Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice; Lo B, Field MJ, editors. Conflict of Interest in Medical Research, Education, and Practice. Washington (DC): National Academies Press (US); 2009.

5 Conflicts of Interest in Medical Education

Medical education prepares physicians for a lifetime of professional work. Education that is objective and that teaches students how to critically evaluate the evidence prepares physicians to keep current with scientific advances throughout their professional lives.

This chapter is organized around the concept of the learning environment, which shapes and reinforces the professional attitudes and behavior of physicians throughout the continuum of learning that begins in medical school and extends through residency training and to lifelong learning. Learning environments in medicine are diverse. They include conference rooms and lecture halls, patient care locales (such as inpatient service and outpatient practice locations), laboratories, and the Internet. Some continuing education programs take place at restaurants or resorts.

If the learning environment provides the stage for education, the curriculum provides the script. Reviews of undergraduate and graduate medical education often emphasize the "formal curriculum" (i.e., required courses and explicit educational objectives).[1] That formal curriculum aims to help students develop the core competencies that are defined by accreditation agencies. Each educational activity has learning objectives, and the totality of educational sessions must address all the core competencies.

The learning environment also includes two other elements: the informal curriculum (i.e., ad hoc interactions among teachers and students) and the hidden curriculum (i.e., institutional practices and culture) (see, e.g., Hafferty [1998], Ratanawongsa et al. [2005], Cottingham et al. [2008], and Haidet [2008]). Ideally, these two elements convey messages that are consistent with the formal curriculum, but in practice they may not. For example, the formal curriculum might include course work on medical ethics, research methodology, and appropriate relationships with industry. Concurrently, the informal and hidden curricula might be characterized by disparaging faculty comments on their institution's conflict of interest policies and the failure of institutions to adopt and implement sound policies.

Unfortunately, some aspects of each curriculum may contribute to undesirable attitudes or practices. The Association of American Medical Colleges (AAMC) observed in a 2008 report that the conflicts created by a range of common interactions with industry can "[f]or medicine generally, and for academic medicine in particular … have a corrosive effect on three core principles of medical professionalism: autonomy, objectivity, and altruism" (AAMC, 2008c. 4). Members of the U.S. Congress have also expressed concern about commercial relationships in medical education, primarily continuing medical education (see, e.g., Finance Committee, U.S. Senate [2007]). In contrast to the requirements for recipients of U.S. Public Health Service research awards, the federal government does not require the recipients of direct or indirect funds for medical education to establish and administer conflict of interest policies.

This chapter next provides a brief background on the current context of medical education. It then examines the literature on conflict of interest issues and responses in the learning environments of undergraduate, graduate, and continuing medical education. The discussion covers access to educational environments by sales representatives of medical product companies (e.g., drug detailing, which is a visit to a doctor by a sales representative for a pharmaceutical company), the provision of drug samples and other gifts to faculty and students, and industry-sponsored scholarships and fellowships. A separate section considers a concern that cuts across all phases of education: intellectual independence in presentations and publications and the risks associated with speakers bureaus and ghostwritten publications. (Chapter 4 discussed concerns about how researcher conflicts of interest might affect their advice or supervision involving the research of medical students, residents, fellows, and junior faculty.)

The committee concluded that, in general, industry financial relationships do not benefit the educational missions of medical institutions in ways that offset the risks created. The chapter thus ends with recommendations that are intended to protect the integrity and limit the potential for undue industry influence in medical education. As explained in Chapter 1, the committee focused on conflicts of interest involving physicians and biomedical researchers; but much of the core rationale for the recommendations may be relevant to nursing, pharmacy, dentistry, and other professions, even though

some of the specifics might differ. Chapter 6 considers many of the same issues in the context of physicians in practice outside academic settings.

BACKGROUND AND CONTEXT

Scale and Oversight of Medical Education

American medical education evolved during the 19th and early 20th centuries from pure apprenticeships to proprietary medical schools of variable quality to a reformed and formal educational system that stresses both science and professionalism. During the middle decades of the 20th century, an increasingly elaborate structure of graduate (post-M.D.) medical education emerged, characterized by multiyear residencies in medical specialties beyond the traditional internship year. The latter half of the century saw the growth of requirements by state licensing boards and specialty certification boards for demonstrated participation in accredited continuing education activities (Caplan, 1996).

Today, the scale of American medical education is impressive. The United States has

- 130 accredited medical schools (AAMC, 2008d),[2] approximately 400 major teaching hospitals (Salsberg, 2008), more than 100,000 faculty members (Salsberg, 2008), and approximately 75,000 medical students (AAMC, 2008e);
- 8,355 accredited residency programs for 126 specialties and subspecialties (2006–2007) and more than 107,000 active full-time and part-time residents (2005–2006) (ACGME, 2007b); and
- 740 national providers of accredited continuing medical education (and 1,600 accredited state providers)[3] that reported more than 7 million physician participants in their programs (ACCME, 2008a, 2009), a number that includes multiple registrations among the nation's more than 800,000 active physicians (a count that includes medical residents) (Salsberg, 2008).

The Liaison Commission on Medical Education (LCME) is the oversight agency that is responsible for the accreditation of the nation's medical schools. Its members are appointed by AAMC and the American Medical Association (AMA). The Accreditation Council for Graduate Medical Education (ACGME) accredits residency training programs in the United States. The sponsoring institution for a residency program may be a hospital, medical school, university, or group of hospitals (ACGME, 2008). Accreditation bodies define the core competencies for students, residents, and fellows and ensure that the formal curriculum covers all essential aspects of medical education. ACGME board members are appointed by AAMC, AMA, the American Board of Medical Specialties, the American Hospital Association (AHA), and the Council of Medical Specialty Societies (CMSS). Accredited continuing medical education providers are accredited by the Accreditation Council for Continuing Medical Education (ACCME). Its member organizations are AHA, AMA, AAMC, CMSS, the Association for Hospital Medical Education, and the Federation of State Medical Boards. State medical societies may also accredit providers within a state.[4] In addition, AMA, the American Academy of Family Physicians, and certain other groups set standards and certify credits for specific courses that physicians can take (from accredited providers) to meet state licensure board and other requirements for accredited continuing medical education (see, e.g., AMA [2006, 2008b]).[5] Accredited providers usually issue certificates to document that a physician has completed a certified course. Consistent with common usage, this report uses the phrase accredited continuing medical education to refer to education that is (1) presented by accredited providers and (2) certified for course credits.

Changing Environment and Fiscal Challenges

Academic medical centers dominate the provision of undergraduate and graduate medical education. The institutions consist of two related enterprises: a medical school that trains physicians and conducts research and a system that provides health care services. The latter system may include teaching hospitals, satellite clinics, and physician office practices. Academic health centers include other health professions schools, such as a school of dentistry, nursing, or pharmacy (Wartman, 2007).

In recent years, academic medical centers have struggled financially because of low levels of payment for poor and uninsured patients, reductions in the Medicare indirect medical education adjustment for hospital payment rates, and lower profit margins for the provision of hospital services to Medicare patients. (In the late 1990s, medical schools also

faced declining admissions, but admissions increased from 2003 to 2007 [AAMC, 2008a].) At the same time, teaching hospitals have faced rising costs because of the incorporation of new medical informatics systems and expensive medical technologies and restrictions on the numbers of hours that residents may work. The Medicare Policy Advisory Commission has characterized 53 percent of major teaching hospitals as being under high financial pressure—compared to 28 percent of hospitals overall (MedPAC, 2009). Given these circumstances, financial support from industry may seem attractive.

Physicians in training also face financial challenges. In 2006, the median levels of debt of medical students graduating from public and private medical schools were $120,000 and $160,000, respectively (Jolly, 2007). Medical school graduates can expect to pay approximately 9 to 12 percent of their after-tax income after graduation for educational debt service (Jolly, 2007). This level of indebtedness and the delayed gratification of a profession that requires years of training before independent practice is permitted can contribute to a sense of entitlement, which, in turn, may position medical students, residents, and fellows to be strongly influenced by gifts and attention from representatives of pharmaceutical and medical device companies (see, e.g., Levine [2008]). Sierles and colleagues (2005) found that 80 percent of the medical students that they surveyed believed that they were entitled to gifts. In addition, as discussed in Chapter 6, once they are in practice, limits on reimbursements for physician services make debt repayment more of a burden than in the past and may make gifts and other financial relationships with industry more appealing.

