rather, any such support should be coordinated through a centralized office in a given institution, and “[i]n no case should the medical center permit CME funding directly to individual faculty.” It also proposed that “academic medical centers should strongly discourage participation by their faculty in industry-sponsored speakers bureaus.”

In 2009, the Institute of Medicine issued a report entitled “Conflict of Interest in Medical Research, Education and Practice.” In its section on education, the Institute of Medicine recommended that “faculty should not participate in speakers bureaus and similar promotional activities in which they either present content directly controlled by industry or formulate their remarks to win favor and continued speaking fees,” and it called for a “broad-based consensus development process to propose a new system of funding accredited continuing medical education that is free of industry influence, enhances public trust in the integrity of the system, and provides high-quality education.”

As recently as 2006, an article in JAMA by a group of leaders from academic medical centers that called for an end to direct industry sponsorship of CME drew heated rebuttals. But since then, several major academic medical centers have established tougher new rules banning commercial relationships in several areas of training. Often, these initiatives came in response to concerns raised by medical students individually or through the American Medical Student Association, which has taken an active lead in this area. In 2008, Stanford Medical School announced that it would no longer accept course-specific industry funding for CME, requiring that any such support be given instead to a pooled school-wide education fund. Although initial skepticism greeted the notion that any drug company would provide general educational support without linking it to a particular therapeutics area or faculty member, earlier this year Stanford announced a $3 million open-ended educational grant from Pfizer, with use of the funds to be totally determined by the medical school. The University of Pittsburgh Schools of the Health Sciences have recently adopted a similar policy. The Sloan-Kettering Cancer Institute has gone further and banned industry support in any form for CME.

Although it is too early to discern the effects of these changes, there is widespread belief that despite the Pfizer-Stanford grant, the volume of funding that companies will be willing to commit to such general educational pools will be substantially less than they are now spending on more tightly controlled product-linked programming. This would be compatible with the explanation that such funding (often dispensed via the marketing department) is primarily aimed at increasing product sales, rather than as a form of general corporate “good citizenship.” The coming years will determine whether this concern is borne out.

Options for the Alternative Funding of CME
We agree with the Macy Foundation, the Institute of Medicine, the Association of American Medical Colleges, and other groups that have called for ending or strictly limiting industry support of medical education at all levels. Because many clinicians, academic institutions, and professional organizations have become reliant on industry funding, this raises the question of where support for such programs would then come from.

The education of medical trainees and practitioners is a public good; there is ample justification for federal and state
support of such education, especially for CME. Governments support other forms of higher education in which the life-and-death stakes are not as high and issues of potential bias are not as worrisome. One attractive means of publicly supported CME is “academic detailing,” initially developed by one of us (J.A.) in the 1980s. In this approach, medical school faculty working through a nonprofit organization with no ties to any pharmaceutical company perform a rigorous review of the evidence on optimal management of a given clinical topic (eg, hypercholesterolemia, or the evidence-based use of antplatelet agents). That organization then condenses these syntheses into user-friendly, clinically relevant summaries of evidence-based recommendations. It then trains nurses, pharmacists, or physicians to present this information interactively in “educational outreach” to physicians in their own offices, in an encounter that is similar in some respects to the sales visits of drug company detailers but devoid of a commercial agenda. The Cochrane Collaborative has reviewed the growing literature evaluating this approach and concluded that it is an effective means of improving prescribing practices. Several states (including Pennsylvania, Massachusetts, New York, South Carolina, and Vermont, as well as the District of Columbia) have established publicly funded academic detailing programs to offer physicians such noncommercial evidence-based education on medication use. We participate in such programs, the materials for which are made available publicly at no cost through http://www.RxFacts.org. Senator Herb Kohl (Democrat, Wis) has introduced legislation that would provide federal funding for such programs on a wider scale, with the provision that those preparing or implementing such educational activities have no financial ties to the companies whose products are being discussed.

In addition, as more care is delivered through integrated health systems, such organizations will realize the clinical and economic value of investing in the continuing education of their practitioners. Third-party payers, including the federal government, should have similar incentives to pay for CME, as long as its content is determined by a truly independent group of professionals and not subject to influence by any public or private payer (which could introduce an opposite but equally problematic problem of potential bias). Entities responsible for healthcare financing and delivery are likely to realize eventually that if industry-sponsored education skews care toward more costly alternatives, supporting such programs themselves will be an important means of reducing unnecessary costs, as well as ensuring the quality of care.

Another obvious solution is for physicians to foot the bill for our own continuing education. Some clinicians may object that an end to company underwriting of CME programs will increase the cost they must pay for CME courses or lectures or require them to pay for their own food at mealtime talks. But despite the commoditization of so much of health care, medicine remains a profession; one of the hallmarks of professionalism is accepting the responsibility for one’s own lifelong learning. Professionals in other fields (such as lawyers or accountants) pay for the costs of their own continuing education, or the firms that employ them do so. Medicine is unusual among the professions in that so many of us expect the vendors with which we do business to underwrite the costs of our ongoing education. Those of us who offer and take CME lectures and courses will also need to accommodate ourselves to less lavish settings, gastronomy, and amenities to accompany our educational experiences.

