Pharmaceutical Industry Financial Support for Medical Education: Benefit, or Undue Influence?

Howard Brody

Introduction

As early as the 1960s and 1970s, astute commentators began to call into question the degree of influence that the pharmaceutical industry was exercising over all aspects of medical research, education, and practice in the U.S.[1] More recently, a spate of books and articles demonstrates that the issue has only become more serious in the last decade or two.[2]

My focus in this paper will be on the industry's influence on medical education. The influence that the industry exerts on undergraduate and graduate medical education (that is, the training of medical students and residents) often occurs through the system of pharmaceutical sales representatives, who also "detail" drugs to practitioners; or through the influence that the industry exerts over medical research. I will therefore devote my attention here primarily to the system of continuing medical education (CME) by which practitioners receive information about medical advances. The pharmaceutical industry currently supports about one-half of the costs of CME in the U.S., so it seems appropriate to question the degree of industry influence over the content of CME.[3]

Defending Industry-Supported CME

Many physicians as well as advocates of the pharmaceutical industry defend current CME practices.[4] The following arguments are generally raised.

1. Rapid advances in medical science increase pressures on physicians to stay current in their field. CME is one tool to accomplish this educational task. But the costs of CME are rising and other funding sources are uncertain, making it reasonable for CME organizers to turn to the industry for assistance.
2. Ultimately, the patient benefits when physicians are well-informed about the latest therapeutic advances. The fact that the industry gains goodwill, and some increased sales, from its sponsorship of CME does not change that underlying reality.
3. CME programs are governed by a detailed set of regulations, designed to minimize the influence of the sponsor upon the content of CME and to maintain the independence of both organizers and speakers. (As we will see below, since the regulations previously in effect were deemed by

Howard Brody, M.D., Ph.D., *is the Director of the Institute for the Medical Humanities and John P. McGovern Centennial Chair in Family Medicine, University of Texas Medical Branch, Galveston. He is the author of* Hooked: Ethics, the Medical Profession, and the Pharmaceutical Industry *(Rowman and Littlefield, 2007).*

some to be insufficient, even stricter rules were put into place in 2004.)

4. Since new drugs are part of the general advance in therapeutics, patients will be best served when their physicians know as much as possible about these drugs as soon as possible. Even though independence from commercial sponsors may be a valued goal in CME, it is nevertheless true that speakers more closely allied with the company that has researched and then manufactured a new drug, would be in the best position to explain the properties of that drug to physicians.
5. Companies make greater profits to the extent that they discover and market useful new drugs. To assist in this process, it is natural that they would turn to the most talented physicians and medical scientists as their paid consultants. If regulators were successful in banning from CME programs all those who had financial ties to the industry, then physicians would necessarily be deprived of the most expert speakers on the topic and would have to make do with second-rate education.

A Visit to the Exhibit Hall

The arguments in defense of industry support offer a generally benign view of the typical CME program. Physicians learn useful, up-to-date information while the industry generously foots much of the bill. How does this view match up with reality?

One way to begin to understand the extent of industry influence in CME is to pay a visit to the exhibit hall of a medical conference. This portion of the meeting is reserved for exhibits and booths set up by drug and device manufacturers and anyone else wishing to sell a product or service to the attendees, and willing to pay a fee to the conference organizers for the privilege. The commercial exhibitor therefore must pay two costs: first, the rental of exhibit hall space, and second, the actual cost of erecting, supplying, and staffing the exhibit booth or activity.

E. Fuller Torrey, a distinguished American psychiatrist, commented on the lavishness of these exhibits at the Seventh World Congress of Biological Psychiatry, held in Berlin in 2001.[5] On strolling about the hall, he encountered an artificial garden (sponsored by Janssen-Cilag), a brook flowing over picturesque rocks (Lundbeck), and a 40-foot rotating tower (Novartis). Torrey was especially intrigued by the display set up by Organon to advertise its antidepressant drug, Remeron. In a colorful tent, attractive young women wearing genie costumes were taking Polaroid photos of each visiting psychiatrist's "aura." Torrey asked one of the genies whether it seemed wise to the company to associate their product with "auras, magic, New Age thinking, and anti-science."[6] The woman in reply merely pointed to the long line of psychiatrists, all waiting their turn to have their "auras" photographed while hearing the pitch for the drug.

The arguments in defense of industry support offer a generally benign view of the typical CME program. Physicians learn useful, up-to-date information while the industry generously foots much of the bill. How does this view match up with reality?

On talking with some of the organizers, Torrey determined that approximately half of the 4,000 attendees at the meeting had had their ways paid by a pharmaceutical company. Besides paying for all the travel expenses and registration, the companies typically hosted lavish parties for their attendees. Torrey calculated that the entire pharmaceutical industry's financial footprint at this one meeting cost approximately $10 million.