Industry Funding of Medical Education

During most of the 20th century, medical product companies were not major participants in medical education. The exception was sales representatives, who provided information to residents and faculty as well as to nonacademic physicians. In the latter decades of the century, however, medical product companies became increasingly involved in sponsoring continuing medical education, including grand rounds and other academic-based programs. In a 2008 report on industry funding of medical education, a task force of AAMC observed generally that

> Over recent decades, medical schools and teaching hospitals have become increasingly dependent on industry support of their core educational missions. This reliance raises concerns because such support, including gifts, can influence the objectivity and integrity of academic teaching, learning, and practice, thereby calling into question the commitment of academia and industry together to promote the public's interest by fostering the most cost-effective, evidence-based medical care possible. (AAMC, 2008c. iii)

The committee found no data on the amount or proportion of undergraduate or graduate medical education supported by industry. It also found little systematic information on specific categories of financial support, for example, grants for residencies or fellowships, direct or indirect financial support for grand rounds, or donations for buildings or other capital items. The most extensive information on academic institutions' ties with industry comes from a 2006 survey of department chairs at medical schools and the 15 largest independent teaching hospitals (67 percent response rate). The responses indicated that 65 percent of clinical departments received industry support for continuing medical education, 37 percent received industry support for residency or fellowship training, 17 percent received industry support for research equipment, and 19 percent received unrestricted funds from industry for department operations (Campbell et al., 2007b). The committee did not categorize industry payments for meals, gifts, and visits by sales representatives as support for medical education because these activities do not fit the learning objectives in the formal curriculum.

Information on industry funding for accredited continuing medical education comes from yearly surveys by ACCME. Figure 5-1 shows that commercial sources (excluding advertising and exhibits at programs organized by accredited providers) provide a substantially larger share of income for education providers today than they did in 1998. By 2003, about half of all funding for accredited continuing medical education programs came from commercial sources. The fees paid by program attendees once provided the majority of provider income, but today industry-supported programs are often provided free or at reduced cost to physicians (Steinbrook, 2008a).

LEARNING ENVIRONMENTS IN MEDICAL SCHOOLS AND RESIDENCY PROGRAMS

The ultimate mission of medical education is to prepare physicians to provide effective, safe, high-quality, efficient, timely, affordable, and patient-centered care to patients. In revising the standards that provide the framework for essential aspects of medical education, both LCME and ACGME have recently emphasized how the learning environment can affect the development of core professional values and core competencies, including how to critically review the evidence and to commit to lifelong learning about scientific advances.

Both LCME and ACGME recognize the power of the local learning environment to shape the knowledge, skills, behaviors, and attitudes of the next generation of physicians. To achieve accreditation, institutions providing undergraduate or graduate medical education must have curricula and resources that, among other requirements, (1) promote the development of appropriate professional attributes; (2) help learners at all levels think critically and appraise the evidence base for research reports, practice guidelines, and marketing materials; and (3) provide appropriate role models and mentoring. In addition, a standard on the creation of the appropriate learning environment must be implemented (LCME Standard MS-31-A). Recently, ACGME has required institutions to have a statement or institutional policy that addresses interactions between vendor representatives or corporations and residents and their programs (Requirement III. B.13 [ACGME, 2007a]).

The Learning Environment in Undergraduate and Graduate Medical Education as a Target of Industry Influence

Scope of Relationships Between Industry and Students, Medical Schools, and Teaching Hospitals

Interactions between medical students and industry are common. Table 5-1 summarizes the results from a survey of third-year medical students at eight major medical schools. Almost all students had received an industry-provided lunch or other gift. More than one-third had attended a social event hosted by a drug company.

Information from two surveys of residency directors similarly documents frequent interactions with pharmaceutical companies. For example, a 2002 survey of emergency medicine residency program directors found that approximately 40 percent allowed industry to fund social activities, and a similar percentage allowed pharmaceutical representatives to teach residents (Keim et al., 2004). Twenty-nine percent said that industry travel support could be made contingent on residents attending an industry event. Only 50 percent said that they always or very frequently followed ACGME recommendations for industry funding of core lectures, and 10 percent said that they always or very frequently allowed pharmaceutical representatives unrestricted access to residents. In a 2002 survey of psychiatric residency program directors, 88 percent reported that they allowed industry to provide lunches for their residents, and among this group, the mean was about five lunches per week (Varley et al., 2005). Approximately a third of the programs solicited travel funds from industry (31 percent) or allowed residents to seek such funding from industry on their own (34 percent).

Value of Relationships

Some interactions with industry can have educational value, for example, when an industry scientist participates in a seminar on drug development strategies or when a device company representative provides supervised training on a complex and innovative medical device that has recently been approved for marketing. Other examples may include unrestricted grants to academic medical centers that support student or resident research stipends or participation in scientific conferences. On a much larger scale, universities have benefited from company gifts for buildings, research programs, and auditoriums.

Pharmaceutical companies argue that their representatives provide information on new drugs. Yet, medical students, residents, and fellows have ready access to the latest scientific information through faculty members, information technologies that allow them to search the medical literature, and open-access sources of evidence-based literature reviews and summaries. The committee recognizes that some medical students and residents who have become accustomed to interactions with representatives may value the meals that they receive as a respite and may view the gifts that they bring as either inconsequential or as an appropriate reward for their demanding schedules and economic sacrifices.

The discussion below focuses on several different types of academic-industry relationships and the literature about their consequences. Each section includes a discussion of private- and public-sector responses to concerns about the extent and consequences of these relationships. In addition to consulting reports by AAMC and other groups, the committee examined the policies of a number of medical schools. It found many of these policies at or available through links from the websites of the American Medical Student Association (AMSA) and the Institute on Medicine as a Profession (IMAP). The AMSA website also includes the organization's scorecard, which presents school-by-school ratings of various policy elements (e.g., the policy on the acceptance of gifts) and which has received considerable attention from the media.[6]

The committee notes that the recommendations in the 2008 AAMC report on medical education apply off campus as well as on campus. The report calls for academic medical centers to "communicate to off-site training facilities their expectation that the off-site venues will adhere to the standards of the academic center regarding interactions with industry" (AAMC, 2008c. 10).

Site Access by Drug and Device Company Representatives

Issues and Evidence

Drug detailing, that is, a visit to a doctor by a sales representative for a pharmaceutical company, is a common way that companies promote their products and establish relationships with physicians in academic and community settings. In 2004, an estimated 36 percent of the $57.5 billion that pharmaceutical companies spent on product promotion went for detailing (Gagnon and Lexchin, 2008).

Medical device companies also employ sales representatives to promote their products to physicians and hospitals, although the responsibilities of some of these representatives may be more complex. They may provide training, equipment calibration, and additional services or advice related to implants and other sophisticated technologies used in the operating room and elsewhere (see, e.g., ECRI Institute [2007]). In one instance, the Food and Drug Administration (FDA) has required physicians to be trained by company representatives as a condition for the approval of a device (see, e.g., FDA [2004b] and Dawson [2006]).

The committee did not locate any information about how drug or device detailing activity differs between academic and nonacademic settings or how specific tactics of detailing and their effects may vary by setting or type of physician (e.g., resident versus faculty member versus community physician). Interactions with drug company representatives are common in academic settings. Medical students average about one interaction with drug company representatives a week, and 80 to 100 percent of students report interactions (see, e.g., Bellin et al. [2004], Sierles et al. [2005], and Fitz et al. [2007]). As described by one faculty member,

> [d]rug company representatives are a major presence. They sponsor Journal Club (where trainees learn to review new data and research), they pay for many of our weekly speakers and regularly offer free dinners for the residents and faculty. They enjoy free access to our mailboxes and regularly detail our trainees in their offices, hallways and in our little kitchen. (Shapiro, 2004, p. F5)

Medical students and residents reported that they received insufficient training in interacting with drug representatives. Studies also indicate that students and residents believe that their own prescribing behavior is not affected by drug company gifts, although they believe that the prescribing behavior of their colleagues is (Sierles et al., 2005; Zipkin and Steinman, 2005). Limited evidence suggests that educational interventions "show some promise" in affecting the attitudes and behaviors related to relationships with industry (Carroll et al., 2007).

Overall, research suggests that drug company representatives may influence prescribing patterns and requests for additions to hospital formularies. The effects appear to be modest but consistent across various kinds of research and disciplines. One review concluded that the "pharmaceutical industry has a significant presence during residency training, has gained the overall acceptance of trainees, and appears to influence prescribing behavior" (Zipkin and Steinman, 2005, p. 777). Another review (which was not limited to educational settings) concluded that detailing "affects physician

prescription behavior in a positive [i.e., the more detailing that there is, the more of an effect that it has] and significant manner" (Manchanda and Honka, 2005, p. 787).

Taken together with the information reviewed below on the role of drug samples and gifts (which typically accompany sales visits), the literature suggests that academic medicine and the public have reason to be concerned about the easy access of sales representatives to medical students, residents, and faculty. In addition, the committee could find no evidence that the exposure of students and residents to drug and device sales representatives—without additional training and supervision—contributes to the achievement of learning objectives or the development of core competencies, for example, increasing an individual's ability to critically evaluate presentations or promoting adherence to evidence-based clinical practice guidelines.

Responses

AAMC has recommended tight limits on site access by sales representatives from medical product companies, particularly uninvited and unscheduled visits and unsupervised access to individual students and residents (see Box 5-1) (see, e.g., AMSA [2008a] and AAMC [2008c]). The recommended rules for device representatives are somewhat less stringent than those for drug representatives and allow limited exceptions for training on the use of complex new devices and the other activities mentioned above. A number of medical schools and teaching hospitals have adopted policies consistent with the AAMC recommendations.

