A Perspective on Commercial Relationships Between Ophthalmology and Industry

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Relationships between physicians and industry including pharmaceutical companies and device manufacturers are being closely scrutinized by the public and the media. These companies can contribute beneficially to patient outcomes by supporting research that improves eye care. However, ethical issues may arise that affect practicing ophthalmologists, researchers, academic faculty, and ophthalmologic organizations. These topics were discussed at a symposium sponsored by the American Ophthalmological Society in May 2008. After this meeting, the council of the society developed this perspective to clarify some of the issues at the interface of industry and ophthalmology. The perspective is intended to provide some guidance to physicians, researchers, and professional societies and to enhance further dialogue.

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Ethical issues regularly arise in relationships between ophthalmologists and industry. The following vignettes provide examples of such ethical dilemmas:

1. A prominent ophthalmic specialist consults for many companies in his/her field and receives handsome compensation for his/her time. In addition, he/she receives substantial support for social events and continuing education courses at his/her institution. His/her personal research occasionally receives industry support. He/she believes that this involvement does not affect his/her opinions, his/her patient care, or the content of his/her lectures. He/she believes he/she is not hesitant to speak his/her mind about the sponsor’s products.

2. After departmental grand rounds, lunch is provided for residents at a prestigious academic institution. Lunch is paid for, almost invariably, by one particular pharmaceutical company, with its representative interacting with the residents on a first-name basis.

3. A prominent clinician investigator gives a presentation at a national meeting using slides provided by a drug company with its logo on every slide. He/she was not a key figure in the study presented; his/hers was one of many centers in the study. He/she does not have access to the study database. A favorable interpretation of the data is presented.

4. A private practitioner in a small rural office allows a drug representative to buy lunch for his/her staff and meets with this drug representative once a month to learn the latest about the company’s products.

These are a few of the multiple interactions that occur daily between ophthalmologists, ophthalmic researchers, and pharmaceutical and device manufacturing company representatives. In some circumstances, the distinctions between right and wrong, or ethical and unethical, are clear; in other circumstances, they are more difficult to discern. In May 2008, the American Ophthalmological Society sponsored a symposium to discuss physician

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and researcher interactions with industry. We hoped to clarify these issues and to assist clinicians, researchers, teachers, and organizations in deciding which behaviors are appropriate for our profession. A digital video of the 2008 Knapp symposium is available at the society’s Website (http://www.aosonline.org/annualmeeting/knapp08_video.html). This perspective was stimulated by this symposium and is presented to enhance these discussions.

What is meant by being a professional, and what is professional behavior? Ophthalmology is part of the profession of medicine; ophthalmologists have a duty to do what is in the patient’s best interest. Another important covenant exists between the physician and society; physicians must consider society’s interests. We have an individual and collective duty to uphold these promises of our profession. A business does not have a promise to patients to do what is in their best interest or collectively in the best interest of society; businesses have a fiduciary responsibility to maximize profit for their shareholders.

It is important to understand why society has decided to allow medicine to function with special privileges. As with circumstances when individuals seek spiritual or legal help, medicine deals with the vulnerable. For centuries, it has been presumed that it would be in the best interest of society if physicians could live up to a professional promise and be trusted to perform ethically, with the patient as the primary consideration.

A physician becomes a professional only after extensive training that has a substantial intellectual curriculum with the objective of benefits to the patient. A professional takes oaths (promises) to behave in a specific manner that is respectful of patients and the profession. This includes commitments that are self-effacing and may require sacrifices. To quote from the principle of ethics of the Code of Ethics of the American Academy of Ophthalmology: “Ophthalmologic service must be provided with compassion, respect for human dignity, honesty and integrity. Competence involves technical ability, cognitive knowledge and ethical concern for the patients.” These statements are inspirational and do not have enforcement mechanisms.

The American Academy of Ophthalmology Code of Ethics does have specific rules that are enforceable, and failure to abide by these rules can result in consequences varying from censure to suspension of membership. For example, “communications to the public must be accurate. They must not convey false, untrue, deceptive, or misleading information. Also, ‘A conflict of interest exists when professional judgment concerning the well-being of a patient has a reasonable chance of being influenced by economic interest in, commitment to, or benefit from professionally related commercial enterprises.’ These are some of the principles ophthalmologists agree to uphold to maintain our promise and, thus, our social status as professionals.