What impact did this have on the content of the meeting? The best attended sessions were about psychiatric drugs, and the most popular speakers had been sponsored by the industry, typically receiving an honorarium of $2,000-$3,000 as well as travel expenses and business-class airfare. Torrey located one session held in a back room, for a very sparse audience, about non-drug approaches to mental health. The speaker ruefully told Torrey that he "felt like the legitimate act at a burlesque show, included only to keep the cops out."[7]

Psychiatrists, it seems, are near the top of the list for gifts and favors from the industry.[8] My own specialty of family medicine provides an alternative view of the exhibit hall. The "word on the street" among family physicians in past years was that the exhibit hall at the annual scientific meeting of the American Academy of Family Physicians (AAFP) represented a rather extreme display of gluttony, with physicians trolling the hall with huge carry bags to assure that they collected as many giveaways as possible. The potential for embarrassment reached such a level that the organization sought to rein in these excesses.

If restraint is the current name of the game, one might not know this from viewing the portion of the AAFP website devoted to the annual meeting (to be held next in Boston on October 14-17, 2009). The site contains a special link for "assembly partners."[9] Exhibitors are reminded, "Family physicians care for *all* ages, *both* genders, *each* organ, and *every* disease. Reach 5,000 family physicians in one spot — exhibit at the AAFP Scientific Assembly, the one medical meeting you can't miss!"[10] Other pages stressed how many physicians later purchase products seen at the meeting, and provide statistical breakdowns of how many prescriptions per day the attendees write in their practices.[11] Besides renting exhibit space, companies were encouraged to advertise in many other ways, including the "AAFP Doctor's Bag" delivered to attendees' hotel rooms, and also "comfort stations" (presumably to assure that biological needs do not limit marketing opportunities). Mailing labels could also have been purchased from the AAFP, so that companies could get a jump by advertising to attendees even before they arrived.[12]

Unless specifically guided there, the average AAFP member would have no reason to click on the Web pages provided for the "assembly partners" or exhibitors. It is not clear how the AAFP leaders would feel if their rank and file members viewed these pages and wondered about how they themselves were being "marketed" to the pharmaceutical industry by their own professional society. It is also not clear what the AAFP would think about the general public viewing this portion of its website.

Robert Goodman, leader of the movement called No Free Lunch, an activist campaign designed to reduce industry influence in medicine, has in previous years sought to set up a booth for his organization in the exhibit halls of both the AAFP and the American College of Physicians. Initially both organizations refused him admission, though those decisions were later reversed when members protested on Goodman's behalf. The reasons given for the initial refusals suggested that the primary goal of excluding No Free Lunch was not to upset the commercial exhibitors who were paying major dollars for their booths.[13]

Ethics and Rationalization

Why should any of this matter? We live in a capitalist society. If physicians were to attend a major sporting event, they would naturally expect to see every surface, vertical or horizontal, plastered with advertising. Why should we imagine that medicine itself should be any different?

Briefly, the ethical concerns presented by commercial influence in medical education primarily involve trustworthiness and conflict of interest.[14] The professional obligation of the physician is to serve as a patient advocate, and to seek to give advice which benefits the patient. Exactly how far physicians must go in putting aside all other interests in order to serve the patient might be debated. Nevertheless, patients feel justified in trusting the physician to make recommendations in their own interest — not, for example, to advise surgery just to earn a fee when a non-surgical approach might produce a better outcome. Professionals ought to aspire to *trustworthiness* — to conduct themselves in such a manner that the public would feel that the high level of trust that they bestow on the professionals is fully justified. A professional worthy of the title cannot be satisfied with blind trust — with trust that the patient grants only because he is unaware of the true state of affairs.

Why should any of this matter? We live in a capitalist society. If physicians were to attend a major sporting event, they would naturally expect to see every surface, vertical or horizontal, plastered with advertising. Why should we imagine that medicine itself should be any different?

The idea of conflict of interest is closely tied to the concept of trust in a professional role.[15] A conflict of interest arises when physicians put themselves in a situation where the reasonable onlooker might fear that a person subject to the forces of normal human psychology would be tempted to place the primary duty to serve the patient secondary to some other interest. In the example of the surgery, one could argue that fee-for-service reimbursement of physicians constitutes this sort of conflict of interest. Surgeons with a normal psychological makeup, knowing that they will be paid a good deal more for doing surgery, could be tempted to advise the patient to have surgery even if it was not needed. (Therefore, many patients would seek a second opinion before agreeing to surgery, thus reinforcing the belief that conflicts of interest exist).

My core argument is that the physician who personally accepts the largesse of industry so as to be able

to attend a CME event at a lower cost than he might otherwise have to pay, or the physician who attends a CME event knowing that the bulk of the costs of the conference was borne by industry, puts himself in a conflicted situation. The reasonable patient, knowing the tendency of commercial interests to bias information that those interests believe that they have paid for, might now have considerably less trust in this physician's ability to provide appropriate medical recommendations that will serve the patient's interest (as opposed to the commercial interests of the sponsors). If the physician could have received education from another (non-commercial) source, but elected instead due to the various perks or the "aura" photos to attend the commercially biased event, then in this way he has demonstrated that he is less trustworthy.