A quality assurance and risk management document prepared by the ECRI Institute (2007) recommends several additional safety and administrative provisions for device representatives who are allowed access to the operating room.[7] The recommendations include training requirements for device representatives as well as procedures to ensure patient safety, privacy, and informed consent and to prevent kickbacks (ECRI Institute, 2007). In addition, the ECRI Institute document suggests that medical schools have not provided adequate training in the use of devices. It emphasizes that hospitals and physicians are responsible for seeing that personnel have the appropriate training on the use of the devices that they regularly use, so that reliance on device representatives is limited and appropriately supervised.

Drug Samples

Issues

Physicians and patients often value drug samples provided as gifts because they allow physicians to send a patient home with a medication that can be evaluated for its short-term effects and side effects without requiring the patient to fill and pay for a full prescription. For low-income patients, many of whom are treated at academic medical centers and teaching hospitals, samples can provide access to needed medications (Daugherty, 2005). Some research has, however, suggested that poor or uninsured patients are somewhat less likely than higher-income or insured patients to receive a drug sample (Cutrona et al., 2008). Drug samples may also be used by physicians themselves or their families. In a 1997 survey of residents, 32 percent of all medications used by residents were obtained from drug sample cabinets or directly from drug representatives (Christie et al., 1998). As discussed in Chapter 6, some professional societies approve such use.

Other research points to risks associated with physician acceptance of drug samples. In academic medical centers, drug samples may be associated with the prescription of new brand name drugs in situations in which the sample drugs are different from the physician's preferred drug or are not recommended by evidence-based practice guidelines or in situations in which less expensive drugs or generic equivalents are available for the same indication. One study of a sample of university-based physicians' responses to several clinical scenarios found that from 17 to 82 percent of the physicians would dispense a drug sample, and, in two of three scenarios, a great majority would do so instead of using their usually preferred drug—largely on the grounds that use of the sample would avoid costs to the patient (Chew et al., 2000). Residents were more likely than attending physicians to report that they used drug samples. In a second study, which involved residents in an inner-city clinic, half were randomized to forgo the use of available free drug samples. They were more likely than the control group to choose unadvertised drugs and were more likely to use over-the-counter drugs. The authors concluded that access to drug samples influences residents' prescribing decisions (Adair and Holmgren, 2005). A third study found that physicians who prescribed angiotensin-converting enzyme inhibitors or calcium channel blockers (a departure from the recommendations of the Joint National Commission on High Blood

Pressure Treatment) were more likely than other physicians to report that they provided patients with samples of antihypertension medications (Ubel et al., 2003). This relationship persisted even after physician and practice variables were taken into account.

Responses

Concerns about the possible negative effects of drug samples have led some academic health centers to restrict or ban their provision. For example, some medical schools require drug samples to be received and distributed by a medical center pharmacy and prohibit their direct provision to individual physicians (see, e.g., University of Massachusetts [2008]). Other policies may allow donation of products only for purposes of evaluation or education and not to support "patient care purposes on an ongoing basis" (University of California, 2008, p. 4). When the University of Michigan Health System (2007) prohibited the distribution of drug samples in patient care and non-patient care areas, it provided committee-approved vouchers for starter medications for clinic patients and for limited exceptions if a clinic director believed that a sample of a specific drug was clinically necessary. The most common provision among the policies reviewed by the committee was a prohibition on the personal use of samples by physicians or their family members.

AAMC (2008c) recommends that samples—if their distribution is by the institutions—should be centrally managed, when feasible (e.g., when timely access to the medications is possible). It warns that the "acceptance and use of drug samples transmits the message to students and trainees that information about samples received from industry sales personnel is sufficient without independent critical evaluation" (p. 16). The recommendation does not mention the personal use of samples by physicians or their family members or staff.

In a March 2009 report, the Medicare Payment Advisory Commission recommends that the U.S. Congress require manufacturers and distributors of drugs to report their distribution of drug samples. It also recommends that the secretary of the U.S. Department of Health and Human Services make the information available for analysis through data use agreements.

Gifts from Medical Product Companies

Issues

As noted earlier in this chapter, surveys indicate that almost every medical student has received a meal and a small noneducational gift from a drug company and that other interactions are common as well (see, e.g., Sigworth et al. [2001], Bellin et al. [2004], Sierles et al. [2005], and Fitz et al. [2007]). In one study, residents were asked to empty their pockets of pens, penlights, calipers, and other items (Sigworth et al., 2001). Ninety-seven percent of the residents had at least one item marked by a pharmaceutical insignia, and about half of the items carried by residents were so branded. More than 90 percent of the residents said that they thought that interactions with drug company representatives influenced their prescribing.

The committee found no studies documenting an educational benefit of these kinds of gifts from industry. Although medical students or residents may find the gift of an expensive textbook welcome, nothing similar to the benefits of academic-industry collaboration in biomedical research has been argued for gifts from industry in medical education.

In contrast, studies of medical personnel combined with social science research provide reasons for concern about the risks of industry relationships and gifts, even small gifts. The paper by Jason Dana in Appendix D reviews this literature. It suggests that even small gifts can be influential. Furthermore, because influence may operate at an unconscious level, it can distort the choices of people who believe that they are objectively making decisions. Disclosure of interests and education about bias may be useful, but they cannot be relied upon to overcome the potential for undue influence and bias associated with conflicts of interest. A number of studies suggest that medical residents, faculty, and other physicians tend to think that they themselves are less likely than others to be influenced by gifts or other interactions (see, e.g., McKinney et al. [1990], Steinman et al. [2001], Halperin et al. [2004], Zipkin and Steinman [2005], and Morgan et al. [2006]).

Few studies have specifically investigated the effects of industry relationships on teaching. One study compared the attitudes of internal medicine residents and faculty about the impact of gifts or income from industry on teaching within and outside the institution (Watson et al., 2005). In general, students were more likely than faculty to perceive industry

influence in association with gifts or income. Both students and faculty perceived visiting attending faculty as more susceptible to such influence than regular faculty, and both perceived off-site teaching as more subject to influence than on-site activities. For example, residents were more likely than faculty to believe that gifts or income from industry influences how attending physicians teach on rounds (47 versus 34 percent), during in-hospital lectures and journal clubs (58 versus 30 percent), and during out-of-hospital dinner lectures and journal clubs (80 versus 57 percent). For responses about the effects on visiting attending physicians, the numbers were even higher, with 89 percent of residents and 72 percent of faculty reporting that they believed that gifts or income from industry affected teaching by this group during out-of-hospital dinner lectures and journal clubs. Moreover, 62 percent of residents and faculty believed that annual income or gifts of less than $10,000 could influence an attending physician's teaching. Sixty-five percent of residents and 74 percent of faculty preferred that speakers disclose all financial relationships with industry rather than just report relationships that speakers considered relevant to the educational topic. Although these findings are from a single study in a single institution, they do raise particular concerns about presentations given outside the medical school setting.

Responses

AAMC (2008c) recommends that schools ban the acceptance of industry-supplied food or meals, except in association with ACCME-accredited educational programs. This ban should apply both on and off campus. A few universities (e.g., the University of Michigan and Yale University by 2005) initiated restrictions some years before the AAMC statement. Schools that ban vendor-provided meals on campus (e.g., Stanford University) may not be explicit about the acceptance of meals at off-site locations, although several schools (e.g., Yale University) also discourage this.

As discussed in more detail in Chapter 6, AMA allows gifts of modest value that are viewed as having some benefit to patients (e.g., meals as part of an educational activity) or the physician's practice (e.g., notepads). The policies of several medical centers (e.g., Wake Forest University, Case Western Reserve University, and the University of Minnesota) are similar to this policy.

In addition to policy changes within the academic community, the Pharmaceutical Research and Manufacturers of America (PhRMA) recently revised its voluntary *Code on Interactions with Healthcare Professionals* (PhRMA2008, effective 2009). Except for the section on scholarships and education funds, the document does not refer specifically to interactions in academic settings. As discussed further in Chapter 6, the revised code more strongly discourages "noninformational" physician-company relationships, such as the provision of tickets to sporting events, token consulting arrangements, speaker training programs at resorts, and meals by sales representatives outside a physician's office or other medical setting.

Industry-Sponsored Scholarships and Training Positions

Issues

Little information on the extent of industry funding for undergraduate and graduate medical education is available, although AAMC has stated that medical schools have become increasingly dependent on such funding for such major activities. The committee is aware of industry-funded residencies or fellowships in a few areas, for example, dermatology residencies funded by companies making dermatologic products (Kuehn, 2005); industry-funded fellowships in rheumatology (Goldblum and Franzblau, 2006); and industry support for psychiatry resident fellowships, awards, and the Chief Resident Leadership Conference (APA, 2008).

The rationale for industry funding of residencies and fellowships seems to rest on physician or researcher shortages in certain specialties and the desire to attract more individuals to these areas through additional industry-supported training positions. For example, the American Academy of Dermatology (AAD) launched an initiative in 2004 to fund 10 dermatology residency positions (Kuehn, 2005). The AAD created a fund to accept donations from the academy, pharmaceutical companies, and other interested parties. Awards were assigned to 10 university programs ($60,000 per year for 3 years), and no recipient would be identified as having been funded by a particular company or companies.