To preserve our professionalism, it is clear that changes must be made in ophthalmologist-industry relationships. Some argue that complete divestiture of industry support for individual ophthalmologists and their organizations is the only righteous path. However, we do not live in an idealist’s vacuum. There are clearly advantages to maintaining communication and collaboration with industry that result in improved patient care. However, relationships that cede to industry the research and continuing medical education (CME) agendas should be averted. In short, we must modify our dealings to enable ophthalmologists to regain and retain the public trust.

This perspective discusses physician or researcher interaction with industry. This interaction is addressed at 5 levels: practitioner, researcher, academic physician, teacher (CME), and professional organizations. We hope this perspective will provide some guidance to physician and organizational behavior and will encourage further discussions.

**PRACTICING OPHTHALMOLOGISTS AND INDUSTRY INTERACTIONS**

The practicing ophthalmologist, whether in academia or private practice, makes therapeutic choices daily for the benefit of his or her patients. The ophthalmologist’s duty is to the patient when making those choices. If that duty is compromised because of the ophthalmologist’s relationship with industry, the ophthalmologist is betraying, at least in part, the trust implicit in the physician-patient relationship. Examples of compromised duty would include prescription of medication or implantation of a device when an alternate choice would have been more suitable to the patient’s best interest. *Compromised duty* is not synonymous with bias, defined in this context as a general preference toward a therapeutic choice; that is, a bias toward industry or its products does not create the ipso facto presumption of compromised duty to the patient. However, a compromise of duty to the patient is a potential consequence of bias that must be consciously averted. Bias is not proportional to the amount of a financial relationship; even seemingly trivial amounts can create strong biases.

In presentations by professionals to other professionals, disclosure of conflicts of interest is a commonly used remedy for potential bias. If the listener knows that a conflict of interest exists, the veracity of the speaker may be questioned by the listener. However, disclosure is an even more complex issue in the context of a physician-patient relationship. Patients are generally inexperienced in how to deal with disclosed conflicts and may simply discount them, expecting that the ophthalmologist is acting in their best interests despite the conflict. Nevertheless, patients have consistently voiced their right to know about relevant financial relationships their health care providers have. Several states have enacted laws requiring the reporting for public scrutiny of all physician income from industry exceeding a threshold level as low as $25. If an ophthalmologist is unwilling to be fully transparent about such relationships, disclosing them for all parties to see, the presumption is that there is something to hide.

Most academic physicians practice in institutions that have rules governing faculty behavior, usually addressing research interactions with industry but often specifically concerning relationships with sales and marketing representatives. Private practitioners, especially those not affiliated with large groups, have virtually no external supervision of their industry relationships other than guide-
lines from Pharmaceutical Research and Manufacturers of America and are forced to seek their own path. In the absence of rules, a degree of personal vigilance based on a set of principles is required.

In the next section, we discuss common forms of interactions between practicing ophthalmologists and industry. While it is true that banning these relationships entirely would eliminate potential bias, it would also eliminate whatever value such relationships have for the ophthalmologist, patients, and society as a whole. There are ethical challenges inherent in each type of relationship, and we discuss a variety of approaches to them that are intended to mitigate but not necessarily eliminate the bias they may create.

**DRUG REPRESENTATIVES, SAMPLES, AND GIFTS**

All practicing ophthalmologists will encounter drug representatives. They tend to be attractive, personable individuals whose success depends on establishing relationships with individual physicians to convey information about the company’s products. Drug representatives are trained to be knowledgeable about their products so that they do not go against US Food and Drug Administration regulations. Typically, the information, samples, and gifts they bring to the encounter are about the company’s new drugs that still have patent protection. The role of the drug representative is to acknowledge that the ophthalmologist already knows a great deal about the product and to solicit the ophthalmologist’s opinion about the use of the drug in a certain category of patient. Information is then provided as a response to the ophthalmologist’s opinion. The intent is to influence the future behavior of the ophthalmologist by implying that a new medicine might be better for patients than the generic alternative or a competitor’s product.

The personal relationship with the ophthalmologist sought by the drug representative is capable of producing a bias toward products. At the least, maintaining a purely professional relationship rather than a friendship helps to mitigate that source of bias (eg, by requiring an appointment). Another professional choice would be to refuse offers of food or other gifts accompanying a sales visit. Most drug representatives are respectful of the limits the ophthalmologist places on their relationship for fear of losing contact altogether.

Free drug samples are intended to be used as “starter” supplies to determine whether adverse effects develop before the patient is required to purchase the medicine. Most ophthalmologists also give them to indigent patients and use them to provide patients with enough medication until the pharmacy benefit plan will allow a refill. However, noble the intention, most drug samples do not go to the indigent. Leaving free samples, together with the requirement that the ophthalmologist sign for them, ensures that the drug representative will have regular contact with the physician. Some institutions require that their pharmacies distribute free samples to discourage their use for purposes other than indigent care, given their experience that free samples might encourage the use of more expensive medicines rather than generic alternatives. Other physicians do not accept free samples of medications when a generic substitute (not necessarily an equivalent) exists, thus averting the temptation to provide samples of and later prescribe more expensive medications.