It is important in understanding the ethical nature of conflict of interest to note that no actual violation of one's duty need transpire. The physician who attends the CME program might somehow rise above all temptations, and make recommendations to patients based solely on the best scientific evidence. A conflict of interest has occurred simply due to the social arrangements that would lead reasonable members of the public to be concerned that trust in the crucial professional role may have been breached.[16]

In the case of the surgeon recommending an operation, the conflict of interest may be unfortunate and yet unavoidable. No one has yet found a way to pay physicians in such a way that *no* incentives are created to favor some modes of treatment (or non-treatment) over others. This has led some critics to argue that the entire "ethical" controversy regarding medicine and the pharmaceutical industry is overblown — medicine, no matter what we might do, is rife with conflicts of interest. We expect physicians of scientific attainment and good character to rise above these conflicts and serve the patient well; the pharmaceutical situation is no different from any other area of medicine.[17]

This criticism in turn points out yet another wrinkle in attempting to assess the ethical issues at the medicine/pharmaceutical industry interface. As perplexing as other issues in medical ethics may be — e.g., embryonic stem cell research, physician-assisted suicide — we generally expect that the advocates for the various ethical positions will speak their minds candidly. A complication of the medicine-pharmaceutical industry relationship is the extent to which both parties have encouraged each other, over many decades, to engage in extensive *rationalizations* that disguise the true nature of the behaviors in question.[18] The most common forms of rationalization include:

- Information obtained from pharmaceutical sales representatives, or from industry-sponsored events, is educational — not marketing.
- If a pharmaceutical spokesperson told me anything that was scientifically inaccurate, I could immediately detect it.
- I can accept gifts or payments from the industry without feeling any obligation to prescribe their products and without influencing my judgment.
- Conflicts of interest are ubiquitous in medicine anyway, so the specific conflicts represented by accepting gifts from the pharmaceutical industry produce no problems.

These beliefs are all belied by the available data, though a full discussion of the empirical basis for this claim is beyond the scope of this paper.[19] For our purposes, it is sufficient to note that in trying to get at the ethical truth, and in proposing solutions to any problems that are found, these rationalizations must first be carefully dissected.

CME and Industry: Current Status

CME is a precisely defined activity because a single organization, the Accreditation Council for Continuing Medical Education, oversees all other organizations that are allowed to grant official credit hours to physicians for attending CME events. A pharmaceutical company wishing to transmit information to physicians can do one of two things. It can invite a group of physicians to dinner and present a speaker chosen by the company to speak on a certain topic. Or it can work in tandem with an officially accredited organization to present a session at an ACCME-approved meeting, such as the Berlin Congress or the AAFP annual scientific assembly. For many reasons the industry often prefers the latter course. Physicians are often required to accumulate a certain number of CME credits annually to maintain medical licensure and specialty certification, and they view the granting of CME credits as suggesting an educational quality-control process. Physicians therefore wish to attend events offering formal CME credit, and the industry wishes to oblige. Part of the reason the industry obliges is that these meetings, as currently conducted, are remunerative. It has been estimated that for every $1.00 the industry invests in CME or similar meetings, it reaps $3.56 in increased sales.[20]

In 2006, all CME programs in the U.S. took in revenues of approximately $2.385 million. Of this, as noted above, almost exactly half was from commercial sources.[21] In 2004, the last year for which this breakdown was available, about 98 percent of all

"commercial support" came from the pharmaceutical industry.[22]

There is considerable diversity in how much the various CME-credit-granting organizations depend on the pharmaceutical industry. Organizations such as medical education and communications companies (MECCs) are essentially creatures of the industry, relying on drug firms for more than 80 percent of their revenues. Some health care organizations, such as managed care plans, Veterans Administration hospitals, and the like, derive only 20 percent or less of their CME revenues from industry. Lastly, a middle group gets between 45 and 50 percent of their revenue from industry — a standard percentage for all CME organizations. This middle group includes the largest providers of CME programs (in terms of hours of credit granted), including the specialty societies like the AAFP and the American Psychiatric Association, state and local medical societies, hospitals, and medical schools.[23]

The ACCME requires that its member organizations follow strict guidelines to prevent undue commercial influence and bias, in large part by requiring the disclosure of the commercial ties of any speakers, and the independence of the group that selects the topics and content for the meeting from industry funding. One might wonder, then, why an organization such as a MECC, which derives nearly all of its revenue from the industry, is allowed independently to decide which meetings under its sponsorship receive CME credit, as opposed to having to be reviewed by a less commercially dependent organization such as a state medical society. Arnold Relman, a former editor of the *New England Journal of Medicine* and vocal drug-industry critic, has attacked the ACCME guidelines process for allowing these inherent conflicts of interest.[24]

Carl Elliott makes more sweeping claims about the extent to which the industry can manipulate the entire CME enterprise. Besides having so many of its own people at the table when the ACCME is writing its guidelines — and controlling so much of the funding of the MECCs — the industry heavily supports many of the professional societies that are responsible for such a large percentage of CME credit hours, like the AAFP and American Psychiatric Association.[25] Many of the larger medical societies appear to depend on industry for about one-third of their operating revenues, though exact figures are often kept secret.[26] Elliott might have added here that industry controls a good deal of CME content due to the fact that it funds so many of the clinical trials that provide the evidence basis for the educational programs, thereby allowing it the leverage to influence published trial results.[27]

These multiple layers of influence lead to multiple layers of conflicts of interest. According to Elliott,

