

Conflicts of Interest and Medical Practice

A position statement of the American College of Physicians (ACP) observed that “[p]hysicians 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” (Coyle et al., 2002a, p. 397). This chapter examines these relationships and the sources of conflicts of interest in the context of practicing physicians’ primary professional obligations.

Professionals are granted important privileges—including the power to set educational and ethical standards—in return for maintaining competence, being trustworthy and ethical, and working to benefit patients and society. The power to set standards creates certain tensions. As Pellegrino and Relman (1999) have written, “[t]oo often, ethical goals have been commingled with protection of self-interest, privilege, and prerogative. Yet, effacement of self-interest is the distinguishing feature of a true profession that sets it apart from other occupations” (p. 984).

In the realm of patient care, threats to professionalism and questions about conflicts of interest may arise in several situations, some of which involve pharmaceutical, medical device, and biotechnology companies and some of which do not. This chapter focuses on physician financial relationships with industry that usually are not intrinsic to medical practice and that can be avoided. These relationships create conflicts of interest when physicians

- accept company gifts of various kinds, including meals and drug samples;

- act as promotional speakers or writers on behalf of companies;
- or
- have a financial interest in a medical product company whose products they prescribe, use, or recommend.

In addition, conflicts of interest arise from the ways in which physicians are paid for their services. These conflicts are inherent in any payment system, although each payment method raises different concerns. Physician ownership of health care facilities and self-referral practices also present important and widespread conflicts of interest that have challenged government in its efforts to manage, limit, or eliminate them.

This chapter begins with a brief discussion of physician payment and facility ownership interests as parts of the broader context of medical practice. As planned by the Institute of Medicine, this study was not intended to consider recommendations on physician payment; that is a primary charge of the Medicare Payment Advisory Commission (MedPAC; a body that advises the U.S. Congress). The committee also was not constituted to consider physician ownership and self-referral issues, which would have involved the in-depth examination of a complex regulatory and commercial environment. Therefore, the discussion of these topics is only brief.

The chapter then examines industry promotional activities aimed at practicing physicians and also reviews the responses to concerns about physician financial relationships with industry from private organizations and public agencies. Because the committee considered financial relationships with industry in the context of physicians' professional obligations, the chapter includes a discussion of professional codes of conduct and statements on conflicts of interest in medical practice from professional societies. The chapter concludes with recommendations for the physician community; health care providers; and pharmaceutical, medical device, and biotechnology companies.

THE BROADER CONTEXT: PHYSICIAN PAYMENT, SELF-REFERRAL, AND CONFLICTS OF INTEREST IN MEDICAL PRACTICE

The environment of medical practice has changed significantly in recent decades. Physicians providing patient care have experienced reduced autonomy, increased administrative burdens, and declining incomes. As shown in Figure 6-1, the real income of physicians from medical practice declined about 7 percent from 1995 to 2003, a pattern that contrasts with that for other professional and technical workers. Flat or declining fees from public and private payers appear to be a major contributor to the trend (Tu and Ginsburg, 2006). Although the committee did not locate a

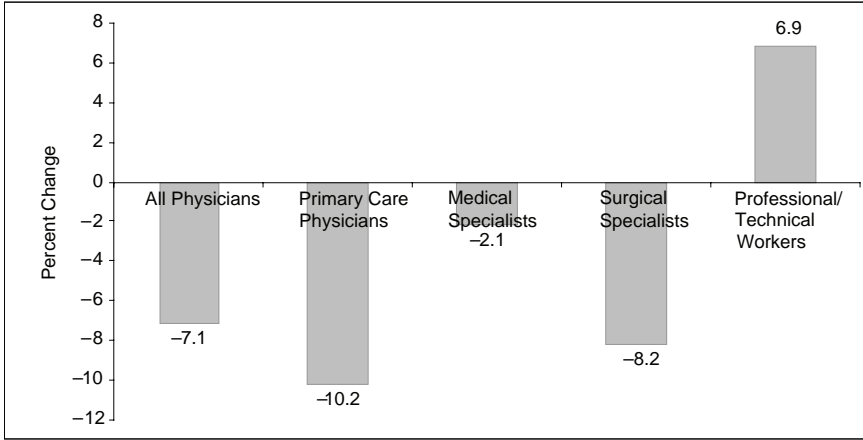


FIGURE 6-1 Percent change in average net physician income, adjusted for inflation, 1995 to 2003. Physician income data are based on reported net income from the practice of medicine (after expenses and before taxes). SOURCE: Tu and Ginsburg, 2006.

more recent analysis of trends, some data (e.g., comparisons of Bureau of Labor Statistics physician and surgeon income data for 2006 and 2007) suggest a more favorable income picture in recent years.

Physician Payment and Conflicts of Interest

Researchers and policy makers have devoted considerable attention to the day-to-day incentives for inappropriate clinical practice related to physician payment arrangements. Each major method of paying physicians has the potential to put physicians' primary interest in promoting the best interests of their patients at odds with their secondary financial interests.

Many studies have concluded that paying physicians for each service that they provide creates incentives for physicians to increase the volume of services, which also increases their income and society's spending for health care (see the reviews by CBO [1986], OTA [1986], PPRC [1987], Smith [1992], and Hsiao et al. [1993]). In addition, the appropriate pricing of specific services and categories of services is a concern (see, e.g., Ginsburg and Grossman [2005] and Bodenheimer et al. [2007]). Higher levels of reimbursement for procedures (e.g., surgeries, invasive procedures, diagnostic imaging, and chemotherapy) compared with the level of reimbursement for non-procedure-related services (e.g., history taking, medical evaluations, and counseling) have contributed to an escalation in the use of procedures and to the shift in the performance of certain lucrative procedural services

from hospitals to physicians' offices. One analysis of information from national surveys and long-term, in-depth studies of 12 local markets concluded that physicians' business practices contribute to higher costs and that "policymakers may need to revisit regulation of physicians' conflicts of interest and consider how their financial incentives could be realigned" (Pham et al., 2004, p. 70).