Inexpensive gifts including pens, notepads, and patient education items, all prominently featuring drug logos, are another part of the drug representatives’ resources. However small these gifts may seem, they trigger the expectation of reciprocation. Considerable research has shown that the receiver of gifts is predisposed to return the favor, think more kindly of the giver, or both. Yet, many physicians honestly believe they are immune from these reciprocal obligations while being skeptical that their colleagues are influenced. One can ask whether the value of these small gifts is great enough to risk the consequences of their acceptance. Quality patient education alternatives to those distributed by drug representatives are freely available on the Internet.

**DINNERS AND SPEAKERS’ BUREAUS**

Practicing ophthalmologists are often invited to industry-sponsored events that offer CME units. The venue is usually attractive. Speakers are selected by industry from their speakers’ bureau. Typically, “thought leaders” from academic centers are selected and paid to deliver these lectures. Often an intermediate for-profit entity (a medical education and communication company [MECC]) is hired by industry to officially sponsor such events. These MECCs are not bound by US Food and Drug Administration rules and guidelines of the Pharmaceutical Research and Manufacturers of America and, thus, speakers are less encumbered by rules regulating issues such as recommended dosages or off-label use of medications. Direct solicitation to host CME events are made by MECCs to drug companies with a clear message that an increase in product use is a desired outcome. A professional response to such CME invitations warrants an objective assessment of why such events are offered and whether evidence-based education can be received.

For CME dinners and other company-sponsored events, the experts are often members of the company’s speakers’ bureau. The invitation to speak is inviting, particularly when a career is just beginning. But at what cost? Speakers intuitively recognize that their tenure on the speakers’ bureau is contingent on their not saying anything negative about the company’s products, though such a contingency is not stated. Local experts may depend on the exposure during these dinners to expand their referral base and become better known in the local ophthalmic community. Recently, because of scrutiny by the US Food and Drug Administration, speakers have been required to use approved slides from the company or have their own slides reviewed by a third party weeks in advance of an event. Many speakers have withdrawn from speakers’ bureaus because these rules remove content control from the speaker, where it should always reside. Others do not participate because they believe it is inappropriate for ophthalmologists to participate in product marketing.

**MEDICAL ADVISORY BOARDS**

Medical advisory boards are portrayed by industry as representing the most expert of experts. Trips to vacation
destinations are typically offered. A detailed nondisclosure agreement is required because proprietary information is imparted. In reality, the presentations emphasize studies favorable to the company's products, and the feedback requested is to help the company understand professional objections to the product(s) so that the drug representatives can more effectively offer rebuttals when making sales calls. Although the meetings are supposed to be of scientific merit, marketing personnel are often present. Such advisory boards are distinct from those composed of scientists, whose expertise is needed for product development and which create no conflict of duty to the patient. However, advisory boards composed of clinicians whose presence is wanted primarily for product marketing create serious conflicts of duty.

CLINICAL STUDIES SPONSORED BY INDUSTRY

One commonly practiced shortcut for phase 3 drug studies is to use clinicians in private practice because the scrutiny of private institutional review boards is less time-consuming than those of traditional academic institutional review boards, and studies can be concluded sooner. Typically, the payment is per patient enrolled, a contract rather than a grant, and the payment is always more than the costs incurred. It is common for incentives to be aligned to increase enrollment, with less than rigid inclusion criteria. Further, phase 4 “switch” studies result in a patient's medication being switched to the company's medication. In any case, these data are controlled by the company, and the practicing ophthalmologist (or for that matter, the ophthalmologist) usually has little say in its analysis or later publication. Participation in such studies has an “opportunity cost,” taking time and personnel away from investigator-initiated research.

CONCLUSIONS ABOUT PRACTICING OPHTHALMOLOGISTS AND INDUSTRY INTERACTIONS

Manifestation of professional behavior is ultimately an individual responsibility. While individual behavior may be constrained by laws, rules, or guidelines, such constraints are always subject to bypass by clever companies and ophthalmologists. Only a personal commitment to professionalism by each ophthalmologist is likely to be effective. The tendency to deny that ophthalmologist-industry relationships create real bias must be confronted. Ophthalmologists must also consciously reject the notion that we are entitled by virtue of our long training and hard work to gifts and dinners and to CME of questionable scientific merit. Only then will it be possible to identify problematic situations so they may be averted or mitigated. Any strategy that places an intermediary between the company and the ophthalmologist, such as an unrestricted grant contributed to a pool, is a desirable mitigation. Dialogue with industry and its representatives can lead to mutual understanding of ophthalmologists’ need to retain professionalism and industry's need to develop and sell its products, and, it is hoped, to craft ways in which both can achieve their objectives.