> Most of the people involved in these operations do not see any harm in taking a piece of the industry money for themselves. The academic researcher says: what's the harm if I take money for signing onto a MECC-produced editorial as long as I agree with everything that is in it? The doctor says: what's the harm in attending an industry-funded symposium in Boca Raton as long as I look at the presentations with a skeptical eye? The department head says: what's wrong with taking money from Janssen or Merck to fund our Grand Rounds program if it means we can bring in more high-profile speakers? The journal editor says: what's wrong with publishing an industry-funded editorial or review article as long as it gets appropriate peer review? The ethicist says: what's wrong with funding our centers with industry money as long as the gifts are unrestricted and the funders are not issuing any orders? But it is only when all these cogs click together that the machinery is put into motion.[28]

What evidence is there that as a result of all this, the actual prescribing behavior of physicians is altered? The data on the impact of CME are weaker than in some other areas of the medicine/pharmaceutical industry relationship. Given the numerous forces that collectively account for what prescriptions a physician chooses to write, it is notoriously hard to design studies to prove that one single factor is causal. A pair of studies conducted in the late 1980s concluded that the content of CME meetings is influenced by the commercial sponsorship, and that later prescribing by attendees was likely to favor the products of the CME commercial sponsor.[29]

We have been focusing so far on CME, but one might wonder what the medical students think as a result of observing all these levels of commercial entanglement (and the rationalizations thereof). Only one study to date has looked at medical student attitudes. In a survey of 1,143 students in their third year of training (the first year in which they spend almost all of their time in hospitals or clinics) at eight U.S. medical schools, 93 percent reported being asked or required by the physician in charge to attend a drug-company-sponsored lunch at which a lecture was being given. Perhaps most worrisome, 80 percent of this sample reported believing that they were *entitled* to any gifts that the pharmaceutical industry elected to bestow on them.[30]

Can the Situation Be Improved?

Elliott is quite optimistic that the ethical problems around CME can be resolved: "If the right constituencies could be mobilized, the mess would not be that hard to clean up.... Medical organizations could hold conferences without drug industry perks, just like other professional societies.... Academic physicians could treat lectures and grand rounds as part of their duty as teachers, rather than as a way to generate extra income."[31]

At the other extreme is the former president of Harvard Derek Bok. Discussing the problem of "universities in the marketplace," Bok is sure of two things: (1) the problems posed by the commercialization of academe are serious, and (2) they are remediable. In only one area does his optimism waver. CME, he believes, is a lost cause: "The dependence on corporate support has reached such a point that it will be difficult for medical schools to free themselves of industry influence."[32]

My own view with regard to conflicts of interest in medicine and the influence of the pharmaceutical industry is to favor a divestment strategy over a management strategy. The latter, by far the more popular in today's literature, assumes that medicine's entanglements with the pharmaceutical industry are either inevitable, or else bring so many benefits that it would be ridiculous to try to dispense with them. All we can do, therefore, is *manage* the conflicts of interest. The favorite management strategy for conflicts of interest is disclosure. If the speaker at the CME program simply tells the audience the list of the 15 drug companies for whom he is a paid speaker or consultant, he may then proceed with impunity.[33]

Elliott is quite correct when he labels disclosure a fraud as a "solution" to the ethical problem of conflict of interest. The real problem, he notes, is not secrecy but power.[34] If the physician discloses to the patient that he takes a variety of freebies from the drug industry and therefore naturally feels beholden to them, but the patient has no other place to go to get medical care, then the disclosure has hardly helped matters. The divestment strategy, in contrast to the management strategy, argues that medicine must disengage from most *fiscal* entanglements with the pharmaceutical industry.[35]

In response to criticisms that its earlier rules focusing on disclosure had been inadequate to remove substantial industry bias from its programs, the ACCME issued new guidelines in 2004.[36] These new guidelines are intended to be more strict in creating firewalls between funding and program planning, and in restricting speakers who receive substantial industry support from speaking at CME conferences and especially from using CME materials prepared by industry. According to my schema, the new guidelines still represent a management strategy rather than a true divestment strategy, albeit with more stringent safeguards.

The staff of the U.S. Senate Finance Committee issued a report on the ACCME in April 2007. The report questioned whether the new ACCME regulations could be taken seriously when the organization's procedures guaranteed that nine years might elapse between the occurrence of a gross rules violation and the sponsoring organization's eventual loss of accreditation.

The Washington Legal Foundation, which receives a good deal of funding from the pharmaceutical industry, had been prepared to launch a legal challenge to the ACCME guidelines, as part of its general defense of "free commercial speech."[37] However, the ACCME was allowed to put its guidelines into place, and the industry appears to have acquiesced to these new standards.

The industry may have accepted the ACCME guidelines partly because of a threat from a different quarter. In 2003, the Office of the Inspector General, Department of Health and Human Services issued a report on the anti-kickback implications of relationships between medicine and the pharmaceutical industry. The report strongly suggested that companies might run afoul of the federal anti-kickback law if they failed to separate their CME funding from their sales and marketing operations.[38] Evidence to date suggests that the threat of anti-kickback prosecution has increased the industry's willingness to work within the new, stricter ACCME guidelines.[39] It might therefore seem prudent to give the new guidelines several additional years to work before calling for a more radical "divestment" solution.