Payments to physicians on a capitated basis (i.e., a fixed, per person payment for a patient population) and managed care restrictions on referrals and certain services raise concerns about the underprovision of needed care (see, e.g., Hillman [1987], GAO [1995], Rodwin [1996], and Sulmasy et al. [2000]). In general, payment methods have become more complex as public and private health insurers have offered incentive payments to physicians related to quality standards, patient satisfaction, and better patient outcomes (see, e.g., Epstein et al. [2004], MedPAC [2005c], Rosenthal et al. [2007], and Nicholson et al. [2008]).

Self-Referral and Physician Ownership of Health Care Facilities

A former editor of the *New England Journal of Medicine* observed that "[p]hysicians have been conflicted about their dual roles as professionals and businessmen for millennia, but this dilemma has sharpened in recent years as income from the practice of medicine has faltered" (Kassirer, 2001, p. 159). The dilemma is particularly evident, first, in the growth of physician ownership of (or other business arrangements with) outpatient diagnostic or treatment centers and specialty hospitals to which they refer patients and, second, in the increase in expensive in-office ancillary equipment (e.g., equipment used for imaging and other diagnostic services ordered by the physician owner). As described by Pham and Ginsburg (2007)

The allure of profitable services has led to increased physician ownership of ambulatory surgical, imaging, and endoscopy centers and other free-standing facilities such as specialty hospitals. For example, the number of cardiac and orthopedic specialty hospitals serving Medicare patients grew from twenty-one in 1998 to sixty-seven in 2003, the majority of which were for-profit and owned in part by physicians. The number of ambulatory surgery centers (ASCs) grew more than 35 percent between 2000 and 2004, with 83 percent of existing centers partly or wholly owned by physicians. In addition, physicians have brought the capacity for more diagnostic and therapeutic procedures into their practices. (p. 1591)

Physicians' ownership interests in facilities to which they refer patients constitute a conflict of interest. Their secondary interest (i.e., increased income from increased services) has the potential to bias physicians' primary interest in their patients' welfare. Such conflicts of interest may harm

patients who receive unnecessary services and may also harm society, which is burdened by excess spending on these services. In fact, some research has contradicted claims that physician ownership improves access for underserved populations (see, e.g., OIG [1989], Hillman et al. [1990], and Mitchell and Scott [1992]).

Concerns about physician self-referral have prompted the passage of complex federal legislation and the implementation of regulations (often collectively referred to as the “Stark laws,” after the sponsor of relevant provisions in the Omnibus Budget Reconciliation Act of 1989 and other legislation). In general, federal law prohibits physicians from referring Medicare or Medicaid beneficiaries to entities for “designated health services” if the physicians or their immediate family members have ownership or investment interests in the entities or have compensation arrangements with the entities (42 USC 1395nn and 42 USC 1396b(s)).¹

In 2008, the Centers for Medicare and Medicaid Services issued a new rule requiring physicians to disclose to patients the physician’s ownership of or investment in hospitals (CMS, 2008). It is too early to evaluate the experience with this requirement, although the discussion reviewed in Chapter 3 suggests that the need for caution in assuming the effectiveness of disclosure alone as a safeguard against making biased recommendations. In 2009, MedPAC recommended that Congress require hospitals and other entities that bill Medicare to report physician ownership interests (direct and indirect) and that this information be posted on a public website (MedPAC, 2009). MedPAC also recommended that the secretary of the U.S. Department of Health and Human Services submit a report on the types and prevalence of financial arrangements between physicians and hospitals.

INDUSTRY PROMOTIONAL ACTIVITIES AND PRACTICING PHYSICIANS

Scope and Nature of Marketing Activities

Marketing is a major expense for pharmaceutical companies. A recent analysis estimated that pharmaceutical company expenditures for promotional activities were \$57.5 billion in 2004, including \$20.4 billion for

¹ “Whole” hospitals are not included under the law, which some suggest has been a factor spurring the growth of physician-owned specialty hospitals (Mitchell, 2008). The law also does not cover the purchase and use of imaging and other ancillary equipment within a physician’s office. Designated health services include clinical laboratory services; inpatient and outpatient hospital services; diagnostic radiology services; radiation therapy services and supplies; durable medical equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health care services; physical therapy services; outpatient prescription drugs; occupational therapy services; and parenteral and enteral nutrients, equipment, and supplies.

detailing (sales visits) by drug company representatives, \$15.9 billion for drug samples, and \$2.0 billion for meetings (Gagnon and Lexchin, 2008). Little information is available on the marketing of medical devices and biologics.

Pharmaceutical company representatives use a variety of interpersonal techniques, including gift giving, to establish relationships with physicians and promote their products.² They may calibrate their approach to their assessments of the physician's personality and intellectual style (see, e.g., Roughead et al. [1998], Fugh-Berman and Ahari [2007], and Greene [2007]). In addition, companies have information on individual physician prescribing practices that they can use to target physicians and then monitor the effects of their relationships (Steinbrook, 2006). As described in Chapter 1 and discussed further in this chapter, some of that information is compiled from physician data sold by the American Medical Association (AMA).

