Physician–Industry Relations. Part 1: Individual Physicians

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This is part 1 of a 2-part paper on ethics and physician–industry relationships. Part 1 offers advice to individual physicians; part 2 gives recommendations to medical education providers and medical professional societies.

Physicians and industry have a shared interest in advancing medical knowledge. Nonetheless, the primary ethic of the physician is to promote the patient's best interests, while the primary ethic of industry is to promote profitability. Although partnerships between physicians and industry can result in impressive medical advances, they also create opportunities for bias and can result in unfavorable public perceptions.

Many physicians and physicians-in-training think they are impervious to commercial influence. However, recent studies show that accepting industry hospitality and gifts, even drug samples, can compromise judgment about medical information and subsequent decisions about patient care. It is up to the physician to judge whether a gift is acceptable. A very general guideline is that it is ethical to accept modest gifts that advance medical practice. It is clearly unethical to accept gifts or services that obligate the physician to reciprocate.

Conflicts of interest can arise from other financial ties between physicians and industry, whether to outside companies or self-owned businesses. Such ties include honorariums for speaking or writing about a company's product, payment for participating in clinic-based research, and referrals to medical resources. All of these relationships have the potential to influence a physician's attitudes and practices. This paper explores the ethical quandaries involved and offers guidelines for ethical business relationships.

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In 1990, the American College of Physicians published a position statement titled "Physicians and the Pharmaceutical Industry" to address ethical issues in relationships between industry and the medical profession (1). The statement, which was prompted in large part by evidence of the drug industry's influence on physician behavior and concern for professional integrity and patient care, examined potential conflicts of interest in relationships with industry and provided ethical advice in certain areas. Since the statement was originally released, evidence of industry's influence on medical practice, research, and education has continued to emerge, and physician–industry relationships have multiplied. Once again, the American College of Physicians–American Society of Internal Medicine reminds physicians and industry to be vigilant about potential conflicts and ethical problems. The College recognizes that while there are no easy answers to many ethical questions, guidance in certain areas can be useful.

This is part 1 of a 2-part paper on ethics and physician–industry relationships. In part 1, the College offers recommendations to individual physicians, mainly clinicians and clinician-researchers, regarding acceptance of gifts and other financial relationships with industry. Part 2 addresses medical education providers and medical professional societies that accept corporate funding for organizational projects or membership events, such as meetings and symposiums (see pp 403-406).

Despite the introduction in the early 1990s of ethical standards for physicians regarding physician–industry relationships, concerns persist and evidence accumulates that commercial rewards can unduly affect clinical judgment (2–9). Industry allocates substantial resources to promote its products to physicians. In 1999, the pharmaceutical industry spent nearly $8.0 billion (U.S.) to send sales representatives to physician offices and to exhibit products at medical conferences and events (10). Such costly corporate overtures raise questions about undue influence and could undermine genuine educational efforts.

In addition to the pharmaceutical industry, physicians are increasingly courted by newly emerging indus-

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tries (biotechnology, pharmacogenetics, e-commerce), and potential conflicts of interest, whether real or perceived, are pervasive. Physicians meet industry representatives at the office and at professional meetings, collaborate in community-based research, and develop or invest in health-related industries. In all of these spheres, partnered activities often offer important opportunities to advance medical knowledge and patient care, but they also create an opportunity for the introduction of bias.

This paper offers two positions to help guide individual physicians in making ethical decisions about interacting with industry. The positions are based on the profession's fundamental principles of responsibility, that is, acting in a patient's best interests (beneficence), protecting the patient from harm (nonmaleficence), having respect for the patient and fostering informed choice (autonomy), and promoting equity in health care (justice). To uphold these principles, the primary purpose of entering relationships with industry should be the enhancement of patient care and medical knowledge. While the ethics of medicine and the ethics of business sometimes diverge, both are legitimate, and a thoughtful collaboration of physicians and industry can result in the best of patient care.

Position 1. Industry Gifts, Hospitality, Services, and Subsidies

The acceptance of individual gifts, hospitality, trips, and subsidies of all types from industry by an individual physician is strongly discouraged. Physicians should not accept gifts, hospitality, services, and subsidies from industry if acceptance might diminish, or appear to others to diminish, the objectivity of professional judgment. Helpful questions for gauging whether a gift relationship is ethically appropriate include 1) What would my patients think about this arrangement? What would the public think? How would I feel if the relationship was disclosed through the media? 2) What is the purpose of the industry offer? 3) What would my colleagues think about this arrangement? What would I think if my own physician accepted this offer?