Some early indicators, however, are not promising. The staff of the U.S. Senate Finance Committee issued a report on the ACCME in April 2007. The

report questioned whether the new ACCME regulations could be taken seriously when the organization's procedures guaranteed that nine years might elapse between the occurrence of a gross rules violation and the sponsoring organization's eventual loss of accreditation.[40] In August 2007, the ACCME issued "policy updates," which do little more than restate its previous policies. The one area of apparent change is the demand that "commercial interests" that currently own firms that grant CME credit must divest within the following two years.[41] (According to ACCME definitions, a drug company is a commercial interest, but a MECC, which may receive more than 80 percent of its funding from drug companies, is not.) Critics of the medicine/industry relationship take these developments as a sign that little has changed.[42]

In Defense of a Management Approach

To summarize my argument thus far, I have labeled the new ACCME guidelines as a further, though stricter management approach. If they prove not to be effective in limiting industry influence over CME content and delivery — and I have noted a few preliminary reasons to be skeptical — then I would advocate moving even farther toward a divestment solution. But perhaps, in my rush to advocate radical action so as to deal with perceived ethical threats, I have underestimated the virtues of the management approach. What more can be said in defense of a management approach to CME?[43]

The defender of the management strategy might object that my "rationalization" charge against current defenses of industry sponsorship is more rhetoric than substance. Does rejecting the suggestion, "It's not marketing, it's education" entail that the content of a sponsored CME program is *all* marketing with *no* education? If we look askance at the claim, "Scientifically trained physicians can be trusted to distinguish quality information from commercial hype," does that imply that physicians have *no skills whatsoever* in assessing the quality of the evidence being presented? By contrast, it would seem reasonable to demand a more nuanced accounting. CME programs sponsored by drug companies may contain marketing pitches, but they may also contain a good deal of useful information. Physicians may have difficulty at times identifying subtle marketing influence, but they ought over the long haul to be able to distinguish what evidence makes the most sense, most of the time. The appropriate response would therefore not condemn commercial sponsorship *in toto*. A much finer-grained approach is needed to sift through the content, identify the specific areas of concern, and work to contain or to eliminate those problems.

The reason to adopt the finer-grained approach is magnified by the practical realization that currently, the pharmaceutical industry foots the bill for at least half of the total CME budget in the U.S. These figures suggest a dismal prospect if that level of support were suddenly to disappear. CME may be a very imperfect means of educating practitioners to new medical information, but it is not at all clear what would replace this modality if half of it were to go away. The lag time between new discoveries and their practical adoption, already of concern to quality experts, would probably be worsened.

As attractive as this more moderate posture sounds on first hearing, I will persist in referring to these views ultimately as rationalizations. First, it is important to recall that dire predictions as to what would happen to CME if industry funding were to be reduced or eliminated assume no changes in the level of CME expenditure. It assumes that CME programs must be held in the same fancy hotels and other facilities now used, and must feature the same lavish spreads of food and drink. It assumes that speakers will continue to require the current level of honoraria (as well as, in some cases, first class airfare and luxury hotel accommodations), instead of (as Elliott has sensibly suggested above) being willing to reduce their fees in the name of their professional responsibility to educate their peers. In short, predictions of disaster are disingenuous when one has not even begun to explore the sorts of reasonable economies that could perhaps reduce the present cost of CME programs.

When we look closer at the arguments offered in favor of maintaining the status quo with only minor adjustments, we come to see the general nature of the rationalization process that obscures the serious ethical issues at the interface between medicine and industry.[44] Physicians face a tension between a comfortable, habitual pattern of behavior (accepting certain benefits bankrolled for them by the drug industry) and an emerging understanding of an ethical duty (re-establishing trustworthiness in the face of an increasingly worrisome conflict of interest). An ethically responsible way to address this tension would be first to take the ethical issues seriously; then to ask whether there are practical alternatives to these comfortable, habitual practices; and lastly only defend the practices if the proposed alternatives all turn out after careful investigation to be inadequate. The way of rationalization, by contrast, starts with the assumption that the comfortable, habitual behaviors must be maintained no matter what, and then seeks reasons why the ethical problems are illusory or the patterns of behavior actually have none of the unfortunate consequences attributed to them.

The other comfortable assumption that goes unchallenged, according to this more "moderate" position, is the desirability of getting information on new therapeutic advances to physicians as quickly as possible. If, in the case of rofecoxib (Vioxx) and its cousins in the COX-2 class of anti-inflammatory medications, physicians had instead been slower to become informed about the purported therapeutic advance, then 140,000 people in the U.S. might have been spared from serious coronary heart disease.[45] It may seem unfair to discuss a drug that was introduced with great fanfare, but then removed from the market due to unanticipated adverse reactions. Yet a careful review of drugs introduced into the market in recent years will show that Vioxx has a distressing number of close relatives — drugs whose efficacy was exaggerated or whose averse reactions were minimized (or both) by industry marketing campaigns. Some novel medical information should ideally be disseminated quickly; other novel information ought if anything to be held back for more careful analysis before it is applied at the bedside. The current method of educating physicians — CME, visits from detail representatives, and advertising — does a very good job of disseminating a new discovery when the result is the increased sale of a more expensive drug. By contrast, a new discovery that a cheap generic drug is superior to expensive competitors for a common disease such as hypertension, or that lifestyle change is superior to drugs for the prevention of Type II diabetes, would be disseminated very slowly if at all when commercial sponsorship dictates the rate of information transmission. Our highest ethical priority ought to be to seek an alternative approach to education, not reasons to keep the current system in place.