Companies may also use physicians as marketing agents. For example, an article in the *Wall Street Journal* reported data from a market research firm showing that in 2004 pharmaceutical companies sponsored some 237,000 meetings or talks that featured physicians and 134,000 meetings or talks conducted by sales representatives, up from about 60,000 talks of each type in 1998 (Hensley and Martinez, 2005). The same article also cited an internal study conducted by Merck that estimated that discussion groups led by physicians yield almost twice the benefit in terms of additional prescriptions as discussion groups led by sales representatives.

A specific example of the use of physicians for marketing involved a new vaccine for human papillomavirus and cervical cancer. The project signed up "hundreds of doctors and nurses . . . as unofficial spokesmen" who were trained by the pharmaceutical company and were "provided with a multimedia presentation and paid \$4,500 for each 50-minute talk, delivered" at company-sponsored meals (Rosenthal, 2008, unpagged).

The scope of pharmaceutical company payments for speeches given by physicians is suggested in a report by the Vermont attorney general based on information received under the state's payment disclosure law (see Chapter 3). Between July 1, 2006, and June 30, 2007, pharmaceutical companies in that state spent almost \$3,140,000 on payments to physicians and other providers; 52 percent of the payments were for speaker fees and 30 percent were for food (Sorrell, 2008). As discussed below, companies may

² A press release from PeopleMetrics Rx about a study of the influence of drug sales representatives on physician prescribing practices stated that the study found "that sales representatives must develop personal relationships with their physicians to achieve the highest levels of engagement" and that "emotional components such as friendship with the reps are the strongest indicators of Fully Engaged physicians [which] . . . has a positive impact on the duration and frequency of meetings and physician prescribing patterns" (*Business Wire*, 2008).

also market to community physicians through “seeding trials” of medications approved by the Food and Drug Administration.

Surveys of Physician Relationships with Industry

Surveys show that relationships with industry are common among physicians across the nation. In a national probability sample of more than 3,100 physicians, 94 percent reported that they had had some type of relationship with industry during the preceding year. These relationships were primarily the receipt of food in the workplace (83 percent) or drug samples (78 percent) (Campbell et al., 2007a). Thirty-five percent received industry reimbursement for costs associated with professional meetings or continuing medical education; and 28 percent received payments for activities such as consulting, serving on a speakers bureau, or enrolling patients in clinical trials. Cardiologists were more than twice as likely as family practitioners to receive payments, but family practitioners met more frequently with industry representatives than physicians in other specialties. Physicians in solo/dual or group practices met more frequently with representatives than physicians practicing in hospitals and clinics. In sum, relationships between physicians and industry are common and vary by specialty, practice type, and professional activities.

Another national survey of physicians also found that relationships with industry are common: 92 percent of physicians had received free drug samples; 61 percent had received meals, tickets to entertainment events, or free travel; and 12 percent had received financial incentives to participate in drug trials (KFF, 2002). The survey found that 15 percent of respondents thought that drug representatives provided “very useful” information, with another 59 percent describing the information as “somewhat useful.” Only 9 percent thought that the information was “very accurate,” whereas 72 percent thought that it was “somewhat accurate” (KFF, 2002).

A study of community obstetricians-gynecologists reported that most physicians believed that it was appropriate for physicians to accept drug samples (92 percent), a lunch at which information was provided (77 percent), or an anatomical model (75 percent) (Morgan et al., 2006). Just over half (53 percent) thought that it was appropriate for a physician identified as a “high prescriber” to accept a representative’s invitation “to sit in” on a market research meeting as a well-paid consultant. In response to a question about whether interactions with industry should be more strictly regulated, 40 percent disagreed, 34 percent agreed, and 26 percent were neutral. As was found in a number of other studies, the respondents thought that other physicians were more likely (probably or almost surely) to be influenced by receiving a drug sample than the respondents were (38 percent for other physicians versus 33 percent for the respondents). The researchers found no

association between the responses and familiarity with the codes of conduct of professional societies.

The studies reported here and in Chapter 5 occurred before the Pharmaceutical Research and Manufacturers of America (PhRMA) revised its *Code on Interactions with Healthcare Professionals* in 2008. These revisions, which set some limits on gift giving and other relationships and which are discussed further below, took effect in January 2009. The Advanced Medical Technology Association (AdvaMed) adopted similar revisions in its *Code of Ethics on Interactions with Health Care Professionals*, effective in July 2009. Thus, it is too early to gauge the effects of these changes on physician relationships with pharmaceutical and medical device companies.

Participation of Community-Based Physicians in Clinical Trials

As mentioned in Chapter 4, physicians in private office settings are increasingly participating in clinical trials that are sponsored by industry and managed by contract research organizations or research site management organizations. The percentage of clinical trials conducted in academic health centers has decreased, and academic health centers are now in the minority among the locations for clinical trials (Klein and Fleischman, 2002). The marketing aspects of some of these trials were described above. The involvement of practicing physicians in clinical trials in the community has potential benefits. For example, their patient pool may be more representative of all patients with the condition being studied than the patient pool of academic physicians, so the results may be more generalizable. Furthermore, the recruitment of participants and the conduct of the study may be more rapid and less expensive in the community setting than in academic medical centers. In addition, such trials may be educational for the participating physicians.

Several concerns have, however, been raised about conflicts of interest in industry-sponsored trials involving community physicians. First, payments to participating physicians may provide incentives to enroll and retain patients, but they may also exceed actual expenses. In guidance provided to pharmaceutical companies, the Office of the Inspector General of the U.S. Department of Health and Human Services has cautioned against payments that exceed fair market amounts for “legitimate, reasonable, and necessary services” (OIG, 2003, p. 21). Second, practicing physicians may have a powerful influence over their patients, perhaps more so than physicians in academic centers, which have high rates of turnover of residents, fellows, and faculty and which allow investigators studying common diseases to recruit participants who are not their personal patients.