RESEARCHERS AND INDUSTRY INTERACTIONS

A primary goal of research is to create new knowledge that benefits society. In health care, the goal is to improve health. Basic research may lead to “breakthrough” drugs or devices that transform the health of society. Clinical research may lead to improved treatments of diseases or improved procedures. Industry-sponsored research over the years has greatly benefited patients. Pharmaceutical manufacturers, for example, have had a key role in the discovery and development of important drugs such as the statins. In ophthalmology, the development of ranibizumab to treat ocular neovascularization comes to mind. Industry-sponsored research, whether basic or clinical, has the additional goal of increasing profits for the stockholders or owners of a private corporation. Thus, industry may preferentially look for profitable research and products such as additional topical β-blockers and prostaglandins that offer financially lucrative markets, as opposed to research in which profit is less certain. One concern is that industry-sponsored research too often leads to “me-too” drugs and devices rather than riskier breakthrough products. A relationship with industry may create a conflict of purpose. This is not to say that academic-industry relationships are bad, just that the fiduciary responsibilities are different and that each party must understand the motivations and goals of the other.

Another concern is the diversion of research personnel and resources to industry-sponsored research from other research endeavors. The increase in patents and intellectual property licensing agreements has been explosive. The responsibility of the physician-researcher is to identify potential conflicts of interest in industry-sponsored research and to act responsibly; that is, the physician must honor the professional promise to act in the best interest of patients. That responsibility should be at the foundation of any effort to facilitate a relationship with industry. This responsibility extends to academic departments and to academic medical centers in which research is part of the mission. That mission should include fidelity to the promises of the profession. If research resources are used to move forward the commercialization of discoveries more than to create the knowledge that leads to new discoveries, it may result in universities being perceived as agents of industry and not of society.

Specific areas of concern include physician participation in industry-sponsored research and clinical trials. The information that is created must be available to the researcher and, hence, to the patient and the public. Recent events have highlighted the deleterious results when information is withheld, suppressed, or manipulated by corporate sponsors. The concept that the conflicts of interest that emerge from academic-industry relationships can always be managed is uncertain, and its foundation requires critical reflection. The methods used to create new knowledge benefit from open access and sharing rather than secrecy. Society may not be served if physicians, academic departments, and universities are not the stewards of knowledge and cede that duty to industry. Thus, there is need for freedom for researchers to openly and completely discuss the results of research.

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and to have in place independent data and safety monitoring and other elements of responsible research that protect patients and researchers. Registration of clinical trials and reporting of negative results are other critical issues if physicians are to function ethically while collaborating with industry.

CONCLUSIONS ABOUT RESEARCHERS AND INDUSTRY INTERACTIONS

Industry-sponsored research can benefit society and patients but requires awareness of the conflicting goals of the sponsor and the researcher. Principles of conflict management include awareness of the opportunity costs of such research, the need for respect of the physician’s professional commitment to the patient, and the requirement for transparency of the research results.

ACADEMICS AND INDUSTRY INTERACTIONS

Those who teach medicine are part of not 1, but 2 respected and learned professions: medicine and academia. There is a societal need for health from the perspective of medicine and for the expansion and sharing of knowledge from the perspective of teaching. Virtually all ophthalmologists teach in some capacity, whether it is to their staff, their patients, their colleagues, or their future replacements. Herein, the term “academic environment” applies to those involved in the teaching of ophthalmology residents and fellows. Though the obvious prototype is that of a medical school-affiliated university program, others who teach within less traditional models are included.

Contemporary pressures on teaching in academia include lack of resources, pressure of time, and rules and regulations that govern content. Several critical elements are necessary for effective education. First, the integrity, or moral identity, of the teacher must be unimpeachable. Students know when a teacher cares. Second, a teacher must speak with authority, with expertise commensurate with the material being presented. Third, an effective teacher enters into dialogue with the students and is open to discovering new truths from inquiring minds.