Finally, consider the effect of another unexamined assumption — that those physicians and scientists who have the closest financial ties to the industry are *therefore* the most "expert" and ought to be highly sought after as CME presenters. What sort of message does this assumption send to young investigators just beginning a career in medical research? The ethical concerns over conflict of interest and trustworthiness suggest that they ought to be encouraged to avoid financial ties with pharmaceutical companies. Instead, the current CME system presents to them as role models those physician-scientists who are most eager to jump onto the industry gravy train, and who then, at least in venues such as Torrey's Berlin Congress, appear to be the most eagerly courted CME speakers (as well as the ones best positioned to land lucrative industry-funded research grants). Accepting the status quo virtually guarantees yet another generation of conflicted scientists generating commercially biased data, which can then be fed to practitioners by conflicted CME speakers.

Conclusion

The CME issue seems to me to strike at the very core of medicine's claims to be a *profession*, and to adhere to a professional ethic. One of the defining characteristics of a profession is its own collective responsibility to assure the adequate education of its members. In a rapidly advancing field like medicine, this means that ongoing continuing education is a professional necessity.

American physicians as a group are wealthy enough to pay for their own CME programs. They have a clear choice. They can choose to pay very little, and have bare-bones conferences over coffee in a meeting room of the local hospital, with nearby experts agreeing to provide the presentations at no or low cost as a matter of professional obligation. Or they can choose to meet in more luxurious surroundings, bring speakers from a greater distance, and pay a correspondingly higher registration fee.

Instead of these choices that are fully consistent with professional integrity, American physicians have accepted the notion that they are entitled to Lexus-level CME programs while paying Hyundai prices. The pharmaceutical industry has been very happy to feed this sense of entitlement by bankrolling the difference. Physicians and their industry handlers have then jointly offered up an array of rationalizations to make all of this seem completely normal and acceptable: "It's education, not marketing," "I'm a trained scientist — if they try to slip in bias or spin, I know right away," "So long as the speaker discloses any conflicts of interest, everything is kosher."

I am not sure which is the more severe condemnation of our professionalism — our willingness to be bought; or our willingness to rationalize and deny, to make it seem as if we are not being bought. In any event, if there is a part of medicine that ought to be as free from industry influence as possible, it is our own education.[46]

Note

This article was originally presented at the Fourteenth Annual Thomas A. Pitts Memorial Lectureship in medical ethics at the Medical University of South Carolina, Charleston on September 7-8, 2007.