Rationale

Physicians understand that to maintain their professional objectivity they must be mindful of potential biases in medical information (7, 11). In fact, the entire infrastructure of science and much of physician education is built on the fundamental notion of eliminating, or at least controlling for, the many and powerful biases inherent in generating and interpreting scientific data. Ethically and professionally, the objective evaluation of medical information is critical for deciding on best clinical practices (beneficence) and avoiding risks to patient safety (nonmaleficence) (12–14). Thus, physicians have an obligation to themselves, their profession, and society to evaluate, correct for, and eliminate potential bias in medical information from all sources.

Recent studies and reports have examined industry influence on physician objectivity and behavior (15, 16), particularly prescribing practices, formulary choices, and assessment of medical information (3, 7, 17–25). Physicians frequently do not recognize that their decisions have been affected by commercial gifts and services (26) and in fact deny industry's influence (3, 15, 17–22), even when such enticements as all-expenses-paid trips to luxury resorts are provided (23). Research, however, shows a strong correlation between receiving industry benefits and favoring their products (23, 25, 27).

What Would My Patients Think about This Arrangement?

The dictates of professionalism require the physician to decline any industry gift or service that might be *perceived* to bias their judgment, regardless of whether a bias actually materializes. A perception that a physician is dispensing medical advice on the basis of commercial influence is likely to undermine a patient's trust not only in the physician's competence but also in the physician's pledge to put patients' welfare ahead of self-interest. Recent research on patient attitudes shows that patients are more likely than physicians to perceive industry gifts as inappropriate or influential on medical practice (19, 28, 29). More particularly, a significant number of patients believe that industry gifts bias their physicians' prescription practices and ultimately drive up medical costs. Patients make a distinction, however, between acceptable and unacceptable gifts. Most think that inexpensive incentives designed for office use (pens, notepads) and patient care (drug samples, medical texts) do not have a negative effect on health care. They are much more likely, however, to disapprove of items for

personal use (radios, coffeemakers), especially as the gifts become more costly (dinners, trips) (28, 29).

What Is the Purpose of the Industry Offer?

The potential for bias in industry-prepared information becomes especially precarious when such information is accompanied by a gift or free service. Even when the amenity is medically related, a major aspect of the offer involves the establishment of a gift relationship, a phenomenon much studied in social science research. In culture after culture, there has emerged "a vivid sense of the immense pervasiveness of the social obligation" that a gift elicits (30). Social scientists agree that the prevailing purpose of the gift is to establish the identity of the donor in the mind of the recipient and to oblige the recipient to reciprocate (30–32). It is not just lavish amenities that are in question. The acceptance of even small gifts can affect clinical judgment and heighten the perception (as well as the reality) of a conflict of interest (12).

From a certain perspective, drug samples can be characterized as "gifts." Because physicians can distribute such medications to patients at no apparent cost (33), the practice may seem to promote the profession's core principle of equitable access and justice in health care. The practice does allow the patient to try out a new medication before being committed to an expense. However, the sample mainly serves to encourage physicians to prescribe the new product. Research shows that once a patient exhausts a free supply of medication, the physician typically writes a prescription for the same brand (33, 34). Because few samples are for older or less expensive products (35), higher patient costs generally result. Moreover, physicians and their families and staff use approximately one third of the samples (33, 34, 36, 37), which illustrates how the practice fosters access to physicians' offices and encourages a gift relationship.

In addition to drug samples, industry may distribute product literature or "patient care services," such as education aids or disease management software. It is understandable that, in a busy practice, physicians would welcome industry's materials and technologies to keep themselves and their patients current with the latest developments in the medical field. Physicians must keep in mind, however, that industry-supplied medical information, although neutrally packaged, is in fact promotional (4). Physicians should never rely solely on industry-provided information or services as a substitute for an objective review of the literature and understanding of patients' conditions.

What Would My Colleagues Think about This Arrangement?

The issue of industry gifts, hospitality, and subsidies arises as early as medical school and residency programs (18, 20–22, 27, 38–42). Medical students and physicians-in-training often have opportunities to receive instructional materials, medical equipment, or even educational dinner programs. While it is recognized that such arrangements can benefit the medical education experience and that medical students and residents have unique financial and work circumstances, it is also necessary to note that medical training includes instruction on professional ethics, including appropriate relationships with industry. Medical students, physicians-in-training, and practicing physicians should apply the same ethical standards to their interactions with industry (43).

