

Physicians and the Pharmaceutical Industry

American College of Physicians*

A responsible and productive alliance between the medical profession and the pharmaceutical industry is unquestionably beneficial to medical progress. However, not all interactions between the two merit unconditional praise. This position paper addresses controversial issues related to the ethics of physician encounters with industry. The Ethics Committee of the American College of Physicians acknowledges that there may be no easy answers to many of the questions raised by these issues, but it has identified certain areas where specific guidance may be provided to supplement continued reliance on individual physician judgment.

In recent years there has been increasing awareness of ethically unsound relationships occurring between individual physicians and the pharmaceutical industry (1-5). These relationships are generally initiated during shared endeavors in the areas of continuing medical education and drug development. In both of these spheres, partnered activities offer important opportunities to impartially advance the state of medical practice and thus improve patient care. However, some collaborative arrangements between physicians and industry that purport to provide such opportunities may be subverted to fulfill proprietary objectives rather than educational goals. Of particular concern are instances in which physicians accept extravagant gifts or stipends for participation in industry-supported programs.

It is difficult to estimate the number of dubious interactions between physicians and the pharmaceutical industry. No surveillance program exists to gather the type of data needed to elucidate the scope of the problem. Moreover, there will always be dissent regarding the threshold beyond which an amiable climate of interaction will be perceived as an indulgent one. Physicians often accept payments, gifts, or hospitality from drug or equipment manufacturers. The issue here is not gifts or honoraria in themselves, but rather that excessive or inappropriate rewards impair public confidence in the integrity and judgment of the profession and may compromise physician clinical judgment. Concern that physicians are placing themselves in potentially compromising, if not indefensible, ethical situations has been expressed on many occasions (1-5).

Many persons and groups have recognized the need to formulate policy to help guide the activities of individual physicians, professional societies, and educational institutions in their relationships with industry. Useful guidelines have been prepared by a number of organizations, including the Royal Australian College of Physicians, the American College of Cardiology, the American College of Obstetricians and Gynecologists, the Infectious Diseases Society of America, and the American Academy of Ophthalmology. Of particular relevance is the report of the Royal College of Physicians, "The Relationship between Physicians and the Pharmaceutical Industry," which provides recommendations based on an inquiry into physician behavior with respect to the drug industry (6).

Position 1

Gifts, hospitality, or subsidies offered to physicians by the pharmaceutical industry ought not to be accepted if acceptance might influence or appear to others to influence the objectivity of clinical judgment. A useful criterion in determining acceptable activities and relationships is: Would you be willing to have these arrangements generally known?

Rationale

Various industry-funded amenities are now part of the drug promotion and continuing medical education (CME) scene. They range from trivial gifts to all-expense-paid trips for two to resort settings for special CME programs. Elegant dinners, recreational outings, and tickets for celebrity performances reside somewhere in the middle. These offerings are almost always given and accepted in the name of hospitality. Their capacity to influence the independent judgment of physicians has neither been proved nor disproved.

It is a fundamental tenet of the medical profession that physicians should make their clinical decisions on the basis of medical knowledge without commercial influence. The issue at hand is not the validity of this principle, but the frequently voiced contention that accepting a gift from industry will have no effect upon one's patient management choices. Although this contention is generally expressed with complete conviction, it is likely that persons may underestimate effects on their choices.

Avorn and colleagues (7) have shown that physicians are not always able to recognize the commercial messages and inputs that ultimately bear on therapeutic decisions. In a survey of primary care physicians about their perceptions of the efficacy of two highly promoted agents, propoxyphene-containing analgesics and cerebral vasodilators, a much more favorable attitude to these drugs was discerned than could be supported by the convincingly negative scientific reports of their

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value. Yet, the same group of physicians claimed to be much more influenced by scientific literature and academic sources than by commercial sources of information. The authors concluded: "Physicians who held advertising-oriented beliefs about the index drugs were generally unaware that they were strongly influenced by non-scientific sources" (7).

Physicians must regularly confront issues of bias in evaluating medical information. In fact, the entire elaborate structure of science and medical education is directed at the fundamental problem of eliminating, or at least controlling for, the many and powerful biases inherent in generating and interpreting the data of science.