References

1. D. May, "Selling Drugs by 'Educating' Physicians," *Journal of Medical Education* 36, no. 1 (1961): 1-23; M. Silverman and P. R. Lee, *Pills, Profits, and Politics* (Berkeley: University of California Press, 1974).
2. H. Brody, *Hooked: Ethics, the Medical Profession, and the Pharmaceutical Industry* (Lanham, MD: Rowman and Littlefield, 2007); M. Angell, *The Truth about the Drug Companies: How They Deceive Us and What to Do about It* (New York: Random House, 2004); J. P. Kassirer, *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health* (New York: Oxford University Press, 2005); J. Avorn, *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs* (New York: Knopf, 2004); J. Abramson, *Overdo$ed America: The Broken Promise of American Medicine* (New York: HarperCollins, 2004); L. J. Weber, *Profits Before People? Ethical Standards and the Marketing of Prescription Drugs* (Bloomington: Indiana University Press, 2006).
3. *ACCME Annual Data Report 2006*, *available at* <http://www.accme.org/dir_docs/doc_upload/f51ed7d8-e3b4-479a-a9d8-57b6efedc27a_uploaddocument.pdf> (last visited May 20, 2009).
4. One defense of current industry involvement was authored by the then-president of the Pharmaceutical Research and Manufacturers of America (PhRMA); A. F. Holmer, "Industry Strongly Supports Continuing Medical Education," *JAMA* 285, no. 15 (2001): 2012-2014. For the claim that physicians with the closest ties to industry are therefore the best-informed presenters of CME, see brief of the Washington Legal Foundation opposing new ACCME guidelines (*infra* note 37 and accompanying text).
5. E. F. Torrey, "The Going Rate on Shrinks: Big Pharma and the Buying of Psychiatry," *American Prospect*, July 15, 2002, at 15-16.
6. *Id.*, at 15.
7. *Id.*, at 16.
8. G. Harris, "Psychiatrists Top List in Drug Maker Gifts," *New York Times*, June 27, 2007, at A14.
9. See AAFP, "Assembly Partners," *available at* <http://www.aafp.org/online/en/home/cme/aafpcourses/conferences/assembly.html> (last visited May 20, 2009). Note that as a matter of course, Web pages for the annual scientific assembly are taken down within a few months after completion of the meeting, to be replaced later on by advance announcements for the next year's meeting; the URL may change from one year to the next.
10. AAFP, "Exhibitor Information," *available at* <http://www.aafp.org/online/en/home/cme/aafpcourses/conferences/assembly/exhibits.html> (last visited May 20, 2009). Note that this quote was taken from the link posted in 2007.
11. AAFP, "Attendee Demographics," *available at* <http://www.aafp.org/online/en/home/cme/aafpcourses/conferences/assembly/exhibits/interested/benefits/demographics.html>; "Attendee Buying Power," *available at* <http://www.aafp.org/online/en/home/cme/aafpcourses/conferences/assembly/exhibits/interested/benefits/buying.html> (last visited May 20, 2009).
12. AAFP, "Marketing Opportunities," *available at* <http://www.aafp.org/online/en/home/cme/aafpcourses/conferences/assembly/exhibits/current/marketing.html> (last visited May 20, 2009).
13. For a description of the organization, No Free Lunch, see <http://www.nofreelunch.org> (last visited May 20, 2009); for news reports of the attempts to erect booths at meetings, see <http://nofreelunch.org/news.htm> (last visited May 20, 2009).
14. See Brody, *supra* note 2, at 23-50.
15. E. L. Erde, "Conflicts of Interest in Medicine: A Philosophical and Ethical Morphology," in R. G. Speece, D. S. Shimm, and A. E. Buchanan, eds., *Conflicts of Interest in Clinical Practice and Research* (New York: Oxford University Press, 1996): at 12-41.
16. *Id.*
17. R. A. Epstein, "Conflicts of Interest in Health Care: Who Guards the Guardians?" *Perspectives in Biology and Medicine* 50, no. 1 (2007): 72-88.
18. I argue elsewhere that this tendency toward mutual reinforcement of rationalization can be traced back to deliberate advertising strategies adopted by the industry as far back as the 1950s; see Brody, *supra* note 2, at 146-147. An early perceptive statement of this problem follows: "The degree to which the profession, mainly composed of honourable and decent people, can practice such self deceit [that is, the view that they can accept gifts and benefits from industry while their judgment remains untouched] is quite extraordinary." See M. D. Rawlins, "Doctors and the Drug Makers," *The Lancet* 2, no. 8397 (1984): 814. A recent study on the extent to which this rationalization pervades physicians' thinking is S. Chimonas, T. A. Brennan, and D. J. Rothman, "Physicians and Drug Representatives: Exploring the Dynamics of the Relationship," *Journal of General Internal Medicine* 22, no. 2 (2007): 184-190.
19. See generally Brody, *supra* note 2. An excellent source of evidence-based information about the influence of pharmaceutical marketing is <http://www.drugpromo.info> (last visited August 17, 2007).
20. L. Walker, "ROI for Meetings Beats Detailing and DTC," Medical Meetings website, July 1, 2001, *available at* <http://meetingsnet.com/medicalmeetings/ar/meetings_roi_meetings_beats/index.html> (last visited May 20, 2009). The same figure was repeated in a more recent press account; see M. Healy, "In Short, Marketing Works," *Los Angeles Times*, August 6, 2007.
21. See *ACCME Annual Report 2006*, *supra* note 3.
22. *ACCME Annual Report 2004*, *available at* <http://www.accme.org/dir_docs/doc_upload/2130a818-1c9f-400b-9d54-56b3f8f9a2f6_uploaddocument.pdf> (last visited May 20, 2009). More precisely, this portion of commercial support came from "firms that manufacture products regulated by the FDA," that is, pharmaceutical, biologic/vaccine, and biotechnology companies.
23. See Brody, *supra* note 2, at 204-205. These figures represent 2003, the latest year of data available at the time that the detailed breakdown was carried out.
24. A. S. Relman, "Separating Continuing Medical Education from Pharmaceutical Marketing," *JAMA* 285, no. 15 (2001): 2009-2012.
25. C. Elliott, "Pharma Goes to the Laundry: Public Relations and the Business of Medical Education," *Hastings Center Report* 34, no. 5 (September-October 2004): 18-23.
26. See Brody, *supra* note 2, at 215-220.
27. For a review of the evidence that industry-sponsored trials are often biased, and that the industry often suppresses trial data that are unfavorable to sales, see Brody, *supra* note 2, at 97-138. A research trial sponsored by the industry is more than four times more likely than a neutral trial to reach conclusions favorable to sales of the drug. See J. Lexchin, L. A. Bero, B. Djulbegovik, and O. Clark, "Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review," *BMJ* 326, no. 7400 (2003): 1167-1170.
28. See Elliott, *supra* note 25, at 21. The reference to the academic researcher signing the article produced by the MECC refers to the practice of ghostwriting, in which a drug firm has an article written it its own specifications to transmit its preferred commercial message, an academic physician attaches his name as sole author (for a fee usually of around $1000), and the article is submitted to a medical journal with no evidence of industry authorship. For more on ghostwriting, see Brody, *supra* note 2, at 130-135.
29. M. A. Bowman, "The Impact of Drug Company Funding on the Content of Continuing Medical Education," *Mobius* 6, no. 1 (1986): 66-69; M. A. Bowman and D. L. Pearle, "Changes in Drug Prescribing Patterns Related to Commercial Company Funding of Continuing Medical Education," *Journal of Continuing Education in the Health Professions* 8, no. 1 (1988):