Responses

AAMC (2008c) recommends that academic medical centers establish and implement policies requiring that industry funds for scholarships and similar purposes be given centrally to the administration of the medical center. In addition, industry should have no involvement in the selection of recipients, and no "quid pro quo [should] be involved in any way" (p. 21). The objective is to "prevent the establishment of one-on-one relationships between industry representatives and students and trainees" and minimize "the possibility that these funds will be perceived or used as direct gifts" (p. 21). The committee supports the AAMC recommendations. AMA and PhRMA both permit industry funding of scholarships for medical students, residents, or fellows to attend carefully selected educational conferences when the selection of recipients is made by the academic or training institution.

Changing the Environment or Creating Educational Interventions

To the extent that industry influence operates at an unconscious level, the most effective strategies for reducing the risk of undue influence may involve changing the environment in ways that eliminate or reduce the source, especially when the source offers little or no countervailing educational benefit. That is a major rationale for the policies cited above that eliminate gifts, meals, and other noneducational interactions from the learning environment. Some evidence suggests that the learning environment influences attitudes. Two studies have reported that residents who trained in environments that restricted interactions between industry representatives were less likely than residents who trained in environments without such restrictions to view promotional interactions as being beneficial (Brotzman and Mark, 1993; McCormick et al., 2001). One literature review found weak evidence that trainees who were exposed to educational interventions may be "less accepting of pharmaceutical industry marketing tactics" than those who are not (Carroll et al., 2007, p. e1533). The review noted that two studies that involved industry personnel in the design of the educational intervention found that the participants were more positive toward industry and industry representatives than they were before the intervention.

Some research—including research in academic medical centers as well as community settings (see, e.g., Solomon et al. [2001])—suggests the value of "academic detailing" or educational outreach programs provided by clinical pharmacists or other experts as an objective educational alternative to the activities of medical product companies. Because these programs are aimed at physicians outside academic institutions, this research is reviewed in Chapter 6.

THE LEARNING ENVIRONMENT IN ACCREDITED CONTINUING MEDICAL EDUCATION

Physicians commit to life-long learning to keep pace with new knowledge and skills and to maintain their current skills. Most state licensing boards, specialty boards, and hospitals require accredited continuing medical education for relicensure, recertification, or staff privileges. Thus, it is important to promote a constructive learning environment in this arena as well as in undergraduate and graduate education. This discussion focuses on accredited continuing medical education. (As noted earlier, this report uses the phrase accredited continuing medical education to refer to education that is presented by accredited providers and is certified for course credits.)

Providers of accredited continuing medical education are more numerous and diverse than providers of undergraduate and graduate medical education. The major ACCME-accredited providers are physician membership organizations (n = 270), publishing/education companies (n = 150), medical schools (n = 123), and hospitals and health care delivery systems (n = 93). In 2008, ACCME had 740 accredited providers of continuing medical education, and state medical societies accredited approximately 1,600 additional providers (ACCME, 2008a, 2009). What ACCME calls "publishing/education companies" are often described as "medical education and communication companies," or MECCs, and that term is used here. According to data reported by the Society for Academic Continuing Medical Education (SACME) for 2006, about 40 percent of medical schools held commercially sponsored "satellite" meetings in conjunction with national professional society meetings, and 70 percent of these meetings were managed by communications companies (SACME, 2007).

Table 5-2 shows the shares of total income, participants, hours of instruction, and activities (all providers) accounted for by several types of accredited continuing medical education providers. Medical schools accounted for a considerably larger share of total hours of instruction than might be expected from their share of the total income received by education providers. In contrast, MECCs (publishing/education companies) account for a considerably smaller share of all instructional hours than of total income.

Accredited continuing medical education programs embedded in medical schools are shaped in part by the missions, culture, and challenges of the larger institution. The programs' members are represented by SACME, which describes its mission as promoting "research, scholarship, evaluation and development" of educational and professional development programs "to enhance the performance of physicians … for purposes of improving individual and population health" (SACME, 2008anpaged). Professional society programs are also shaped by the missions, culture, and resources of the society. Most MECCs are for-profit organizations. They are represented by the North American Association of Medical Education and Communication Companies, which is "dedicated to providing representation, advocacy, and education for its members" (NAAMECC, 2009).

The curriculum for accredited continuing medical education is also diffuse. All states except Colorado, Indiana, Montana, New York, South Dakota, and Vermont have some requirements for accredited continuing medical education for physicians who want to maintain (reregister) their license (AMA, 2008a). The policies are generally not specific about the content of the accredited continuing medical education, although a number of states have certain content requirements, for example, palliative and end-of-life care or patient safety (AMA, 2008a). Medical specialty boards have more specific and coherent requirements. They have also recently adopted a "maintenance of certification" model for ensuring continuing physician competence, and this model has implications for the future content of accredited continuing medical education.[8] Approximately 85 percent of U.S. physicians are board certified, so recertification requirements affect the majority of physicians (ABMS, 2007).

In addition to accredited continuing medical education, physicians also have access to an array of nonaccredited education programs sponsored by a wide range of public and private organizations. Many conferences sponsored by the National Institutes of Health and other government agencies do not offer credit, although some do. Hospitals sponsor a range of medical staff education programs that do not offer credits. The committee heard testimony that a professional society may organize a scientific meeting of research presentations for which it controls the selection of topics and speakers (ASH, 2008; Kaushansky, 2008). The organization may then seek financial support from industry, often small grants from several companies. Because of limited budget and staff, a small society may not pursue the provision of continuing medical education credits even when it provides safeguards against commercial bias consistent with accreditation standards. When medical product companies organize nonaccredited continuing medical education, the offerings may range from dinner seminars to training on the use of a medical device and satellite symposia at professional society meetings (some satellite symposia offer credit). Some nonaccredited programs controlled by companies may be little more than marketing. Others, such as programs that provide training on the use of a complex new medical device, may meet legitimate education needs, although the presentations may still be more positive about the device than presentations by an independent educational source would be. The committee lacked the resources to investigate nonaccredited activities.

Some medical schools have policies that require their faculty to limit participation in industry-supported programs to programs that meet certain conditions. These conditions may be similar or identical to the standards for accredited continuing medical education (see, e.g., Boston University [2007] and the University of Pittsburgh [2007]).

As noted earlier, the committee commissioned a paper on conflict of interest concerns, policies, and practices in other professions. That paper, which is presented as Appendix C, examines conflicts of interest in law, accounting, engineering, and architecture. In general, other professions differ from medicine in that they have no authority similar to that of physicians to prescribe regulated products for client's personal use and, except to various degrees for law, do not have vulnerable clients.

In some respects, the current system of continuing legal education resembles the system of continuing medical education in decades past. Much continuing legal education is provided by law schools as part of their service mission, although law firms and commercial companies also offer programs. Programs may be offered at no charge or may be paid for by individual lawyers or their firms or employers. Programs sometimes have corporate sponsorship, but the sponsors' products tend to be resources for the lawyer (e.g., software and information resources) rather than for the lawyer's clients and thus do not present the same concerns about bias in presentations that occur in medicine. Although legal continuing education cannot be seen as an exact model for medicine, it does suggest that alternatives (e.g., higher fees and employer subsidies) to the major role of industry funding for continuing medical education may exist.

Industry Funding in Accredited Continuing Medical Education

Survey data from ACCME show that industry funding of accredited continuing medical education increased by more than 300 percent between 1998 and 2007 (ACCME, 2008a, Table 7).[9] Moreover, profit margins increased substantially, from 5.5 percent in 1998 to 31 percent in 2006 (Steinbrook, 2008b). For the many providers of accredited continuing medical education, this combination of increased reliance on industry funding and increased profitability provides strong incentives to resist efforts to curtail such funding.

The contribution of funding from industry (primarily from drug, medical device, and biotechnology companies) varies by the type of provider of accredited continuing medical education (Table 5-3). Funding from industry provides more than half of the total income for medical schools and almost three-quarters of the total income for MECCs. Professional societies (i.e., physician membership organizations) as well as MECCs show a significant margin of income over expenses.

Although professional societies are not as dependent on industry funding for their accredited educational programs as MECCs or medical schools, they receive nearly equal amounts of funding from commercial sources (24 percent) and advertising and exhibit income (25 percent). ACCME's survey does not count the latter as commercial support.

SACME surveys provide additional data on the significance of industry funding for medical school programs. In 2006, the typical (median) medical school received some commercial support for about 45 courses, which represented almost 70 percent of its educational activities (SACME, 2007). About 7 percent of schools reported that the majority of their courses were supported by a single commercial source, and the mean number of such courses across all respondents was two. Respondents also reported that "if commercial support were no longer provided, the typical school would no longer hold 11 courses, representing 23% of the school's courses" (p. 3).

Because they depend on industry for almost three-quarters of their income, MECCs could be severely challenged by an end to direct commercial funding, which some have proposed (Fletcher, 2008), or by a decision by medical product companies to shift their support to academic institutions, as one company recently did (Loftus, 2008). They could still have a role if academic medical centers continued to contract with them to manage or administer some of their continuing medical education programs.