Objective evaluation of medical information is important for technical reasons; that is, the best clinical practice depends, over time, on such objectivity. Equally important, however, is the ethical responsibility of physicians to their patients, themselves, the profession, and society to evaluate, correct for, and eliminate potential bias in medical information from all sources: academic, professional, and commercial.

The underlying purpose of medical information, particularly data on therapeutics, provided to physicians from commercial sources is, understandably, to promote product sales. Although information from these sources may also promote useful awareness and understanding of therapeutics, the primary purpose of medical information from these sources is not to supply a balanced, unbiased, or objective review of the scientific data. In all instances where medical information is presented to physicians under commercial sponsorship, physicians are ethically obligated to recognize the potential bias inherent in medical information linked, however indirectly, to commercial product promotion. Physicians must not accept gifts, hospitality, or subsidies that might influence or appear to others to influence the objectivity of clinical judgment, and, in the case of information provided by advertising, detail persons, and company-sponsored educational programs, physicians must correct for any bias in interpreting that information.

In recognition that questionable and sometimes flagrant instances of ethical misbehavior were occurring, the Royal College of Physicians appointed a Working Party to review available evidence and to make recommendations to Fellows and Members of the College. Various practices were reviewed, including company-sponsored meetings, hospitality arrangements, gifts and inducements to participants in programs, and subsidization for physicians to attend meetings abroad. The Working Party prefaced its specific recommendations with the following policy statement: "The overriding principle is that any benefit in cash or kind, any gift, any hospitality or any subsidy received from a pharmaceutical company must leave the doctor's independence of judgment manifestly unimpaired. When it comes to the margin between what is acceptable and what is unacceptable, judgment may sometimes be difficult: a useful criterion of acceptability may be 'would you be willing to have these arrangements generally known?' " (6). The American College of Physicians agrees that this is a useful criterion.

The monetary value that would render a gift unac-

ceptable cannot be set with precision. Few would consider the acceptance of a notepad or a ball-point pen an improper act. But those who espouse overall restraint might balk at a more expensive amenity, such as a dinner or a country club outing. The inherent difficulty in defining what makes the fruit forbidden has, to an extent, contributed to behavioral lapses in otherwise ethical persons. In an effort to provide some concrete guidance, the American College of Physicians finds the following to be acceptable: trivial gifts such as pens and calendars; inexpensive gifts of an educational nature such as books; modest hospitality (dinners, other food and drink, receptions) that is clearly related to an educational purpose; honoraria for participation in studies; honoraria for presentations at symposia based on the time and reasonable travel expenses of the physician; trips to educational sites that have been chosen for their convenience, not their recreational or other characteristics unrelated to the educational purpose of the meeting.

Medical students and residents should receive education on acceptable responses to offerings from the pharmaceutical industry. Relationships with representatives from the pharmaceutical industry begin early in the medical career, often during the first year of medical school. Many students and physicians-in-training experience opportunities to receive, as gifts, instructional materials, medical equipment, or even "creature comfort" amenities. Such offerings often raise ethical concerns among them.

Educational institutions and individual training programs should reinforce the sensitivities evoked at this time, or establish sensitivity if it is not evoked, by providing education as well as specific policy concerning acceptable and unacceptable practices. Faculty members should set examples for their students by conducting their own relationships with the pharmaceutical industry in a highly principled manner. One relevant strategy would be to notify drug companies of the scope and boundaries of activities judged to be suitable for a given campus.

Position 2

Independent institutional and organizational continuing medical education providers that accept industry-supported programs should develop and enforce explicit policies to maintain complete control of program content.

Rationale

In the broadest sense, continuing medical education encompasses diverse activities: attending courses, lectures, and grand rounds; engaging in self-study with the aid of texts, periodicals, audio- and videocassettes, computer-based learning programs, and so forth; obtaining consultations on patients; and reviewing information from commercial sources such as advertisements and sales representatives on specific products. It is generally assumed that a vigilant attitude is appropriate in assessing the validity of claims made in promotional materials prepared by industry. However, topics presented in traditional educational programs bearing the imprimatur of reputable academic institutions or profes-

sional societies are expected to receive balanced treatment, free of any proprietary influence. This expectation may not always be met. An unknown, but probably substantial, percentage of the estimated 200 million dollars spent by the pharmaceutical industry annually for medical education (as distinct from promotional activities) is used to subsidize programs given under the auspices of traditional CME providers. This practice of underwriting CME offerings of academic organizations and institutions creates the opportunity for the often subtle introduction of commercially oriented content. Although industry has often made significant contributions to the dissemination of scientific knowledge through sponsorship of CME programs that have been conducted without its influence, the line has almost certainly been crossed on some occasions.