In addition, some clinical trials in community practices may be “seed-

ing” trials that companies design to change prescribing habits rather than to gather scientifically useful information (Hill et al., 2008; see also Psaty and Rennie [2006] and Sox and Rennie [2008]). As described in an analysis of documents obtained during litigation, the strategy of such trials is to “target the [clinical] trial to a select group of customers—in this case, primary care physicians; use the trial to demonstrate the value of [the drug] to these physicians; integrate the marketing division and those responsible for trial-related operations in the field with the highest level of precision; and carefully track marketing-related results, that is, rates of [product] prescriptions written by study physicians” (Hill et al., 2008, p. 253). The company in the case under litigation described the physicians as “key customers” (p. 255) and provided them with materials to market their involvement in the study. It also “hid the marketing nature of the trial from participants, physician investigators, and institutional review board members” (Hill et al., 2008, p. 251). As an additional marketing tool, companies may sometimes employ physician opinion leaders as consultants on the use of a drug under study.

A study by Andersen and colleagues (2006) found that general practitioners involved in industry-sponsored studies increased their use of the trial sponsor’s drugs, which is consistent with the purpose of using the seeding strategy. Whether the increased use was medically appropriate was not evaluated, but seeding studies subvert ethical standards for research conduct and can put patients at risk.

As part of a broad policy that prohibits or limits many types of company payments to physicians and requires disclosure of other payments, Massachusetts recently issued regulations that require disclosure by companies of payments to physicians for studies “that are designed or sponsored by marketing departments of manufacturers or that are undertaken to increase sales of a particular drug, biologic or medical device” (Lopes, 2009, p. 8). Payments for scientific research need not be disclosed.

Community Versus Academic Practice Environment

Chapter 5 reported on the extensive relationships between academic physicians and industry and discussed industry promotional activities undertaken in the context of graduate and undergraduate medical education. It reported on studies that suggest that industry relationships and promotional activities (e.g., detailing visits) in both academic and general practice settings may influence physician prescribing patterns and requests for additions to hospital formularies. It also reported on studies—conducted mostly in academic settings—that indicate that the provision of free drug samples to physicians may contribute to inappropriate prescribing practices, lower

rates of use of generic and over-the-counter drugs, and increased drug costs.

Chapter 5 also noted that trainees in academic settings have ready access to the latest scientific information through faculty experts and advanced information technologies that they may use to search the medical literature; they do not require interactions with company sales representatives to obtain information on a new drug or its use. Faculty members—in addition to being in the forefront of knowledge development and evaluation in their own fields—also have ready access to the expertise of their colleagues. In contrast, community physicians have less access to such expertise, and that has been one argument in support of visits to community physicians by drug company sales representatives. Sales representatives are, however, tasked with promoting their company's products and not with providing a balanced assessment of the evidence for the use of different clinical options, including nonpharmacologic approaches.

One response to the informational needs of community physicians has been the development of accredited continuing medical education programs. Nevertheless, a recent historical review of pharmaceutical marketing and physician education suggested unintended consequences, that is, the provision of “novel sites of intersection between pharmaceutical marketing and physician education” (Podolsky and Greene, 2008, p. 833). Concern about such consequences has, in turn, produced new approaches, including the “academic detailing” programs described later in this chapter.

In research, the community practice environment is clearly different from the environment in academic medical centers and major teaching hospitals. Although the research may be reviewed in advance by an institutional review board, community physicians may receive no training in the standards of the ethical conduct of research, may have little contact with experienced clinical researchers, and may lack the knowledge needed to review contract or research descriptions provided by a company. In sum, the environment in which community physicians interact with industry may be quite different from the environment of academic physicians discussed in Chapter 5.

RESPONSES TO CONCERNS ABOUT INDUSTRY RELATIONSHIPS AND CONFLICTS OF INTEREST IN COMMUNITY PRACTICE

Responses to concerns about physician financial relationships with industry date back many years. For example, in 1972 the U.S. Congress acted to outlaw certain industry payments or other inducements to physicians. The discussion below focuses on the responses to those concerns made by professional societies, industry, and government. It does not examine responses by provider organizations, such as multispecialty group

practices or hospitals. The committee found no systematic information on the responses by such organizations but identified examples of conflict of interest or other policies that restrict certain individual or organizational relationships with industry (see, e.g., Kaiser Permanente/TPMG [2004], Vesely [2005], and Henry Ford Health System [2007]). Consistent with the emphasis on professional values in this chapter, this section begins with a review of professional society policies.

Professional Societies

Several medical professional organizations have adopted guidelines, codes, or other statements that cover physician relationships with industry, but the committee found no comprehensive overview of statements (or the absence of statements) from professional societies. A selective review of society policies suggests that statements about gifts are fairly common, whereas statements about promotional speaking, ghostwriting, and consulting arrangements are not. A number of professional groups have endorsed a charter for medical professionalism that identifies “maintaining trust by managing conflicts of interest” as 1 of 10 key responsibilities of physicians (ABIM Foundation et al., 2002, p. 245).

Box 6-1 includes excerpts from general statements by AMA and ACP on gifts from industry to physicians. The AMA statement, which was first adopted in 1990, has been endorsed or used as a model by a number of other professional societies, including the American Academy of Pediatrics (Fallat and Glover, 2007), the American College of Obstetricians and Gynecologists (Morgan et al., 2006), and the American College of Rheumatology (ACR, 2007). AMA has also made specific recommendations regarding medical device representatives. It emphasizes that information from or training by such representatives should not be a substitute for the appropriate training of physicians and should be subject to facility policies that govern the presence of such representatives (e.g., informing patients, protecting privacy, and credentialing) (AMA, 2007).