13-20. See also J. Lexchin, "Interactions between Physicians and the Pharmaceutical Industry: What Does the Literature Say?" *Canadian Medical Association Journal* 149, no. 10 (1993): 1401-1407; M. E. Dieperink and L. Drogemuller, "Industry-Sponsored Grand Rounds and Prescribing Behavior," *JAMA* 285, no. 11 (2001): 1443-1444; and R. W. Spingarn, J. A. Berlin, and B. L. Strom, "When Pharmaceutical Manufacturers' Employees Present Grand Rounds, What Do Residents Remember?" *Academic Medicine* 71, no. 1 (1996): 86-88.

30. F. S. Sierles, A. C. Brodkey, and L. M. Cleary et al., "Medical Students' Exposure to and Attitudes about Drug Company Interactions: A National Survey," *JAMA* 294, no. 9 (2005): 1034-1042.
31. See Elliott, *supra* note 25, at 22.
32. D. Bok, *Universities in the Marketplace: The Commercialization of Higher Education* (Princeton: Princeton University Press, 2003): at 206.
33. See Brody, *supra* note 2, at 287-298.
34. See Elliott, *supra* note 25, at 22.
35. See Brody, *supra* note 2, at 287-298. Also see A. Schafer, "Biomedical Conflicts of Interest: A Defence of the Sequestration Thesis," *Journal of Medical Ethics* 30, no. 1 (2004): 8-24.
36. ACCME, *ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities*, *available at* <http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf> (last visited May 20, 2009).
37. See Washington Legal Foundation Press Release, *available at* <http://www.wlf.org/upload/1-30-03ACCME.pdf> (last visited May 20, 2009). When I last searched, the actual comment to the ACCME had been removed from the WLF Web site. The issue of freedom of commercial speech is too complex to be adequately addressed here. See, for example, P. Chen, "Education or Promotion? Industry-Sponsored Continuing Medical education (CME) as a Center for the Core/Commercial Speech Debate," *Food and Drug Law Journal* 58 (2003): 473-509. I was pleased to read in Notes on the subject a proposed legal approach which seems to me to match well the ethical principles involved — that the responsibility of the government to regulate commercial speech increases to the extent that the commercial entity owns such a monopoly of resources that it effectively prevents dissenting points of view from being heard. See "Notes: Dissent, Corporate Cartels, and the Commercial Speech Doctrine," *Harvard Law Review* 120 (2007): 1892-1913.
38. Office of the Inspector General, "Compliance Program Guidelines for Pharmaceutical Manufacturers," Department of Health and Human Services, Washington, D.C., April 2003. Federal law is implicated, according to the report, so long as any physician in the CME audience is ordering prescriptions that are reimbursed by federal programs such as Medicare or Medicaid. It is argued that a company violates anti-kickback laws if it provides anything of value to the CME provider, in the expectation that in exchange, it will receive an increase in sales. The report basically describes an auditing strategy, and reassures companies that they will pass any audit so long as they maintain a clear organizational barrier between the part of the company that provides CME funding and the part of the company involved in advertising and marketing.
39. See Brody, *supra* note 2, at 209-211 for this argument.
40. Committee on Finance, U.S. Senate, "Committee Staff Report to the Chairman and Ranking Member: Use of Educational Grants by Pharmaceutical Manufacturers," April 2007, at 2, *available at* <http://www.finance.senate.gov/press/Bpress/2007press/prb042507a.pdf> (last visited May 20, 2009).
41. ACCME, *ACCME Policy Updates, August 2007*, at 10, *available at* <http://www.accme.org/dir_docs/doc_upload/31835cb6-55ea-47cb-919f-7c28787b1917_uploaddocument.pdf> (last visited May 20, 2009).
42. For an example of such critical commentary, see <http://carlatpsychiatry.blogspot.com/2007/08/accmes-new-policies-translated.html> (last visited May 20, 2009).
43. I am indebted here to an anonymous reviewer of an earlier draft of this paper for suggesting counter-arguments to my position as expressed above.
44. A. Schafer, "Biomedical Conflicts of Interest: A Defence of the Sequestration Thesis — Learning from the Cases of Nancy Olivieri and David Healy," *Journal of Medical Ethics* 30, no. 1 (2004): 8-24. Schafer uses the term "sequestration thesis" to refer to the position that in the text above I call the "divestment strategy"; see Brody, *supra* note 2, at 287-298.
45. On the problems with Vioxx and related COX-2 drugs, see Brody, *supra* note 2, at 106-113.
46. As this paper was being edited for publication, the Institute of Medicine released its report on conflicts of interest, which strongly endorsed a divestment strategy for CME, proposing that all industry funding be eliminated following a two-year transitional planning period: B. Lo and M. J. Field, eds., *Conflicts of Iinterest in Medical Research, Education, and Practice* (Washington, D. C.: National Academies Press, 2009).