Several means are available for a company that funds an academically sponsored program to tailor the messages the program will contain: The two most important ones are influencing the selection of speakers and topics. In a study done at one medical school, transcripts of two courses, separately funded by rival manufacturers of calcium channel blockers, did show company product bias (8). The bias that is introduced into industry-supported programs presented under academic auspices is almost never obvious. For this reason, it may have greater influence on the unwary participant than overt promotional material.

Physicians generally expect CME offerings sponsored by nonprofit academic institutions and professional societies to be free of commercial bias. When programs accredited by such organizations are supported by industry, safeguards must be in place to ensure that this expectation is met. Guidelines for relationships between providers and industry have been set forth by the Accreditation Council for Continuing Medical Education (9). For a program to be impartial, its program director must be able to make unencumbered choices about subject material and faculty. Conflict of interest may exist if the program director or a faculty member receives separate support as a consultant, investigator, or shareholder from the company underwriting the program. The CME program should include a statement that the faculty member is a consultant or investigator if this is the case, and all sources of support should be stated explicitly. Other disquieting practices that warrant inquiry by a sponsoring organization include the following: control of the course budget by the company, direct payment of honoraria to faculty by the company, company selection of physicians who may attend the program, company access to mailing addresses provided by registrants, and excessive promotional or entertainment activities at the course site.

Position 3

Professional societies should develop and promulgate guidelines that discourage excessive industry-sponsored gifts, amenities, and hospitality to physicians at meetings.

Rationale

The presence of pharmaceutical and equipment manufacturers at medical professional society meetings is

well established. Legitimate displays and teaching exercises that take place in exhibition space, funded lectureships, the printing of abstract booklets, and travel awards based on need (for example, for residents) are acceptable contributions to a meeting. However, large sums of money are sometimes spent on events that have no evident educational or scientific justification and that are designed primarily to court the favor of physicians. Codes defining acceptable industry-initiated practices at annual and other meetings are needed.

Position 4

Physicians who participate in practice-based trials of pharmaceuticals should conduct their activities in accord with basic precepts of accepted scientific methodology.

Rationale

Practicing physicians sometimes participate as investigators in trials of newly developed drugs, using their patients as subjects in these studies. When such trials are conducted for a scientifically valid purpose, they contribute to our understanding of the benefits and risks of a new product. Practice-based drug studies that are, in effect, thinly disguised promotional schemes to entice physicians to use a new product, however, are unacceptable.

Conclusion

The question "Would you be willing to have these arrangements generally known?" is a useful measure of the acceptability of particular interactions between a physician and industry. Physicians should ask it of themselves, and answer it. Physicians and institutions must approach all interactions with self-consciousness and avoid encounters that might influence or appear to others to influence the objectivity of clinical judgment, research, and medical education. Otherwise, the integrity of the profession and the public trust it enjoys will be endangered.

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References

1. Opren [sic] scandal [Editorial]. *Lancet*. 1983;1:219-20.
2. Rawlins MD. Doctors and the drug makers. *Lancet*. 1984;2:276-8.
3. Sivarajan M. Tarnishing the medical profession's image [Letter]. *N Engl J Med*. 1985;312:1132.
4. Smith R. Doctors and the drug industry: too close for comfort. *Br Med J [Clin Res]*. 1986;293:905-6.
5. Goldfinger SE. A matter of influence. *N Engl J Med*. 1987;316:1408-9.
6. The relationship between physicians and the pharmaceutical industry: a report of the Royal College of Physicians. *J R Coll of Physicians Lond*. 1986;20:235-42.
7. Avorn J, Chen M, Hartley R. Scientific versus commercial sources of influence on the prescribing behavior of physicians. *Am J Med*. 1982;73:4-8.
8. Bowman MA. The impact of drug company funding on the content of continuing medical education. *Mobius*. 1986;6:66.
9. Accreditation Council for Continuing Medical Education. Guidelines for commercial sponsorship of CME. Lake Bluff, Illinois: Accreditation Council for Continuing Medical Education; 1984.