Although ACP strongly discourages the acceptance of gifts and poses some pointed questions for physicians to consider before accepting them, it acknowledges that many physicians feel more comfortable with gifts than the tone of its position statement would imply (Coyle et al., 2002a). The statement observes that “[i]deally, 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” but “[a]s a practical matter, many physicians are comfortable” accepting gifts of modest value that may enhance medical practice or knowledge (p. 398).

BOX 6-1
Excerpts from Statements on Gifts by American Medical Association and American College of Physicians

American Medical Association

Ethical Opinion E-8.061: "Ultimately, it is the responsibility of individual physicians to minimize conflicts of interest that may be at odds with the best interest of patients and to access the necessary information to inform medical recommendations. . . . (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. . . . (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads). . . . (7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices" (AMA, 2002 [updated]).

American College of Physicians

"The acceptance by a physician of gifts, hospitality, trips, and subsidies of all types from the health care industry that might diminish, or appear to others to diminish, the objectivity of professional judgment is strongly discouraged. As documented by some studies, the acceptance of even small gifts can affect clinical judgment and heighten the perception and/or reality of a conflict of interest. Accordingly, physicians need to gauge regularly whether any gift relationship is ethically appropriate and evaluate any potential for influence on clinical judgment. In making such evaluations, it is recommended that physicians consider such questions as 1) What would the public or my patients think of this arrangement? 2) What is the purpose of the industry offer? 3) What would my colleagues think about this arrangement? 4) What would I think if my own physician accepted this offer? In all instances, it is the individual responsibility of each physician to assess any potential relationship with industry to assure that it enhances patient care and medical knowledge and does not compromise clinical judgment" (Turton and Snyder, 2007, p. 469, revising Coyle et al., 2002a).

With respect to consulting, the ACP policy also advises physicians to "guard against conflicts of interest when invited to consult or speak for pay on behalf of a company" because "[i]t 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" (Coyle et al., 2002a, p. 399). Furthermore,

Physicians should also be circumspect if asked to deliver educational programming developed by a medical education and communication company. Such companies, which are largely financed through the pharmaceutical industry, are for-profit developers and vendors of continuing medical education. 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. (Coyle et al., 2002a, p. 399)

During the course of the committee’s work, the Council of Medical Specialty Societies (CMSS) initiated a project to collect best practices on disclosure and limitation of conflict of interest and develop a statement on conflict of interest (The Associated Press, 2008). A CMSS task force recently recommended elements that specialty society policies should include, and it also proposed the development by CMSS of a template for such policies. The task force recommended that societies post their policies and provide information about the financial support that they receive from industry (CMSS, 2008). The CMSS earlier adopted a consensus statement on medical ethics that, among other provisions, states that:

- Physicians should resolve conflicts of interest in a way that gives primacy to the patient’s interests.
- Physicians have an ethical obligation to preserve and protect the trust bestowed on them by society (CMSS, 1999, unpagged).

Although this chapter focuses on individual physicians, professional societies as organizations may also have financial relationships with industry. Such relationships include unrestricted educational grants, income from exhibitions and meetings, industry advertisements in the journals of professional societies, and funding for the development of practice guidelines. As discussed further in Chapter 8, such relationships can constitute institutional conflicts of interest, and the committee recommends the adoption of policies on such institution-level conflicts.

The committee found little information about the positions of state medical societies on individual or organizational relationships with medical product companies. The Wisconsin Medical Society announced in 2008 that

its policy (which is not binding on physicians) is now that physicians should not accept gifts from companies whose products they prescribe to their patients. It noted that a “complete ban eases the burdens of compliance, biased decision making, and patient distrust” (WMS, 2008, unpagged).

Industry Codes and Company Actions

As mentioned above, the PhRMA *Code on Interactions with Health-care Professionals* was revised in 2008 (and was effective in January 2009) and the AdvaMed code was also revised in 2008 (and was effective in July 2009). Some of the PhRMA code’s provisions are summarized in Box 6-2. Overall, the revised code discourages noninformational physician-company relationships, such as speaker training programs at resorts and meals provided by sales representatives outside a physician’s office or other medical setting. In addition, the revised code provides that the chief executive officers and compliance officers of companies certify yearly that they have a process in place to implement the code. Companies that do that will be identified on the association’s website; AdvaMed has announced similar plans.

The 2008 revisions to the PhRMA code also include provisions about contracting arrangements. The document describes several factors as relevant to determining the legitimacy of such arrangement, including whether

- a written contract specifies the nature of the consulting services to be provided and the basis for payment of those services;
- a legitimate need for the consulting services has been identified in advance of requesting services and entering into arrangements with consultants;
- the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular health care professionals meet those criteria;
- the number of health care professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining company maintains records concerning and makes appropriate use of the services provided by consultants; and
- the venue and circumstances of any meeting with consultants are conducive to the consulting services, and activities related to the services are the primary focus of the meeting; specifically, resorts are not appropriate venues (PhRMA, 2008, p. 8).