Each of these traits emphasizes the risks of teachers being influenced by any commercial interest. Physicians traditionally have believed that they are above influence when acting in the primary role as physician. Yet increasing industrial presence within ophthalmic academic programs is manifest as sponsorship of clinical research, underwriting of new academic facilities, and grants to fund fellowship positions. Such actions not only should be questioned from the perspective of the professional values of medicine but also from the perspective of the inherent need for integrity and impartiality in educational realms. Inappropriate industry relationships in an academic environment sully both professions.

Great variability exists among institutions as to the freedom with which faculty can develop relationships with industry. Faculty answer to the departmental chair, and typically, the chair reports to the medical school dean. In the 1970s, funding for ophthalmic surgery was far more abundant; patients undergoing cataract, retina, or strabismus surgery brought revenue to inpatient facilities. Reimbursement for ophthalmic surgery was far greater than current rates. Funding was more easily obtained for clinical research. Academic departments burgeoned. However, current economic pressures, changes in the educational model, and higher accreditation standards have contributed to rising academic costs. Eager to sustain and grow, academic programs and institutions struggle to identify new sources of revenue. The potential for collaboration with industry is ripe, not only for CME but also for graduate medical education (GME).

Institutional requirements often dictate behavior in ophthalmology departments. Increasingly, medical schools are regulating specific relationships including participation in speakers’ bureaus, acceptance of clinical research support, disclosure of financial relationships, and the presence of industry representatives at educational functions. Within ophthalmology departments, further delineation of policies may exist. Thus far, national guidelines for appropriate behavior have been crafted for academic medicine, and these published recommendations seek to restrict far more substantially relationships with industry. The current practice of many ophthalmology departments is at variance with some of these recommendations, for example, allowing faculty members to participate in speakers’ bureaus (S.H.D. and R. Shaw, MD, and S. Mundhra, MD; unpublished data, 2008). Most ophthalmology chairs believe that the era of translational research justifies the involvement of industry in clinical research. Virtually all chairs note that industry has approached them for participation in research projects. The decision about participating rests solely on our shoulders. Industry wants to collaborate with us. We must decide whether this compromises our professional standards.

Academic decision makers must evaluate industry relationships in at least 3 specific areas: CME, GME, and research. The most common association is with CME. Academic departments have traditionally sponsored grand rounds, seminars, and courses for practicing ophthalmologists. Reputations and referrals, in part, depend on these public events. Industry funding for such courses is often sought. Often this funding is provided as an “unrestricted educational grant,” giving the impression that the money is unrelated to industry bias. However, industry does not give money unless it can induce physicians to prescribe its profitable drugs and buy its expensive devices. Industry wants physicians to believe there is no bias in their educational programs and, therefore, that there should be no concern about accepting and acknowledging industry’s financial support. Nothing could be farther from the truth. The more detached industry can seem, the better industry likes it. The same can be said for disclosure guidelines for granting CME accreditation. Speakers are required to identify their potential industry conflicts. Nevertheless, the effect on attendees of “first slide” disclosures or agenda footnotes is difficult to measure.

Another aspect of CME relationships pertains to academicians who, identified as thought leaders by industry, join speakers’ bureaus. Although institutional regulations may be tightening insofar as the appropriateness of such actions, current participation is in large part ungoverned
by academic medical centers. That industry thinks of CME as a critical area is reflected in its budgetary allocations, which are in the billions of dollars.\(^{27}\) It is also understandable that industry would turn to respected scientists and teachers as it forms speakers' bureaus.

As with CME, academic medicine looks to outside sources to support GME programs. For the last half century, funding for GME has largely come from federal sources and institutions are paid to train the physicians of tomorrow. To receive federal funding, a training program must be accredited by the Accreditation Council for Graduate Medical Education. The total number of funded slots is capped by a system designed and implemented decades ago. However, the number of accredited programs has grown as new specialties and specialties at both the resident and fellow levels of training have proliferated. Because federal funding is frozen, some GME programs now receive direct funding from industry\(^{26}\); this is particularly the case in dermatology. In ophthalmology, pharmaceutical company–sponsored programs\(^{19}\) support institutions for fellowships; these fellowships are limited to cornea, retina, and glaucoma at certain institutions that perform research in pharmaceutical advances. A more common practice is industry sponsorship of brief programs for senior residents and fellows. Many of these seminars focus on subjects not traditionally emphasized in residency programs, such as practice management. Industry sponsorship of departmental conferences, journal clubs, and wet laboratories is common, including gifts of lunches, textbooks, and even equipment. There are for-profit third-party MECCs with an emphasis on GME rather than CME. All of these interactions with industry can lead to influence and bias, whether apparent or not.