Providers of accredited continuing medical education may solicit industry support for their programs. For example, a medical education company described opportunities to provide educational grants for a large meeting sponsored jointly with an academic medical center, as shown in Box 5-2. Other organizations sell sponsorship opportunities for everything from meeting coffee breaks to hand sanitizers and flash drives.

In addition to support for organizational programs, industry also provides support to individual physicians. On the basis of the findings from a 2004 survey, Campbell and colleagues (2007a) found that 26 percent of physicians reported that industry paid for their admission to continuing medical education meetings and 16 percent reported payments for serving as a speaker or on a speakers bureau.

Conceptually, industry support may be direct or indirect. Direct funding is from the company to the program provider. Indirect funding may occur in several ways. The company may set up a foundation that it substantially controls to provide the funding, or the provider may set up a foundation to receive the funds. Such arrangements may not provide any protection against the company influencing the content of the accredited continuing medical education. Alternatively, the company may provide funds to an intermediary, such as a central continuing medical education office in an academic health center. These arrangements are intended to separate the funding from decisions about the course content. The committee has heard criticisms that despite ACCME requirements that course directors review the course content for bias, the recipient of industry funds may have an implicit understanding that additional industry funds will not be offered in the future if the course does not present topics of interest to the company and use speakers who are favorable to the company's products.

Concerns About Industry Support for Accredited Continuing Medical Education

The substantial support that industry provides for accredited continuing medical education indirectly subsidizes physicians who pay less for many accredited continuing medical education programs than they otherwise would. As the preceding section indicates, industry support also contributes to the financial well-being of many educational providers that depend on it for the major part of their income for the provision of accredited continuing medical education.

The committee found little systematic research on other consequences of industry-supported continuing medical education, for example, whether it promotes bias in individual programs or in overall educational offerings. One study published before the adoption of the first ACCME standards for commercial support compared programs funded by rival pharmaceutical companies and found that the programs favored the products of their funders (Bowman, 1986). A study by Orlowski and Wateska (1992) focused on a kind of industry-sponsored activity that provoked considerable criticism and that now is not permitted for accredited education, that is, a program held at a resort with all expenses paid for attendees and with limited time actually devoted to the educational content. The authors found, using actual prescribing data obtained before and after the activity, that this "elaborate promotional technique … was associated with a significant increase in the prescribing of the promoted drugs at one institution" (p. 273). The investigators also found that the physicians involved did not believe that the activity would affect their practices.

Another study found that courses on primary care directed by academic faculty covered a broader range of topics than symposia sponsored directly by industry (Katz et al., 2002). Moreover, 91 percent of the industry-sponsored symposia were sponsored by a company that had recently obtained FDA approval for a drug related to the symposium topic. The industry-sponsored symposia did not cover prevention screening, dermatological diagnoses, child abuse, alcoholism, or the technology resources available for clinicians, which were considered important in the academic program. In that study, the university-based accredited continuing medical education courses received funding from multiple companies through a MECC to the university. University faculty determined the content of their courses, and the MECC handled marketing and meeting logistics. During meal breaks at these courses, symposia funded by industry were also offered.

Unfortunately, much information about accredited continuing medical education, particularly that offered by for-profit providers, is not based on good data but, rather, is based on personal experiences with covert relationships with providers or inferences made on the basis of the nearly total dependence of these providers on pharmaceutical, medical device, and biotechnology companies. One 2008 article, based on personal experience, describes how accredited continuing medical education providers can tailor programs to secure company grants (Gilbert, 2008, unpaged). A commer cial provider selected a program concept to "provide a platform for one of the sponsors," which was working on a drug covered by the program. The provider also organized informal workshops with experts who were hired on the basis of their support for the sponsor's message.

Using a checklist that they developed to assess bias in education programs, Takhar and colleagues (2007) concluded that 9 of the 17 continuing medical education programs that they assessed were biased (e.g., by limiting the discussion to the sponsor's product and ignoring alternatives). Work is needed to validate this and other instruments that are intended to be used to assess bias in presentations retrospectively or identify presentations at risk of bias during the planning stage (see, e.g., Barnes et al. [2007]).

The Senate Finance Committee staff report on the use of educational grants by pharmaceutical manufacturers noted that ACCME's reports documented numerous cases of undue influence by companies over "supposedly independent educational programs" (Finance Committee, U.S. Senate, 2007, p. 2). For example, during 2005 and 2006, 18 of 76 program providers were found to be out of compliance with at least one of the ACCME standards related to independence, and some were cited for being under the improper influence of industry.

More specific information on industry practices comes from litigation. Prompted in many instances by whistleblower complaints, the U.S. Department of Justice as well as state attorneys general have filed charges against a number of pharmaceutical and medical device companies for illegal practices related to purported educational activities as well as speaking and writing arrangements. In some cases, one focus of litigation has been the giving of educational grants as an inducement to use the company's products, which can be illegal under the Medicare law. In other cases, the focus has been on industry efforts to bias the content of educational programs and presentations, particularly as part of efforts to promote the off-label use of drugs (i.e., for purposes not approved by the FDA), which is also illegal.[10]

Box 5-3 lists some of the cases in which settlements have been reached. Internal company documents that were made public as a result of the first case described in the box provided insights into the use of speakers bureaus (which included chairs of neurology departments), "educational" teleconferences, and grants to medical education companies (with multiple ties to the company) to further marketing objectives for the drug Neurontin (gabapentin) (Steinman et al., 2006; see also Landefeld and Steinman [2009]). The conditions associated with the settlement in the case specified requirements for the company's reporting of its support for continuing medical education and its financial relationships with speakers and participants (OIG, 2004).[11]

Responses to Concerns About Bias in Industry-Funded Accredited Continuing Medical Education

Responses by Private Organizations

Expanded industry support for accredited continuing medical education and the involvement of commercial firms began to become a significant concern in the 1980s and led to ACCME-developed guidelines on commercial support in 1987 and then ACCME-developed standards in 1992. These standards have been criticized as doing little to curb industry influence over the content of accredited continuing medical education (see, e.g., Relman [2001, 2003]; see also Ross et al. [2000], Krimsky [2003], and Brody [2007]). In 2004, ACCME issued new, more restrictive standards.

The accreditation standards now require the disclosure of conflicts of interest by meeting planners as well as speakers. They also require the review of the educational content for bias and the resolution of conflicts of interest in some fashion (e.g., by finding an alternative speaker or identifying and eliminating biased content in a presentation). In addition to the standards, ACCME has developed tools (e.g., definitions, frequently asked questions, and slide presentations) to help educational providers with program implementation.

The SACME survey mentioned above reported that academic providers found the 2004 standards to be difficult to implement (SACME, 2007). Only 5 percent of the respondents considered the standard related to resolving conflicts of interest to be easy to implement. Slightly less than half of the respondents thought that the standards had reduced bias a little or somewhat.

In 2008, the ACCME board of directors adopted a statement that indicated that accredited continuing medical education providers "cannot receive guidance, either nuanced or direct, on the content of the activity or on who should deliver that content" (ACCME, 2008b. 3). The organization also announced that it was devoting more resources to implementation and enforcement, which would eventually require an increase in member fees (ACCME, 2008b). In addition, ACCME issued a request for comments on a proposal related to commercial support, which included as options the elimination of commercial support, the continuation of the current situation, and the development of a new paradigm (ACCME, 2008d). The executive summary for the November 2008 board of directors meeting states that analysis of the comments is continuing and that action is not anticipated before the end of 2009 (ACCME, 2008c).

Notwithstanding the changes in ACCME standards, criticisms of industry funding and influence continue (see, e.g., Steinbrook [2005, 2008b] and Fletcher [2008]). ACCME's limited resources for monitoring adherence to its standards (as of early 2008, it had approximately a dozen staff members) are also a concern (Kopelow, 2008).

Other issues involve the monitoring of the content of presentations. Program-by-program and presentation-by-presentation assessments for bias are labor-intensive activities, and instruments for the systematic assessment for bias need further development and validation. The committee found no studies describing or evaluating the effectiveness, burdens, and adverse consequences of such monitoring for bias overall or by category of accredited continuing medical education provider. ACCME requirements for monitoring may stimulate research in this area.

Some critics raise broader questions about the value, goals, and structure of the current system of accredited continuing medical education (see, e.g., Fletcher [2008]). Some have also proposed ending direct industry support for continuing medical education (see, e.g., Brennan et al. [2006], Fugh-Berman and Batt [2006], CEJA [2008], and Fletcher [2008]). In 2008, the AMA House of Delegates referred back to its Committee on Ethical and Judicial Affairs a proposal that physicians and organizations not accept industry funding for professional medical education (AMA, 2008c; see also Relman [2008]). The summary of a 2008 consensus conference held at the Mayo Clinic describes a conclusion that continuing medical education requires a "strategic management process that focuses on the integrity of an enterprise" and

that deals "in a convincing, transparent and accountable manner issues such as commercial interest influence, conflicts of interest, bias, sources of evidence and the quality of product, process and delivery" (Kane, 2008, p. 8). It also stressed the need for research (and funding for research) to guide reforms.