Partly in response to U.S. Department of Justice litigation and guidance from the Office of the Inspector General of the U.S. Department of Health

BOX 6-2
Summary of Selected Recent Revisions in the PhRMA
Code on Interactions with Healthcare Professionals

Companies should not

- offer health care professionals any entertainment or recreational items or any gifts (e.g., notepads, mugs, and pens) that “do not advance disease or treatment education”;
- create consulting arrangements as inducements or rewards for prescribing or recommending a particular medicine or course of treatment;
- create speaking engagements as inducements or rewards for prescribing a particular medicine or course of treatment or provide speaker payments above fair market value;
- fund continuing medical education programs as inducement to prescribe or recommend a particular medicine or course of treatment;
- directly subsidize the participation of a health care professional in such a program or in other conferences or professional meetings or create token consulting arrangements to do so indirectly; and
- directly provide meals at continuing medical education events.

Companies may, subject to certain standards,

- have sales representatives make informational visits to physicians and provide modest meals in connection with the visit;
- provide financial support to providers of continuing medical education so that they may reduce registration fees for programs;
- support professional and scientific meetings at appropriate locations in accord with the guidelines of the organizations supported;
 - arrange for expert consultants on topics such as the marketplace, patient care, and products;
 - sponsor speaker programs and provide training and reasonable compensation for speakers;
 - provide scholarships for students and professionals to attend educational conferences; and
 - provide educational and practice-related items of modest value to physicians.

and Human Services, some pharmaceutical companies have already revised their contracting practices. In addition, some individual pharmaceutical companies have announced that they will voluntarily post information about a range of payments to individual physicians. For example, Eli Lilly announced that it would create a publicly accessible registry of its payments to physicians beginning in 2009 (Lilly, 2008). Pfizer has released information about its grants and educational awards to medical, scientific, and

patient organizations and has announced that it is eliminating grants to commercial providers of continuing medical education (Pfizer, 2008).

Government Responses

Chapters 1, 3, and 5 discussed various responses by federal and state governments to concerns about financial relationships involving physicians and industry. At the state level, these responses range from laws requiring company disclosure of certain payments to physicians to laws restricting or prohibiting certain relationships. As noted above, some federal agency policies require disclosure of certain physician ownership interests in health care facilities, and MedPAC has proposed a substantial expansion of disclosure of such interests.

As discussed in Chapter 2, conflicts of interest do not necessarily involve actual undue influence, but they may. In some cases, they may be illegal. Federal law prohibits “any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind” in return for ordering, purchasing, or referring patients for services or items covered by a federal health care program (42 USC 1320a-7b(b)). Such remuneration has sometimes been disguised as payments to physicians for education, consulting, or research.

In 2003, the Office of the Inspector General of the U.S. Department of Health and Human Services issued guidance for pharmaceutical companies on complying with federal laws and regulations. The guidance included a discussion of how marketing and other relationships with physicians may be designed to reduce the risk of violations of the antikickback laws (OIG, 2003). It advised, for example, that payments for research, consulting, and advisory services be set at fair market value. The guidance also noted that certain practices that are common in other business areas may be illegal in the context of federal health care programs.

For the most part, prosecutions under the statute have been directed at the companies that offer inducements rather than at the individual physicians who accept them. Cases typically do not go to trial but end in financial settlements and compliance and monitoring arrangements (corporate integrity agreements) of some sort. Box 6-3 summarizes a few illustrative settlements of cases that involved various types of financial relationships between companies and physicians.³

³ At the state level, state attorneys general have reached settlements with companies that are similar to those reached by the U.S. Department of Justice. For example, Oregon was the lead state in a \$58 million settlement that involved 30 states and a 3-year investigation of deception in the marketing of rofecoxib (Vioxx), and the state was also involved in another multistate settlement involving charges of deceptive marketing of valdecoxib (Bextra) and celecoxib (Celebrex) (Oregon DOJ, 2008a,b).

BOX 6-3**Examples of Prosecutions Involving Kickbacks to Physicians**

In 1997, a physician at the Tufts University health maintenance organization reported to federal investigators that a marketer for TAP Pharmaceuticals had offered him an educational grant if he would reverse a health plan decision to list a competing drug in the plan's formulary. Investigators taped company employees offering the physician \$65,000 in "education" grants that he could use for any purpose. To settle these and other charges, the company agreed to pay the government \$875,000 and enter into a corporate integrity agreement (DOJ, 2001; Studdert et al., 2004).

In 2006, Medtronic agreed to pay \$40 million and enter into a corporate integrity agreement to settle charges of improper payments to physicians to promote the company's spinal devices. The improper payments included payments for physicians' attendance and expenses at medical education events and payments made under the guise of consulting, fellowship, royalty, and research activities (DOJ, 2006).

In 2007, the U.S. Department of Justice announced deferred prosecution agreements with four major orthopedic device manufacturers—Zimmer, Depuy, Biomet, and Smith & Nephew—that paid \$311 million to settle allegations that they used consulting agreements and other payments as illegal inducements for physicians to use their products during the period from 2002 to 2006. The companies also entered into corporate integrity agreements that would involve extensive monitoring of their consulting needs and arrangements for an 18-month period (DOJ, 2007a).

In 2008, an Arkansas neurologist settled a U.S. Department of Justice civil suit for \$1.5 million and also pled guilty to accepting kickbacks—gifts, funds for phony research studies, and sham consulting agreements—from Blackstone Medical, a medical device company (Demske, 2008).

In 2008, Merck reached an agreement with the U.S. Department of Justice to pay \$650 million to settle charges that it overcharged Medicaid for three popular drugs and that its sales representatives had devised a variety of illegal arrangements (e.g., payments disguised as being for training, consultation, or market research) to induce physicians to use its products. The company also agreed to a 5-year corporate integrity agreement to prevent future improper conduct (DOJ, 2008).