Physicians do not always agree about the appropriateness of gifts. Ideally, physicians should not accept any promotional gifts or amenities, whatever their value or utility, if they have the potential to cloud professional judgment and compromise patient care. As a practical matter, many physicians are comfortable with limiting their acceptance of gifts to items that enhance medical practice or knowledge and that are of modest value. Differences of opinion will undoubtedly arise because of the ways in which an item or service is valued in different practice environments and communities. Nonetheless, such debates are important because they remind physicians of the need to gauge regularly whether a gift relationship is ethically appropriate.

Recommendations

The inherent difficulty in defining what makes a gift appropriate has, to an extent, contributed to lapses in judgment by otherwise ethical persons. It is difficult to set with any precision a monetary value that would render a gift unacceptable. There is no consensus model for determining relative value, and one will not be recommended here. Instead, some specific guidance is offered in the following examples of generally acceptable industry gifts: inexpensive gifts for office use (such as pens and calendars), low-cost gifts of an educational or patient-care nature (such as medical books), and modest

hospitality (such as a reception or other food and drink) that is connected with a legitimate educational program.

Understandably, even these "generally acceptable" examples are subject to interpretation and will frustrate some readers. Together with the fundamental questions listed in Position 1, physicians should use these recommendations as guides in making a good-faith effort to evaluate the potential for influence and to determine what kinds of amenities are ethically appropriate to accept. It is unethical for physicians to accept any industry gift or subsidy that is predicated on recommending a particular product or taking a particular clinical action. The preceding examples cannot and should not be used as a perfunctory substitute for self-appraisal.

Position 2. Financial Relationships between Physicians and Industry

Physicians who have financial relationships with industry, whether as researchers, speakers, consultants, investors, owners, partners, employees, or otherwise, must not in any way compromise their objective clinical judgment or the best interests of patients or research subjects. Physicians must disclose their financial interest in any medical facilities or office-based research to which they refer or recruit patients.

Rationale

Like gifts, financial relationships between physicians and industry can jeopardize professional objectivity. While collaborations in pharmaceutical development and biotechnology are often effective spearheads for advancing therapies and patient care, research and investment ties can create dual commitments or conflicts of interest (12) and risk the confidentiality of patient information. Some physicians own, hold stock in, or have other financial stakes in the medical industry and biotechnology; others work for industry as researchers or are university-based researchers who receive industry grants. Increasingly, clinicians are invited to act as industry consultants or to participate in clinical trials of newly developed drugs or devices, often by enrolling their own patients as subjects (12, 44).

Ownership or Other Financial Interest in Medical Resources

Physician ownership or other financial interest in medical equipment, health care facilities, laboratories, and other medically related resources raises ethical and legal concerns that physician self-interest may lead to inappropriate self-referrals or overuse of resources. For example, one study found that physician-owned clinics generated 50% more patient visits than independent clinics, suggesting that self-referral had induced unnecessary demand (45). Because a physician's primary duty is to act in the best interests of patients, physicians cannot allow financial arrangements to influence their judgment about what constitutes an appropriate level of care. It is unethical for physicians to overutilize resources or make unnecessary referrals to goods and services for their own financial benefit. It is also unethical to participate in any arrangement that links income generation explicitly or implicitly to equipment or facility usage or revenues generated by investor-physicians. There are instances, of course, in which self-referrals are acceptable, such as in remote or isolated settings where there is a dearth of alternative medical resources. In any event, if physicians refer patients to resources in which they have a material interest, they need to disclose their financial investments and, to the extent practicable, specify alternative sources of goods and services (12).

Consulting, Speaking, or Writing on Behalf of Industry

Industry may pay clinicians well to act as consultants, speak on behalf of a company, or participate in community-based industry trials. As a rule of thumb, related payments from industry are acceptable for teaching and for research that advances medical and professional knowledge (for example, honorariums for presentations at symposiums), commensurate with the extent of the physician's services and reasonable travel expenses.

Physicians should guard against conflicts of interest when invited to consult or speak for pay on behalf of a company. It is likely that a company will retain only individuals who make statements or recommendations that are favorable to its products, thus compromising the physician's scientific objectivity. Physicians should accept honorariums only for services provided and must disclose any industry sponsorship or affiliation and other potential conflicts of interest to formal lecture audiences and publication editors (31, 46).

Physicians should also be circumspect if asked to deliver educational programming developed by a medi-

cal education and communication company. Such companies, which are largely financed through the pharmaceutical industry, are for-profit developers and vendors of continuing medical education (47). It is important that physicians retained as lecturers in such settings control the content of the educational modules they deliver rather than allow their presentations to be scripted by the company. Lecturers should screen industry-prepared presentation aids (such as slides and reference materials) to ensure their objectivity and should accept, modify, or refuse them on that basis. Presenters using such materials should disclose their source to audience members.