Research is central to the mission of all academic institutions. Competition for research funding from the National Eye Institute has grown faster than budgetary increases. Industry has attempted to fill the void. Recognizing the potential for conflict of interest, universities, hospitals, and medical schools, as well as departments, have crafted guidelines for institutional and individual research interactions with industry. Yet there remains an enormous variability in the policies and regulations.

Other ethical dilemmas and potential conflicts exist for ophthalmology departments. Medical centers contract with specific companies for equipment. As critical stakeholders in the decision, nurses and technicians are courted by vendors. Similarly, physicians serving on formulary and budget committees make choices about drugs or equipment that may be supplied by companies with which they have a commercial relationship. Junior faculty are expected to generate revenue or perform research to advance in rank; thus, industry-related activities may be alternatives to government funding sources. In professional organizations, seasoned leaders find that their programs require sustenance by industry revenue. Peer-reviewed journals search to find reviewers without conflicts of interest.

From the perspective of training of ophthalmologists, all forecasters predict that as the baby boomers age, there will be an increased need for ophthalmologists and their services to an extent greater than in any other specialty. With this imperative, our profession must define what is allowable in academic centers in terms of industry relationships. Development of institutional and departmental policies pertaining to such relationships is a first step. Some institutions such as the Mayo Clinic have devised novel mechanisms to govern faculty (see 2008 Knapp symposium presentation by Michael Camilleri, MD, at http://www.aosonline.org/annualmeeting/knapp08_video.html). The crux of the Mayo Clinic policy relates to the financial value of an individual's relationship; the higher the value, the more specific the disclosure requirement and the more oversight the institution requires.

It is incumbent on all faculty to educate themselves on the growing body of knowledge about the slippery slope of industry relationships. Physicians often believe that they cannot be influenced despite extensive evidence that such is not the case. They must also be cognizant of the difference between a search for truth (an academic goal) and the search for profits (a business goal). Ophthalmic faculty should engage in discourse with ethicists and educators.

Education about industry relationships must occur for those within the realm of academic influence. Residents and fellows must be taught about the complexities of industry relationships. Most will proceed into clinical practice, where pharmaceutical and device representatives will be eager to provide them with new “knowledge” and new products. Some will become academicians and, as junior faculty, feel the need to produce revenue and publish articles. Industry contacts can be seductive in providing income and recognition, especially for house staff with low salaries and large debts. The subtle influences of free food under the guise of education or sponsorship of a trip to learn new treatments are temptations to be recognized and averted.

In addition, it should be acknowledged that in our current health care environment, academic departments may be in competition with private practices for patient care and research. It is incumbent on our profession that whether patient care, research, and teaching are at a traditional academic institution or in a private practice–based environment, standards for physician behavior must be beyond reproach. This requires that member organizations adopt and enforce guidelines similar to those of the academic institutions. Such measures by member-based organizations would also mitigate the potentially detrimental effects of MECCs.

All ophthalmologists have the responsibility to read journal articles critically despite increasing regulation pertaining to disclosure of authors’ relationships. Stories of peer-reviewed journals having difficulty finding reviewers without conflict and discoveries of covert industry influence despite apparent disclosure have recently been in the news. Similarly, conflicted thought leaders have been suspected of influencing policy setting such as institutional formularies or clinical guidelines. Specific examples of each of these and more have resulted in a minority, albeit vocal, recommending severing industry relationships entirely.\(^{18}\)

CONCLUSIONS ABOUT ACADEMICS AND INDUSTRY INTERACTIONS

Industry relationships in an academic setting pose particular challenges for our profession. Academic ophthalm-
mologists provide much new information offered to ophthalmologists and, thus, influence the practice of ophthalmology. Further, they serve not only as physicians beholden to patients but as teachers beholden to future ophthalmologists. The questions that academicians choose to pursue in their research should be guided by questions that, if answered, can most benefit society. Academicians, like practicing physicians, in large part do not believe their opinions can be bought despite growing evidence to the contrary. Economic pressures seem to be driving relationships between academic departments and industry. Public scrutiny of academic medical centers may lead to externally or internally imposed regulations governing industry relationships. To prevent this, opportunities exist for academic ophthalmology to more effectively manage existing relationships with industry.

INDUSTRY SUPPORT FOR CME

Support for CME provides the pharmaceutical and device industries powerful means of influencing the medical profession to prescribe their drugs and purchase their instruments, which may not be the best or most cost-effective products.30 Industry cannot be blamed for its role in supporting CME because a legitimate goal of industry is to increase shareholder value.31 The money it spends on CME is clearly spent toward that end.