Defenders of industry-funded medical education for physicians and of direct-to-consumer advertising of prescription drugs argue that even if there are concerns about balance or focus on costly products, company support leads to communication of messages that might otherwise be neglected; examples include the need to control cholesterol, or informing patients of conditions like depression, incontinence, or erectile dysfunction that they might otherwise not have discussed with their physicians. We believe that the wealthiest nation on earth should be able to provide neutral, evidence-based educational messages about medications to physicians and patients without having to accept the trade-off that industrial sponsorship of such education inevitably requires.

The United States currently spends more than $4 billion per year on direct-to-consumer “education” about drugs and 6 to 7 times that amount in industry-funded CME and promotion (including drug samples) for physicians, which are all tax-deductible business expenses. These are sound investments for the companies that make them, because they drive medication use toward the costliest drugs, even if these are no more effective than available products. The costs of this “free” information are thus ultimately borne by consumers and taxpayers. Industry sponsorship of such communication may appear to be cost-saving to the busy practitioner offered a free meal or a low-cost CME course, but as noted by a widely used World Wide Web site that covers industry involvement in medical education, there is no free lunch (see http://www.NoFreeLunch.org).

The Ongoing Development of Medical Practice and Education

The evolution of opinion on industry-supported medical education in cardiology and other branches of medicine mirrors the loss of naïvete we have seen before in the evolution of biomedical science. Before World War II, many clinical trials did not require randomization or control groups or blinding of investigators or patients, in the mistaken belief that patient selection, observer bias, or the placebo effect could never color the interpretation of whether a given treatment worked or not. “After all, we are astute scientific observers and would never let our own expectations or a patient’s self-report influence our judgment about how well a treatment works.” We now know better and understand that a trial that lacks these methodological safeguards can be fatally flawed, and its results would not be taken seriously.
In the mid 20th century, little attention was paid to ethical standards for research that involved human subjects or to the need to obtain informed consent for such studies. “After all, we are concerned, committed physicians and would never intentionally harm a research subject.” We now know better, and it is unthinkable (and impermissible) to conduct a trial without obtaining the consent of subjects and securing approval of the study design by an arms-length institutional review board.

Similarly, as recently as the 1980s, the medical profession generally ignored the potential influence of commercial ties on clinical research; rules about conflict of interest were vague, incomplete, or ignored. “After all, as researchers we would never allow the prospect of personal gain to distort the conduct and interpretation of our clinical studies.” We now know better, and most universities and academic medical centers enforce strict rules that prohibit those with financial interest in a given treatment from studying it in patients.

It is only in the last decade that parallel concerns have become common in considering the role of industry in medical education. Many physicians are still in a stage of denial similar to those that preceded other paradigm shifts: “After all, companies and their spokespeople would never shape an educational presentation just to favor a given product and intelligent physicians would not be influenced if they did.” We now know better, or should. As our understanding of these issues becomes more sophisticated, it is likely that in cardiology and other fields of medicine, industry-sponsored lectures, courses, and gourmet infomercials will eventually go the way of nonrandomized trials, research without informed consent, and clinical studies performed by investigators whose financial well-being depends on the results.

As in the earlier examples from medicine’s development, the issue is not venality or intentional deception. The problem is generally not that manufacturers or the educators they form by investigators whose financial well-being depends on the results. The lessons of behavioral economics, as well as the literature on clinical decision making, provide ample evidence that although we all like to consider ourselves perfectly rational actors, what we believe and the decisions we make can be subtly but heavily influenced by bias, even if such bias was not intentional. Because the clinical stakes for our patients are so high, and because the healthcare system of the coming decade will have to expend its constrained resources in the most cost-effective manner, cardiology and the rest of medicine will need to move beyond having vendors provide or pay for the education of its practitioners. The transition will be challenging for a time, but our patients, the healthcare system, and we as professionals will be better off for it.

Disclosures

Neither Dr Avorn nor Dr Choudhry accepts any personal compensation from any drug or device manufacturer. Drs Avorn and Choudhry are listed as coinvestigators on a grant application submitted to the Agency for Healthcare Research and Quality through the Brigham and Women’s Hospital that proposes adaptation of Agency for Healthcare Research and Quality comparative effectiveness reports for wider dissemination. Dr Avorn also provides pro bono consultative services on appropriate medication use to the Alosa Foundation, a nonprofit 501(c)3 educational organization with no relationship to any drug or device manufacturers; a family member serves pro bono in an administrative capacity, but neither Dr Avorn nor his family member receives a financial benefit of any kind from this work. Dr Choudhry also provides consultative services on appropriate medication use to the Alosa Foundation and is compensated for this work.

References

Response to Avorn and Choudhry
Robert A. Harrington, MD; Robert M. Califf, MD

As is the case in healthy debates between groups with opposing views, there is much overlap between our perspective and that of Avorn and Choudhry on this topic, which suggests that we should feel optimistic about finding the right pathway to dealing with this critical and complex societal challenge. None of us believes that society would be better off without collaboration between academics and the medical products industry. Although Avorn and Choudhry wish to separate the arguments related to industry support of research from the arguments dealing with their support of education, we disagree with that approach, and we do not believe that this is a healthy distinction. Societal interest in the development of innovative medical products and instruction in their use requires collaboration among industry, academic health centers, and professional societies. But we go a step further than Avorn and Choudhry: We believe that industry has a societal obligation to invest in the education of professionals who might use their products. We agree that the medical journal model of a primary sponsorship relationship policy 2009. Available at: http://www.coi.pitt.edu/IndustryRelationships/policy.htm. Accessed June 29, 2009.


Funding for Medical Education: Maintaining a Healthy Separation From Industry
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