Paid efforts to influence the profession or public opinion about specific medical products are particularly suspect. It is unethical, for example, for physicians to accept commissions for articles, editorials, or medical journal reviews that are actually ghostwritten by industry or public relations firms in an attempt to "manage the press" about certain products or services (48).

Participation in Industry-Sponsored Research

Participation in practice-based research can contribute to our understanding of the benefits and risks of a new product, thereby promoting medicine's underlying principles of beneficence and nonmaleficence. Still, physicians are responsible for ensuring that any clinical research in which they participate is potentially of significant value and is ethically conducted (12, 49). In particular, physicians invited to join "postmarketing studies" that require the prescribing of a company's product need to consider the scientific validity of the research and its potential to enhance medical progress (44, 50, 51). Physicians should not participate in studies that are, in effect, thinly disguised promotional schemes to entice physicians to use new products.

Physicians also have an ethical obligation, based on the principle of patient autonomy and informed choice, to disclose their commercial ties to patients who are prospective study participants (12). Physicians who involve their own patients in office-based trials must also be aware of potential conflicts between what is best for the patient-subject and what is optimal for the conduct of the research. In weighing the two interests, clinicians must consider their role as physician first and as investigator second (12, 52). It is reasonable for the clinician to receive compensation commensurate with time and expenses incurred in study recruitment. However, physicians may not accept compensation simply for referring their patients to an industry study, regardless of whether the physician directly participates in the trial. Known as "finder's fees," such arrangements represent pure profit and create an inherent conflict with the best interests of the patient (12, 49, 53).

Finally, physicians involved in commercial trials must guard against bias in publishing research outcomes. Several studies show that physicians with financial ties to pharmaceutical manufacturers are significantly more likely than independent reviewers to report findings that support the sponsor's drugs; likewise, they are less likely to report unfavorable findings (48, 54–57). To maintain objectivity, it is recommended that physicians secure pre-performance agreements with sponsors ensuring that negative results will not be quashed and that findings will be made publicly accessible. Physicians should also be aware that the International Committee of Medical Journal Editors recently agreed not to publish any studies conducted under conditions in which the sponsor can control the data or prevent publication (58). If a company explicitly or implicitly encourages a physician to suppress particular outcomes, the physician must not participate in the research and should report the incident to the institutional review board overseeing the research, and to the U.S. Food and Drug Administration if the research is a drug trial.

Dealing with Institutional Product Bias

Physicians employed by managed care organizations are obligated to abide by drug formularies and practices of pharmacy benefit management. Formularies specify a list of drugs that are considered most useful and cost-effective, and managed care organizations often limit reimbursement to these drugs. Pharmacy benefit management companies, which increasingly are owned by pharmaceutical manufacturers, act as intermediaries among pharmacies, pharmaceutical companies, physicians, and third-party payers to review prescribing practices and negotiate prescription prices. Pharmacy benefit management companies have access to confidential patient records and may try to influence changes in patients' drug regimens, sometimes to reduce costs and sometimes to favor a manufacturer (59, 60). Current

state and federal policies regarding third-party access are not consistent and can, at times, jeopardize the confidentiality of patient information. Cost savings are certainly encouraged, especially as a matter of justice and equity in health care. However, any agreement to change drugs should be evidence-based, not company-biased. If faced with institutional bias in drug formularies, individual physicians should be prepared to insist on waivers for unlisted drugs when it is in the best interests of their patients.

Electronic Technology

Finally, the development of "e-commerce" has led to ethical issues not envisioned in the 1990 position paper. Since that time, the importance of electronic commerce and Internet technology to the practice of medicine has increased dramatically. Health care systems in the 21st century will undoubtedly take advantage of electronic technology to collect and analyze clinical data, support consumer access to health information, and complement the physician's management of patient care (13).

As valuable as consumer access is, information provided electronically can be biased by its sponsor. To mitigate this potential conflict, physicians who have a material interest in "e-health" businesses or who interact with Internet hosts to publish their own Web sites have an obligation to control the site's medical content and regularly maintain it. Such sites should disclose all sources of industry support and clearly distinguish any commercial advertisements or sponsored content from substantive content, both in form and in placement. Physicians with commercially sponsored Web sites also need to alert users if a sponsor plans to conduct any online tracking.

Conclusion

The guidelines offered here identify several examples of financial and other material relationships between physicians and industry, but the list is not exhaustive. As opportunities for commercial ties continue to grow, physicians should be increasingly wary of threats to their professionalism and independent judgment about patient care. Providers of medical education and professional medical societies face similar problems of potential influence. Part 2 of this statement on industry relations will address the ethical risks and responsibilities of professional medical associations and educators.

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