The purpose is the same whether industry funds the CME directly or through unrestricted grants to organizations or MECCs. It is also irrelevant whether the education in the industry-sponsored CME is valuable to attendees or whether the venue gives the industry-supported speaker the opportunity to teach without being told what to say. When the profession accepts industry CME support, the act alone gives physicians the impression that industry is on both their side and the patient’s side. This creates a sense of obligation, a debt to the company that is sufficient for industry to believe that spending money on CME is worthwhile.

Much of what industry spends on physicians is intended to promote feelings of gratitude and goodwill. As long as CME physician attendees are grateful to industry for the support, physicians are influenced in their subsequent prescribing and purchasing decisions. While industry does not want to pay for speakers who will speak ill of their products, it may not care what is said by the speakers. The opportunity for industry to pay a speaker’s expenses and provide an honorarium is sufficient to generate feelings of gratitude and reciprocity on the part of the speaker. The chance for industry to give a medical society unrestricted grants for CME provides the opportunity to establish goodwill within the leadership of the society. Repeated again and again, industry can bring enormous influence to bear on physician teachers, those who typically are thought leaders in their field, and on respected society officers, often without those individuals having any idea that they have been influenced. Having a large cadre of grateful teachers and leaders is part of what industry is getting for its CME money. In addition, the attendees are grateful for the reduced registration fee and subsidized meals. That industry has sponsored the CME event often enables industry representatives to mingle with CME attendees at the meeting. This interaction provides the industry representatives the opportunity for access and influence, perhaps touting a particular drug or device or arranging for a subsequent interaction in the physician’s office.32

Industry has different mechanisms for supporting CME. Sometimes the money is given by what seems to be a competitive application and selection process. Industry is then able to judge where it gets the most for its money in terms of gaining access and influence. The term “unrestricted” is deceiving. Recipients of those grants may believe that industry is simply donating the money for a good cause: education. Perhaps that would be a reasonable interpretation; however, this is only part of the industry marketing approach.

If the medical profession knows that its primary duty is to patients, is there a place for industry in any part of the CME process? Recently the Association of American Medical Colleges Task Force Report on Industry Funding of Medical Education developed background guidelines for the interaction between industry and academic medical centers.33 Among the conclusions of the task force, one relates to industry speakers’ bureaus from whence come many of the teachers in industry CME offerings: “With the exception of settings in which academic investigators are presenting results of their industry-sponsored studies to peers and there is an opportunity for critical exchange, academic medical centers should strongly discourage participation by their faculty in industry-sponsored speakers bureaus.”34(p29)

Disclosures by speakers of their industry conflicts of interest are viewed by some as a way to justify or manage conflict of interest. There is strong evidence that disclosure is of little value to an audience because attendees do not have enough information to understand the ramifications of the conflict.13 Speakers with conflicts of interest may be believed to be more knowledgeable than speakers with no conflicts of interest. In addition, the naming of companies by speakers with conflicts of interest provides an air of respectability for both the companies and the speakers. When an audience sees that the speakers, for whom they have respect, have ties to industry, it may influence the audience to believe that those conflicts are valuable. The CME organizers must have known that these speakers had those conflicts, and because they chose those individuals to speak, the conflicts must not be a problem.

Unwittingly, it is often individual physicians, physician member organizations, and academic medical centers and their departments that facilitate industry marketing. Individual physicians and those who represent organizations and academia should understand the motive of industry sponsorship of CME. Physicians should pay attention to the overwhelming evidence in the literature that industry’s extensive marketing effort to physicians is highly successful in changing behavior. Physicians should recognize that for-profit companies are not charitable organizations and that money spent by the companies has a profit motive. It is the physician’s duty to be certain that he or she is always acting on behalf of patients. In the case of CME, while physicians have a responsibility to teach, the CME teachers and attendees should recognize that industry money in the CME arena is meant to influence behaviors, not just educate.
Lack of bias in the CME content itself is not a justification for accepting industry financial support. Industry’s marketing efforts are not aimed at one teacher, one attending, one course, one organization, or one department. Rather, the marketing efforts work because all of the parts work in concert.36 Physicians should realize that when they accept industry money, the end result, unconnected in the physician’s mind to anything that industry did, is often more prescriptions for expensive and sometimes unneeded drugs and more purchases of expensive equipment of sometimes questionable patient value.

