Editorial

Relationships Between Family Physicians and the Pharmaceutical Industry

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Those of us in the healing professions encounter many situations in which ethical boundaries are both sensitive and unclear. These situations may occur while caring for patients in a clinical setting, while conducting the business of medicine, or while educating physicians. Sometimes these ethical interfaces involve a combination of settings and situations.

In each of these situations, we may interact with proprietary entities that have among their legitimate goals the making of a profit. Toward that end, these proprietary entities may include in their activities assistance to physicians in the multiple arenas of clinical medicine, professional business, and professional education.

Until recently, physicians have been left primarily to their own ethical constructs and consciences in handling their relationships with the pharmaceutical industry and other proprietary entities. But how do we distinguish those activities that primarily support the business of the company from those that primarily support educational efforts?

Because of the indiscretions of a few companies and physicians, however, a variety of external forces have become involved in defining the appropriateness of the relationships between family physicians and the pharmaceutical industry. In many areas, we now have guidance.

During the summer of 1990, the American Medical Association (AMA) convened a conference to explore the relationships between continuing medical education and the pharmaceutical industry. This conference was instrumental in catalyzing a set of principles to guide the relationships between CME providers and the pharmaceutical industry, as articulated by the Accreditation Council on Continuing Medical Education (ACCME).[1]

In March 1991, the ACCME issued its "Guidelines for Commercial Support of Continuing Medical Education." This document must be adhered to by providers of continuing medical education who have, and wish to retain, accreditation by ACCME.

During the same time, the AMA Council on Ethical and Judicial Affairs developed a set of principles to guide individual physicians in their relationships with the pharmaceutical industry. In December 1990, the council issued a report entitled "Gifts to Physicians from Industry."[2] Although they cover many of the same issues and relationships, the AMA document is intended to guide the ethical relationships of individual physicians, while the ACCME document addresses the accreditation activities of CME providers.

For approximately the past 2 years, the American Academy of Family Physicians (AAFP) has addressed these issues as well as the additional issue of direct-to-consumer advertising of commercial products. The AAFP set out to address the ethical aspects of the relationships between physicians, the AAFP, and proprietary entities, and to develop guidelines for the organization and its membership. These activities culminated in the development of an AAFP "White Paper on Proprietary Practices," adopted by the AAFP Congress of Delegates on September 25, 1991.[3] This document embraces and affirms the AMA and ACCME guidelines and further clarifies the relationship between the AAFP and proprietary entities. Indeed, as the Academy's white paper states, "the AAFP extends the AMA guidelines to cover relationships with all proprietary health-related entities that might create a conflict of interest rather than limiting the application of the principles to 'pharmaceutical, device and medical equipment industries.' "

The "White Paper on Proprietary Practices" defines some areas of the industry-provider relationship and refers some issues for further study, development, and interpretation. It does not specifically define the nature of, nor prohibit, industry input into Academy CME

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activities, but it does state that program development, including agenda preparation and speaker selection, will be conducted by the AAFP. Additionally, the document states that all industry funds that support Academy CME activities must take the form of grants to the AAFP rather than be distributed directly by the funding company.

But what is all this about? Why all the flurry of activity? In barely more than a year, large medical organizations and accrediting entities have developed many rules to guide our behavior. Indeed, other regulatory entities such as the Food and Drug Administration (FDA) have now articulated draft guidelines that would further define and regulate the relationships between physicians and pharmaceutical companies. Giant steps have been taken to help ensure the high quality of continuing medical education, the differentiation between education and promotion, and appropriate relationships between proprietary entities and CME providers. Considering the changes in attitude and substance described above, there seems little basis to support the FDA's plan to issue regulations regarding continuing medical education.

Inevitable tension exists between the two goals of education and product promotion. In several public presentations, Frank Davidoff, MD, of the American College of Physicians (ACP), has skillfully pointed out the differences between these two necessary activities. Bias is usually an inherent quality of promotion. The physician is encouraged by a variety of means to choose one product over another. Scientific interchange, on the other hand, and its resultant education should be free of bias, with facts and interpretations presented in balanced fashion.

I make two assumptions: (1) Family physicians have the responsibility to learn about and to detect the difference between education and promotion, and (2) family physicians and their patients are well served when pharmaceutical companies distinguish between education and promotion while engaging in both.

It is in the interest of the pharmaceutical industry for health care professionals to be accurately and adequately educated in clinical areas in which a company may have a product interest. The refinement of knowledge, skills, and attitudes on the part of physicians in any given area of medicine is likely to enhance patient care. We have been grateful for the participation of the pharmaceutical industry in the educational process and look forward to supportive participation in the future. However, promotion must be identified as promotion and education identified as education.

Pharmaceutical presentations to residents are an area in which differentiation between promotion and education is vague. Certainly, glossy presentation materials provided by an employee of a company must be viewed as both promotion and a legitimate business activity. At the same time, residents may learn about new products through this interaction. I believe family practice residency programs should welcome sales representatives into the residency, but within proper guidelines appropriate to the individual residency program. The faculty should be responsible for tuning up its own skills at differentiating education from promotion and for helping residents prepare for this aspect of their future professional life.

Following initial discussions and agreements between the CME provider and the company that is financially supporting the continuing education, the CME provider must be independent in its development of content and speakers for the CME activity, be it in symposia, print, audio or video form. The documents published by the AMA, ACCME, and AAFP, as well as similar statements by certain highly regarded pharmaceutical companies and other specialty societies, provide broad, general guidelines in this regard.

A 1990 paper published by the American College of Physicians entitled "Physicians and the Pharmaceutical Industry" suggested a "sunshine test" to be applied to any relationship between industry and physicians about which there may be question.[4] 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 a proprietary entity.

A concrete and more formalized means of applying light to any arrangement is through the use of disclosure forms. A potential conflict of interest or commitment must be revealed to the planners of a continuing medical education activity as well as to the audience. The completion of a disclosure form by a faculty member or author allows the planners of the activity to consider whether a possible conflict could preclude participation. Certainly, program planners desire faculty who have multiple involvements and are active beyond their own narrow area. Therefore, in most cases, indications of travel or research support should not prevent participation. The AAFP has recently adopted disclosure forms for completion by CME presenters and organizational officials.

We in the healing professions owe our patients high-quality medical care enhanced by continuing medical education activities. We owe the consumers of our educational processes high-quality education that, although in part supported by industry, is free from bias. The AAFP, other medical organizations, and their members are meeting this challenge.

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4. American College of Physicians. Physicians and the pharmaceutical industry. Ann Intern Med 1990; 112:624–6.

See articles on pages 49 and 54.

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