For the orthopedic device companies mentioned in Box 6-3, the deferred prosecution agreements with the U.S. Department of Justice had some features that are similar to those in some of the conflict of interest policies and proposals discussed in this report. One was that the companies agreed to post on their websites the names of physician consultants and the

payments made to them. In addition, new consulting agreements with physicians would require the physicians to agree to reveal the arrangement to their patients. For the 18-month period that they were in place, the deferred prosecution agreements provided that each company must undertake an assessment of its reasonable needs for educational consulting services and new product development consultants. They also provided for a federal monitor at each company to review compliance for all new and existing consulting relationships with the companies.

Academic Detailing and Other Prescriber Outreach Strategies

As one alternative to physician reliance on company sales representatives for information, “academic detailing” incorporates techniques that pharmaceutical company representatives use. Programs may use in-person visits to physicians by a clinical pharmacist or physician, provide educational materials and branded items, and offer individualized feedback on performance. The goal is to reduce inappropriate prescribing of targeted drugs, for example, inappropriate antibiotics and less effective vasodilators and analgesics. Randomized controlled trials have shown that such educational interventions are effective and have not found adverse clinical consequences (see, e.g., Soumerai and Avorn [1990], Solomon et al. [2001], van Eijk et al. [2001], and Simon et al. [2005]; but see also Lu et al. [2008]). These trials support other studies that suggest that the techniques that pharmaceutical company representatives commonly use are indeed effective in changing physician prescribing behavior.

Some states, including Pennsylvania, South Carolina, and Vermont, have initiated programs using such academic detailing. Pennsylvania’s program has an operating budget of approximately \$1 million per year, which funds about 1,000 detailing visits by a paid staff (Reck, 2008). Members of the U.S. Congress have proposed the creation of a federal program that would “provide grants or contracts for prescription drug education and outreach for healthcare providers and their patients” (HR 6752, July 31, 2008).

RECOMMENDATIONS

As described in this chapter, relationships between physicians in practice and drug and medical product companies are extensive and have prompted a range of responses from professional societies, government officials, and others. The environment of community medical practice presents challenges different from those posed in academic and research settings. In particular, physicians in community practice often have weaker ties with institutions than academic physicians and a greater degree of autonomy. In addition,

although Chapters 3 and 5 cite questions about the implementation of conflict of interest policies by academic institutions, these institutions are generally in a stronger position to enforce employee adherence to conflict of interest policies than professional societies are to enforce member adherence to their policies and codes of ethics.

Voluntary Action by Individual Physicians

The committee's first recommendation on conflict of interest in medical practice generally parallels that made for academic medical centers, except that it is directed in the first instance at voluntary action by individual physicians. The recommendation also calls on professional societies and health care providers (including hospitals, nursing homes, and hospices) to adopt supportive policies; but the committee believed that it was appropriate to call on physicians directly to adopt practices that are consistent with high standards of professionalism.

RECOMMENDATION 6.1 Physicians, wherever their site of clinical practice, should

- not accept items of material value from pharmaceutical, medical device, and biotechnology companies except when a transaction involves payment at fair market value for a legitimate service;
- not make educational presentations or publish scientific articles that are controlled by industry or contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged;
- not enter into consulting arrangements unless they are based on written contracts for expert services to be paid for at fair market value;
- not meet with pharmaceutical and medical device sales representatives except by documented appointment and at the physician's express invitation; and
- not accept drug samples except in specified situations for patients who lack financial access to medications.

Professional societies should amend their policies and codes of professional conduct to support these recommendations. Health care providers should establish policies for their employees and medical staff that are consistent with these recommendations.

The teaching mission of academic medical centers—which includes helping learners at all levels to think critically and appraise the evidence and

providing appropriate role models and mentoring—provides strong arguments for the corresponding recommendations in Chapter 5. Furthermore, physicians in academic settings have ready access to objective, up-to-date information about new therapies, which is often not the case in community practice. The committee recognized the differences in academic and community environments but viewed critical thinking and the appraisal of evidence as key components of life-long learning and medical professionalism for all physicians, wherever their site of practice. The committee believes that entering into the relationships listed in Recommendation 6.1 creates unwarranted risks of compromising physician judgment and undermining public trust—risks that are not outweighed by prospective benefits for patients or society.

Evidence cited in earlier chapters and Appendix D suggests that gifts and drug samples can be influential even when their economic value is small. They primarily serve to create goodwill and a sense of reciprocity and partiality toward the marketing representatives who give them. (Gifts include meals provided to physicians and their employees as part of sales visits.) Moreover, some evidence suggests that they are associated with prescribing patterns that are inconsistent with evidence-based practice guidelines. Other evidence cited in Chapter 5 suggests that patients may have more negative attitudes toward such gifts and their potential impact on behavior than physicians do. The committee sees no convincing professional reasons to justify the acceptance of gifts or other items of material value from industry but does see the risk of bias and the loss of public trust.

To the extent that physicians outside academic institutions make educational presentations and prepare scientific publications, they should—like their counterparts who are faculty at academic institutions—refrain from participation in speakers bureaus and similar promotional activities and refuse authorship of ghostwritten articles. A physician should participate in consulting arrangements on the basis of a company's need for the physician's expertise. Such arrangements should be documented in contracts with specific tasks and deliverables and should be paid for at fair market value.

The recommendations about interactions with sales representatives are slightly different for academic and nonacademic physicians. The committee recognizes that physicians in academic settings have different responsibilities as educators and also have excellent access to information about the latest scientific and clinical developments. Physicians in busy community-based practices need objective information about new drugs and devices, as well as information that compares new drugs and devices with existing drugs and devices and that provides alternatives to drugs and devices. By making visits to physicians' offices, company representatives may provide this information in a convenient manner. In the future, however, with the

continued growth of Internet resources and the development of prescriber outreach and other educational programs, alternative sources of timely, objective, up-to-date information should become more available and readily usable.