In a 2008 report on industry funding of medical education, AAMC recommended that academic medical centers set up audit procedures to assess compliance with ACCME standards. The report observed that given "the heavy dependence by academic medical centers on industry funding" for continuing medical education, it was essential that they comply with "evolving" ACCME standards and take other steps to ensure the independence of their program offerings (AAMC, 2008c. 19). The report also recommended that academic medical centers establish a central office through which all requests for industry support and the receipt of funds for continuing medical education would be coordinated and overseen. It further proposed that institutions should prohibit faculty, students, residents, and fellows from participating in non-ACCME accredited industry events that are labeled as continuing medical education. Also, if medical centers allow faculty participation in industry-sponsored, FDA-regulated programs, they should set standards for appropriate faculty involvement.

In its revised code of conduct, PhRMA includes provisions on industry support for continuing educational programs. With an eye to federal kickback laws, it advises companies to separate decision making about educational grants from sales and marketing units and to "develop objective criteria for making CME grant decisions to ensure that … the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment" (PhRMA, 2008). For nonaccredited educational activities, the code provides that the organizers of the activity should control its content, faculty, materials, and similar details. As noted earlier, one pharmaceutical company announced that it would no longer fund educational programs offered by MECCs.

Most medical school policies reviewed by the committee already state that their programs should meet the standards for commercial support set forth by ACCME. Some have instituted further restrictions. In 2007, Memorial Sloan-Kettering Cancer Center announced a 6-month trial period during which it would no longer accept industry funding for its continuing medical education programs (industry provided about 25 percent of total funding for continuing medical education at that institution). To reduce costs, off-site programs were moved on-site, free lunches were eliminated, advertising was cut, and fewer external speakers were used. Although the fees for external participants were raised by 10 to 20 percent, program attendance stayed the same (Kovaleski, 2008). The ban on industry funding is now permanent. At least one other institution has also announced that it will no longer accept direct industry funding for specific accredited continuing medical education courses either on or off campus, nor will it accept payments from third parties that have received commercial support (Stanford University School of Medicine, 2008). Industry support is, however, permitted if it is not designated to a specific subject, course, or program but is for use in a broadly defined field and is provided through a central university office for continuing medical education.

Responses by Public Agencies

As described above, the U.S. Department of Justice and state attorneys general have charged a number of companies with illegal practices related to the funding of educational programs, including accredited programs in some instances. In addition, in its 2003 compliance guidelines for pharmaceutical manufacturers, the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services identified the provision of educational grants as an activity that place a company at high risk for violating federal antikickback rules and certain FDA regulations (OIG, 2003). These compliance guidelines advise manufacturers to separate their grantmaking activities from their sales and marketing activities to "help insure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate" (p. 21). Other activities identified as having a high potential for fraud and abuse include the provision of gifts, entertainment, and personal services compensation arrangements. The OIG guidelines also recommend (pp. 20–21) that manufacturers

1. separate grant-making functions from sales and marketing functions;
2. establish objective criteria for awarding grants that do not take into account the volume or value of the recipient's purchases;

3. establish objective criteria for awarding grants that ensure that the funded activities are bona fide; and

4. refrain from controlling speakers or content of educational activities funded by grants.

The 2007 Senate Finance Committee staff report cited above concluded that most large pharmaceutical companies had established written policies and procedures on educational grants, limited sales representatives from soliciting requests or promising funding, and established a centralized mechanism for administering grants.

GHOSTWRITING, SPEAKERS BUREAUS, AND INDEPENDENCE OF PUBLICATIONS AND PRESENTATIONS

Concerns about Ghostwritten Publications, Participation in Speakers Bureaus, and Other Industry-Controlled Work

Two hallmarks of academic integrity are intellectual independence and accountability for one's work. Certain practices by medical school faculty create a hidden curriculum that subverts the professional values endorsed by the formal curriculum. One example is taking credit as the author of a manuscript prepared by an unacknowledged or inadequately acknowledged industry-paid writer. (An adequate acknowledgment would specify the roles of these writers, for example, as the preparers of the first draft, as well as the roles of the listed authors.) Another example is participating in an industry speakers bureau or other long-term speaking arrangement with a company, regardless of how the relationship is labeled. One concern is that ongoing company payments for presentations (and travel to attractive locations) create a risk of undue influence. A second concern that is frequently tied to the speakers bureau label is that the company exerts substantial control over the content of a presentation. Industry influence in these arrangements may be direct (e.g., when a talk and slides are largely or entirely prepared by someone else or when speakers are instructed to provide the company-prepared responses to questions and avoid the favorable mention of competing products). Influence may also be less direct (e.g., when a company-trained and company-paid physician modifies talks to fit the objectives of the company) (see, e.g., Elliott [2006] and Carlat [2007]). The committee recognizes that companies have an interest in some oversight of presentations for a variety of reasons, including the need to comply with FDA prohibitions on promoting the use of drugs for the treatment of conditions not approved by the agency.

Serving on speakers bureaus appears to be common in clinical medicine. A 2006 survey of academic-industry relationships found that 21 percent of clinical department chairs reported being on a speakers bureau (whereas 2 percent of nonclinical department chairs reported being on a speakers bureau) (Campbell et al., 2007b). As reported earlier, another survey, which was not limited to academics and which asked less specific questions, found that 16 percent of physicians reported serving on a speakers bureau or as a speaker, which could have involved a single presentation (Campbell et al., 2007a). ACGME has expressed concern about "a new variation of a promotional activity in which residents and even medical students receive slides, lecture materials and honoraria and subsequently act as 'experts,' delivering the packaged information at continuing medical education events" (ACGME, 2002, p. 3).

Unacknowledged industry influence over publications is also common. In one study, 13 percent of research articles in major biomedical journals had "ghost" authors, that is, people who filled the criteria for authorship but who were not listed as authors (Flanagin et al., 1998). None of these ghost authors was even acknowledged in the paper. A review of documents obtained during litigation against a major pharmaceutical company concluded that review manuscripts were often prepared by writers for medical publishing companies but authorship was "subsequently attributed … to academically affiliated investigators who often did not disclose industry financial support" (Ross et al., 2008, p. 1800). One incident illustrates that such ghostwriting may be discovered only by accident. An academic physician reported that a MECC sent her a draft manuscript of a review article commissioned by a drug company and invited her to be its "author." She declined, but she was subsequently asked by a journal to review an article that was similar to that article and that now had another author (Fugh-Berman, 2005; see also Eaton [2005]). The analysis by Steinman and colleagues (2006) of documents obtained through litigation cited earlier found that those documents describe plans for recruiting academic authors of a series of ghostwritten articles to be prepared by a medical education company. Box 5-3 included examples of company settlements with the Department of Justice related to speaking and writing arrangements.

Another concern about industry relationships is that academic authors of research articles may not have full access to the data from an industry-sponsored study. This issue was discussed in Chapter 4.

In the setting of medical education, the question is not whether assistance by professional writers and others may improve publications and help busy researchers get important, objectively presented findings into print; it may do both. The questions are whether the assistance is hidden, whether it is intended to promote a company's interests rather than present unbiased information, and whether the author takes credit for work that he or she did not do and thus misrepresents the provenance of the article. Such arrangements (which are essentially gifts) send the wrong message about the values of intellectual independence, professional ethics, accountability, and evidence-based medicine. In the context of research, they raise questions about the objectivity of research reports that other researchers as well as practitioners and developers of practice guidelines rely on.

Responses to Concerns About Independence and Accountability in Writing and Speaking

Medical journal editors (including the International Committee of Medical Journal Editors and the World Association of Medical Editors) have taken steps to eliminate ghostwriting (see, e.g., Rennie et al. [1997], Davidoff et al. [2001], ICMJE [2008], and WAME [2008]). As stated by the International Committee of Medical Journal Editors, "[a]ll persons designated as authors should qualify for authorship, and all those who qualify should be listed" (ICMJE, 2008, p. 3; see also Ross et al. [2008]). The objective of authorship policies is to eliminate unethical practices and generally not to preclude legitimate and properly acknowledged writing assistance (see, e.g., Lagnado [2002] and Woolley et al. [2006]).

As described in Chapter 3, one journal has revised its conflict of interest disclosure form to include questions intended to detect commercial sponsorship and unacknowledged authors after concluding that such questions were necessary to detect ghostwritten or promotional submissions (AFMI, 2008). In its disclosure form for continuing medical education programs, the same professional society asks several questions about relationships with speakers bureaus (e.g., whether an individual is acting independently or as an agent) as well as questions about the receipt of assistance with manuscript preparation from commercial entities (AAFP, 2006b).

In its 2008 report on medical education, AAMC recommended, "[a]cademic medical centers should prohibit physicians, trainees, and students from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, industry or otherwise" (AAMC, 2008c. 22). It noted that properly acknowledged collaborations with industry personnel or medical writers is not ghostwriting. The report also recommends that participation in industry-sponsored speakers bureaus be discouraged.