PROFESSIONAL ORGANIZATIONS AND INDUSTRY INTERACTIONS

Professional organizations have obligations to represent physicians in several areas including education, setting standards for physician professional behavior (codes of ethics), clinical behavior (practice guidelines), and political advocacy.39 A critical relationship exists between physicians and society. The classic triad of contracts (covenants) that physicians have accepted as professionals are with patients, society, and colleagues.36

Conflicts of interest arise because professional organizations are businesses, yet they must represent the values of the medical profession.36 These include respect for the vulnerability of patients and the promise that physicians will do what is in the best interest of their patients. While coordinating the values of medicine with the need to interface with society, they operationalize the relationship between physicians and society.

There are many circumstances in which industry and professional organizations interact. At national, regional, and local meetings sponsored by professional organizations, the interface creates a tension between the interests of commercial sponsors who want to sell something to physicians, other providers, and those who are seeking knowledge to maximize quality patient care. The professional organization walks a narrow line in balancing its own financial requirements and the need to promote opportunities for members to gain new knowledge and maintain the skills and knowledge needed to continue their practice of medicine. When meetings have programs that represent the interests of industry and not of members of a learned profession, it may foster the perception that the professional organization does not uphold the covenants that physicians have to their patients. In turn, this may prove harmful to the relationship our profession has with society. With a hidden corporate agenda, professional organizations are abjuring their responsibility to educate. Specifically, if the educational program is or is perceived to be influenced predominantly by industry needs (e.g., new pharmaceuticals being highlighted rather than comparing the benefits of different medicines and discussing important aspects such as cost to patients and society), industry is using our professional organizations as marketing intermediaries. This tarnishes our ability to act as a profession rather than a guild.37

For any event that is under the aegis of a professional organization that represents physicians, it is essential that the values of medicine be paramount rather than the purposes of industry. Physicians cannot be dual agents, and neither can their professional organizations. When logomania prevails at meetings, it is difficult to avoid the impression of a trade show that has spread beyond the boundaries of the exhibit hall. The program selection must not be biased by preferential treatment to industry-supported papers and posters. The academic program should not be undermined with competing industry events, for example, satellite meetings and pseudoacademic presentations by key opinion leaders on the exhibit floor, that lure attendees from scientific presentations. A balance is needed in which the contractual relationship between industry and medicine results from mutual respect of each other’s values. Desirable changes in the commercial appearance of the meetings of our professional organizations will require a decreased commercial presence and a reduced dependence on financial support from industry.36,39

Professional organizations also develop educational and clinical practice materials that should be free of commercial influence. Authors of guidelines or opinions from the organization must be as free from industry influence as is possible. This requires considerable effort because industry is well aware of the weight of statements that have the imprimatur of a professional organization. Recent media coverage has embarrassed our profession when it was discovered that the authors of publications from a professional organization promoting a product had substantial financial investment in the manufacturer of that product. Journals that are produced under the aegis of a professional organization also require heightened awareness and sensitivity to potential conflicts of interest of journal editors and of authors and reviewers.

The American Ophthalmological Society does not now and has never taken any monies from industry to support its annual meeting or for its publication, Transactions of the American Ophthalmological Society. Our other professional organizations need to consider how they represent our profession and need to actively manage the conflicts that occur when they take money from industry.

CONCLUSIONS OF THIS PERSPECTIVE ON OPHTHALMOLOGISTS AND INDUSTRY INTERACTIONS

This perspective was formulated to review some of the principles that should govern the interface between physicians (or researchers) in ophthalmology and vision science, and the pharmaceutical and device industries. It is not intended to be critical of the pharmaceutical industry but to provide guidelines for the behavior of physicians, researchers, and physician organizations and to provide a framework for discussion of issues.

1. Ophthalmologists are professionals. We are given a place of value in society, with society’s trust. Our first consideration must be the patient’s welfare, and we must consider the needs of society. The same is true of our professional organizations.

2. Taking gifts and other items of value from pharmaceutical companies can change a physician’s perspective and behavior. Although we often believe that we are
immune, studies have clearly shown that our prescribing practices and other aspects of our behavior are influenced by receiving these gifts.

3. We are not entitled. Nothing we did during medical school, internship, or training entitles us to such gifts as free meals, reduced registration fees, and paid travel.

4. We accept additional professional responsibilities when we teach or perform research. Both are founded on seeking of scientific truth to care for our patients.

5. We and our organizations should not be marketers for the company. This compromises our professionalism.

6. The fundamental mission of for-profit pharmaceutical companies and device manufacturers is not charity. When they give away money, rarely is it for the welfare of humanity but to influence behavior to improve their profitability. This is their duty to their stockholders and owners.

7. If we do not behave as professionals, government bodies and society will impose on us regulations that will be onerous. We stand to lose our valued place in society.

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