If a physician chooses to meet with pharmaceutical and device company representatives, certain conditions should apply. Meetings should be at the invitation of the physician and by appointment and should not involve gifts, including meals provided at the physician's office. In limited cases, it may be appropriate for meetings to take place in the presence of patients (with their informed consent), primarily when representatives are providing in-service education or assistance with devices or equipment.

A related issue is drug company access to physician prescribing information. Currently, drug companies can buy coded prescribing information from pharmacy benefits programs and pharmacy chains. Companies can also purchase data from the AMA Masterfile, which links physician license numbers with their names, addresses, and phone numbers. Some physicians and others have objected to this practice (Steinbrook, 2006). In response, AMA now allows physicians who do not want their identifying information to be provided to companies to fill out a form to request that their data not be made available to company sales representatives and their supervisors (O'Reilly, 2006). (Other company personnel could still have access to the information.) It would be preferable and a lesser burden on physicians for AMA to set the default option so that identifying information would not be provided unless a physician affirmatively agrees.

As discussed in Chapter 5, the committee recognizes that access to affordable medications is a serious problem for many Americans, but it believes that reliance on drug samples is an unsatisfactory response. Samples are typically available only for newer and heavily marketed drugs, which may have no proven clinical benefits over alternatives, including less expensive equivalent drugs or generics. Although a sample may be convenient for the patient, it may not be the most appropriate medication. Many samples are provided to patients with insurance coverage and to physicians and their families, groups that do not have impaired access to medications. In such situations, the convenience of samples is outweighed by their potential to undermine evidence-based, cost-effective prescribing. For patients with chronic illnesses who lack the ability to pay for medications, a sample should be a stopgap that is accompanied by referral of the patient to a public or pharmaceutical company assistance program that can provide continuity of treatment. If physicians decide to accept drug samples, they should be given to patients who lack financial access to medications in situations in which appropriate generic alternatives are not available and the medication can be continued at little or no cost to the patient for as long as the patient needs it. The committee recognizes that physicians in

community practice may not have the option of using a centralized system of administration of drug samples, which is available in many academic medical centers. Some committee members were in favor of banning the acceptance of drug samples altogether and advocating for other mechanisms for providing access to drugs for indigent patients.

Recommendation 6.1 does not mention physician disclosure of financial relationships to patients. Patients could obtain that information, however, if the U.S. Congress were to require companies to disclose payments to physicians and to place that information on a searchable public database and also requires hospitals and other health care providers to report physician ownership interests. This option would avoid the interpersonal complexities involved with patients directly requesting or physicians directly providing such information. Patients and their families would need to be informed about the database, possibly through the use of brochures or notices in medical offices. Studies of patient use of the database would be a potential topic for the research agenda recommended in Chapter 9.

Continued Actions by Industry

The next recommendation promotes continued actions by pharmaceutical, medical device, and biotechnology companies to support the core values and missions of medicine. Some but not all of the recommended actions are covered by the revised codes issued by PhRMA (2008) and AdvaMed (2008) and by federal agency guidance to pharmaceutical companies (OIG, 2003).

RECOMMENDATION 6.2 Pharmaceutical, medical device, and biotechnology companies and their company foundations should have policies and practices against providing physicians with gifts, meals, drug samples (except for use by patients who lack financial access to medications), or other similar items of material value and against asking physicians to be authors of ghostwritten materials. Consulting arrangements should be for necessary services, documented in written contracts, and paid for at fair market value. Companies should not involve physicians and patients in marketing projects that are presented as clinical research.

The committee is encouraged that some companies have already taken steps to end company provision of certain gifts and meals and to develop new procedures for contracting with physicians for their consulting work. The revisions in the PhRMA and AdvaMed codes are also encouraging steps, especially if provisions to track and publicize adherence are meaningful. Public disclosure of commitment to the codes should put pressure on

noncomplying companies and should also reduce any competitive disadvantage to those companies that do comply. The committee would, however, like to see the provisions on gifts extended, consistent with Recommendation 6.1. The adoption of Recommendation 3.4 (which proposes that the U.S. Congress establish a program that requires companies to report their payments to physicians, researchers, and institutions) should allow monitoring of some company practices.

If the levels of adherence to the policies and practices recommended here are low, governments may enact legislation to limit physician ties to companies, as the state of Massachusetts has. In general, committee members believed that voluntary limits should be given an opportunity to work and that legislation and regulation should be held as options if they do not. The reasoning was that this approach is more likely to reinforce professional values and allow more nuanced policies and standards that take into account the possibility of unintended consequences and that create fewer administrative burdens to be developed.

Other Recommendations in This Report

Other chapters of this report also offer some recommendations that could affect community physicians. To the extent they are involved in multiple activities that require the disclosure of financial interests (Recommendation 3.3), community physicians might face more specific disclosure requests but also more consistency in requests. If federal legislation requires pharmaceutical, device, and biotechnology companies to publicly report payments to physicians (Recommendation 3.4), some community physicians might choose to forgo certain relationships with industry that they find difficult to explain and justify. Community physicians who teach medical students or residents off-site would be affected by reforms in the policies of medical schools and teaching hospitals (Recommendation 5.1). A new system of funding continuing medical education (Recommendation 5.3) could lead to higher fees for attendees and reductions in the numbers, variety, and locations of course offerings. In addition, physicians who participate in professional society or other clinical practice guideline development activities might be limited in their involvement if they had conflicts of interest, especially conflicts involving promotional activities (Recommendation 7.1).