A few medical school policies reviewed by the committee mention speakers bureaus by name. For example, the University of Massachusetts views speakers bureaus as an "extension of the marketing process" and forbids faculty participation in them. The Mayo Clinic has long prohibited faculty from speaking on behalf of industry, and its current policy prohibits participation in the speakers bureaus of commercial firms because the linkage would imply endorsement by the Mayo Clinic (personal communication, Marianne Hockema, Administrator, Office of Conflict of Interest Review, Mayo Clinic, September 19, 2008). Faculty at the University of Louisville (2008) are "strongly discouraged" from serving as speakers hired by vendors (p. 4). A policy recently adopted by the Johns Hopkins University School of Medicine (2009) states that faculty may not participate on-site or off-site in "activities with any of the following characteristics … a company has the contractual right to dictate what the faculty member says; a company (not the faculty member) creates the slide set (or other presentation materials) and has the final approval of all content and edits; the faculty member receives compensation from the company and acts as the company's employee or spokesperson for the purposes of dissemination of company-generated presentation materials or promotion of company products; and/or a company controls the publicity related to the event" (p. 7). The policy notes that some of these activities occur in the context of speakers bureaus but it is the conditions of an activity that determine whether it is permissible.

In addition, a few medical schools (e.g., the University of California at San Francisco, the University of Louisville, and the University of Colorado) forbid ghostwriting (using that term). A few other medical schools (e.g., Stanford University, the University of Missouri, Emory University, and the University of Rochester) cover the practice of ghostwriting by forbidding medical school personnel from publishing, under their own name, articles that are written entirely or in significant part by an industry employee.

The ACCME standards for commercial support require that presenters disclose relevant financial relationships. They provide no explicit guidance or reference to the appropriateness of commercial assistance in the preparation of talks.

The 2008 PhRMA *Code on Interactions with Healthcare Professionals* notes that companies and speakers should understand the difference between (accredited) continuing medical education and company-sponsored speaker programs (PhRMA, 2008). For the latter, "[s]peaker training is an essential activity because the FDA holds companies accountable for the presentations of their speakers" (p. 9). This is a reference to FDA's ban on company promotion of the use of a medication for the treatment of conditions that have not been approved by the agency (FDA, 1997). The PhRMA code specifies that company policies should provide a cap on the total annual amount that it will pay a speaker and address the "appropriate number of engagements for any particular speaker over time" (p. 10).

RECOMMENDATIONS

Medical Schools and Residency Programs

Policies on Relationships with Industry

This chapter has documented the extensive relationships that exist between industry and medical institutions, faculty, students, and residents and the concerns that have been raised about the risks that these relationships pose to the basic educational missions of academic medical centers and the lack of benefits from such relationships, such as those that support academic-industry collaborations in medical research. It has cited research indicating that even small gifts can be influential and has reviewed the recommendations of organizations such as AAMC and PhRMA. The committee concluded that it is time for medical schools to end a number of long-accepted relationships and practices that create conflicts of interest, threaten the integrity of their missions and their reputations, and put public trust in jeopardy. The risks are substantial and are not offset by meaningful benefits.

RECOMMENDATION 5.1 For all faculty, students, residents, and fellows and for all associated training sites, academic medical centers and teaching hospitals should adopt and implement policies that prohibit

- **the acceptance of items of material value from pharmaceutical, medical device, and biotechnology companies, except in specified situations;**
- **educational presentations or scientific publications that are controlled by industry or that contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged;**
- **consulting arrangements that are not based on written contracts for expert services to be paid for at fair market value;**
- **access by drug and medical device sales representatives, except by faculty invitation, in accordance with institutional policies, in certain specified situations for training, patient safety, or the evaluation of medical devices; and**
- **the use of drug samples, except in specified situations for patients who lack financial access to medications.**

Until their institutions adopt these recommendations, faculty and trainees at academic medical centers and teaching hospitals should voluntarily adopt them as standards for their own conduct.

This recommendation has several targets, most of which focus on promotional relationships. One target is the acceptance by faculty or trainees of items of material value (including small gifts and meals) from industry except in certain situations. These situations, which should be defined in institutional policies, include (1) appropriate payment for legitimate services (such as contracts, grants, and consulting arrangements); (2) charitable donations, which should be given to the institution; and (3) sharing of research materials or data. Under appropriate transfer agreements, the sharing of research materials or data is encouraged, as it promotes medical research. This recommendation covers not only

physical gifts, such as pens, notepads, and meals, but also preferences, such as paid speaking engagements that are intended as rewards or inducements. Consulting arrangements and drug samples are discussed further below.

The second target of this recommendation is the involvement of faculty or trainees in presentations or publications for which they cannot ethically claim credit or intellectual independence. Although no physician or researcher should accept authorship of a ghostwritten academic publication (see the discussion earlier in this chapter), failure to meet this standard is particularly troublesome when it involves faculty who have a special obligation to demonstrate intellectual independence and to act as role models. For similar reasons, faculty should not participate in speakers bureaus and similar promotional activities in which they either present content directly controlled by industry or formulate their remarks to win favor and continued speaking fees. If institutions fail to adopt these recommendations, then acceptance of authorship for ghostwritten publications or industry-controlled presentations would constitute a gift to be disclosed to the institution even if the institution's policies do not explicitly mention these arrangements as gifts.

The recommendation's third target is consulting arrangements. Faculty should engage only in bona fide consulting arrangements that require their expertise, that are based on written contracts with specific tasks and deliverables, and that are paid for at fair market value. As part of their administration of conflict of interest policies, university review of faculty consulting and other contracts is prudent and desirable.

The fourth target of this recommendation concerns access to educational environments by sales representatives of pharmaceutical, medical device, or biotechnology companies. Clinical teaching should be done by faculty, not by marketing agents. The recommended restrictions on site access should not discourage appropriate and productive research collaborations between industry and academic researchers. In addition to promoting scientific progress and the development of useful products, collaborations can provide educational benefits to medical students, graduate students, and postdoctoral fellows who might participate in legitimate collaborative research projects with industry under proper supervision.

As described earlier, the AAMC recommendations and some medical school policies set stringent restrictions on access by pharmaceutical sales representatives but establish slightly less restrictive conditions for access by representatives of medical device companies. The recommendations and policies reflect assessments that access by device representatives—if they are properly managed and appropriately limited—can contribute to patient safety. Nonetheless, the expectation is that faculty will quickly learn how to use complex new devices, including relevant surgical techniques, and will then instruct and supervise residents and fellows rather than rely on company representatives to do so. Access under these circumstances would occur after the institutional purchase of a complex device. For the purposes of device evaluation, access by the device representatives would occur before purchase of the device.

The fifth target of this recommendation, which covers drug samples, presents difficult issues. Caring for patients who cannot afford needed drugs is frustrating for physicians who are trying to meet their professional obligations to act in their patients' best interests. Despite the aid provided through Medicaid and Medicare, other public programs, and the patient access initiatives of pharmaceutical companies, many patients are not eligible for such aid and cannot afford to continue to take medications after they have used a sample. Moreover, although physicians and others may believe that drug samples allow low-income patients access to drugs that they could not readily obtain otherwise, this chapter has cited research that suggests that most samples are not, in fact, given to indigent patients and that access to samples may change trainee behavior such that they move away from practicing evidence-based and lower-cost care. Drug samples are not a satisfactory answer to the serious problem of the lack of affordability of medications for many patients, but the committee was reluctant to call on physicians to abandon them completely in the short term.

For academic medical centers, the use of drug samples may often be managed without a direct interaction between a physician and a company representative. Thus, AAMC recommends and this committee agrees that samples (if the institution permits them) should, whenever possible, be centrally managed in ways that allow timely and appropriate patient access.

In the absence of such centralized arrangements, institutions should limit the provision of free drug samples and provide them only to patients who lack financial access to medications in situations in which generic alternatives are not available and the sample medication can be continued at little or no cost to the patient for as long as it is needed. They should also

help physicians and patients use alternative public and private resources to obtain the needed medications. The proposal by the Medicare Payment Advisory Commission for company reporting and U.S. Department of Health and Human Services analysis of data about the distribution of drug samples cited earlier in this chapter could, if it is adopted, produce helpful information to guide future policies.

The elements of this recommendation apply both to campus settings and to off-site settings, for example, off-site locations for professional meetings and educational programs. They also apply to volunteer faculty who provide clinical education in their offices or in community hospitals. Chapter 6 presents a parallel recommendation (Recommendation 6.1) for physicians who are not affiliated with academic institutions. That chapter also presents a comprehensive recommendation (Recommendation 6.2) that calls for medical product companies to change their policies to be consistent with these recommendations. The committee recognizes that it takes time for academic medical centers to develop policies. It recognizes the value of policy development processes that involve the assessment of local conditions, the inclusion of those who will be affected, and investigation of the experiences of similar institutions.

Until institutions act, faculty, students, and trainees should still change their own behavior so that it is in line with the recommendations presented above. In addition, consistent with Recommendation 9.1, the committee encourages AAMC, AMSA, and similar membership organizations to continue or initiate survey, monitoring, and other activities to promote the reform of conflict of interest policies in medical education.

Education on Relationships with Industry

> **RECOMMENDATION 5.2 Academic medical centers and teaching hospitals should educate faculty, medical students, and residents on how to avoid or manage conflicts of interest and relationships with pharmaceutical and medical device industry representatives. Accrediting organizations should develop standards that require formal education on these topics.**

Changing the environment within educational institutions is important, but medical schools also need to prepare trainees for practice in environments that may be characterized by more permissive standards of conduct regarding drug and device marketing. Faculty will continue to experience a range of situations in which they will interact with industry representatives and will also need to be prepared to act as educators and role models on industry relationships.

The committee recognizes that the evidence on the effectiveness of educational programs of this sort on physician attitudes and behaviors is not strong, but it believes that a basic level of education supports the development of core competencies and prepares students and trainees for future practice. The establishment of educational standards will help ensure that such education is of high quality and receives appropriate attention.

Accredited Continuing Medical Education

The members of the committee had extensive internal discussions about industry support for accredited continuing medical education. Overall, there was general agreement that continuing medical education has become far too reliant on industry funding and that such funding tends to promote a narrow focus on products and to neglect the provision of a broader education on alternative strategies for managing health conditions and other important issues, such as communication and prevention. Given the lack of validated and efficient tools for preventing or detecting bias, industry funding creates a substantial risk of bias, to the extent that industry-reliant providers want to attract industry support for future programs. Although the committee did not reach agreement on a specific path to reform, it concluded that the current system of funding is unacceptable and should not continue.

> **RECOMMENDATION 5.3 A new system of funding accredited continuing medical education should be developed that is free of industry influence, enhances public trust in the integrity of the system, and provides high-quality education. A consensus development process that includes representatives of the member organizations that created the accrediting body for continuing medical education, members of the public, and representatives of organizations such as certification boards that rely on continuing medical education should**

be convened to propose within 24 months of the publication of this report a funding system that will meet these goals.

One option is for this broad-based consensus development process to be convened by the member organizations of ACCME. As described earlier in this chapter, they represent medical specialty boards (American Board of Medical Specialties), hospitals (AHA and the Association for Hospital Medical Education), organized medicine (AMA), medical schools (AAMC), medical specialty societies (CMSS), and state licensure boards (Federation of State Medical Boards). Although these organizations have interests in continuing medical education and in ensuring that continuing education is free of bias and supports core competencies, they do not all have a vested interest in the current system of funding that education.

The consensus development process convened by this or another group should be broad based and should also include representatives of other medical education accrediting bodies (LCME and ACGME), other interested state and federal agencies, public interest and patient advocacy groups, and organizations such as specialty certification boards that rely on continuing medical education. It should also include providers of accredited continuing medical education and industry funders. The deliberations should take into account the findings of other groups that have analyzed funding for continuing medical education or that have made recommendations about improving continuing medical educational methods.

Most committee members believed that a near-term end to industry funding would be unacceptably disruptive for the major providers of accredited continuing medical education, including medical schools and professional societies, which together provide 68 percent of the total number of hours of this type of education (see Table 5-2). A SACME survey found that 77 percent of respondents said that immediate elimination of commercial support would substantially reduce the number of courses at their academic centers and the scope of their programs and could potentially lead to the elimination of programs (SACME, 2008b). Eliminating all industry funding without having in place an alternative model could have other adverse consequences. For example, a surgical society may hold a premeeting accredited workshop involving hands-on teaching of surgical techniques, typically supported by indirect funds from industry. In the committee's experience, the costs of setup and materials for multiple simultaneous workshops can be several million dollars and would be hard to cover by payments from attendees. Furthermore, other innovative educational formats—for example, Internet-based training, simulation-based training, and performance improvement learning activities—also require funding for start-up and updating costs that could be prohibitive for providers to self-fund or fund entirely through nonindustry sources.

A majority of the committee supported the use of a consensus development process to develop a new funding system for accredited continuing medical education that would be free of industry influence but that would leave open the possibility of certain forms of indirect industry funding under conditions that minimized the risk of undue influence on program content. Some committee members supported the use of a consensus development process to develop an alternative funding model but believed that no form of direct or indirect industry funding was acceptable.

Among the options that the consensus development activity could consider are proposals for some kind of pooled funding mechanism. For example, companies could grant funds to some independent central or regional entity that would establish educational priorities and make decisions—perhaps within broad categories—about the distribution of funds on the basis of an independent review of applications from education providers.

Both direct company funding to institutions for specific continuing medical education programs and direct company provision of unrestricted grants to institutions offer clear opportunities for undue influence, particularly for continuing medical education providers that also receive the great majority of their funding overall from companies. A plan for a system free from industry influence would exclude such funding as well as funding from company-controlled foundations.

The committee recognizes that industry willingness to provide funds under a restructured system of funding accredited continuing medical education might be quite limited. Thus, the consensus development process would also need to consider alternative means of financing, steps to reduce program costs, and other strategies that would support high-quality continuing medical education. Options include increased fees for attendees; subsidies from academic medical centers as part of their educational missions; elimination of expensive program locales and amenities; reduced payments

to speakers; collaboration among education providers to share the costs of developing certain expensive programs; and rethinking the purpose and methods of continuing medical education, as is already being done in the development of programs for the maintenance of certification by specialty societies. Higher fees might be a particular burden for physicians with lower-than-average professional incomes, including rural physicians and physicians serving disadvantaged populations.

The committee members who opposed any industry funding of continuing medical education through any mechanism believed that physicians (or their employers) should bear the entire cost of accredited continuing medical education that is required for renewal of licensure and specialty certification. Even giving industry funding and program decision-making responsibility to a central office within a medical school, MECC, or other institution would unnecessarily retain conflicts of interest over the choice of course topics, directors, content and speakers, and the leadership of the continuing medical education office. In the view of these committee members, all industry support for accredited continuing medical education should be rejected, just as it is for most undergraduate and graduate medical education.

In the process of hearing testimony relevant to the issue of funding of continuing medical education, many committee members came to the conclusion that a number of other fundamental problems about the focus and the effectiveness of continuing medical education warranted attention. These issues were outside of the purview of the committee. Some will be considered by another committee of the Institute of Medicine, which is charged with making recommendations about the promotion of more effective methods of life-long education for health professionals (IOM, 2009). Analyses of the financing of continuing medical education are planned in conjunction with that project. Those analyses may provide a better understanding of the implications of different proposals about financing in the context of other changes in the system.

The committee focused on accredited continuing medical education. As noted earlier, some nonaccredited activities with industry support are educational rather than promotional and apply safeguards to prevent bias in the selection of topics, speakers, and materials presented. One example is the scientific symposium that is organized and controlled by a professional society and supported by unrestricted grants from companies. Such meetings may be particularly important for fields with many Ph.D. researchers and relatively restricted budgets. Another example is training in the use of complex medical devices provided by medical device companies under the conditions outlined elsewhere in this report (e.g., no gifts or inducements to use the product).

Other Recommendations in This Report

In addition to the recommendations in this chapter, other recommendations in this report would affect institutions that provide undergraduate, graduate, or continuing medical education. The standardization of institutional disclosure policies and formats (Recommendation 3.3) would require work to change policies and information systems, but in the long term, it should make institutional policies less burdensome across all educational institutions—as well as for individuals who must disclose potential conflicts of interest. Academic medical centers, which have repeatedly been embarrassed by revelations of incomplete and inaccurate faculty disclosures of payments from industry, would benefit from a national program of company reporting of payments to physicians and researchers that would allow the verification of certain disclosures (Recommendation 3.4). Because that reporting program would also cover payments to academic medical centers and other providers of medical education, it could provide an incentive for the adoption of institution-level conflict of interest policies, as recommended in this report (Recommendation 8.1). Accrediting organizations, membership groups such as AAMC and CMSS, and government agencies should also develop incentives for institutions to adopt and implement conflict of interest policies (Recommendation 9.2).

Adoption of the recommendation related to the conduct of research in which an investigator has a financial interest would encourage the development of management plans to protect trainees involved in such research if the institution concludes that the participation by the investigator with a conflict of interest in the research is essential (Recommendation 4.1). To the extent that physicians embrace Recommendation 6.1 to reject gifts and similar ties, it would reduce dissonance when students, trainees, and faculty interact with others in the medical community at professional society meetings and in other contexts. Further steps by companies to reform their policies and practices on gifts and payments to physicians (Recommendation 6.2) would allow medical centers to focus more attention on other issues, for example, consulting and

other contractual arrangements. Finally, academic institutions can play an important role in implementing a program of research on conflict of interest (Recommendation 9.2).

Footnotes

1 The committee follows the convention in medical education of referring to the years of medical school as "undergraduate medical education" and the post-M.D. years of residency and fellowship as "graduate medical education." Unless otherwise described (e.g., research fellows), fellows are physicians in subspecialty training programs. This report refers to "residents" and "fellows" rather than "trainees" (a description commonly used by medical educators).

2 The count includes four schools granted preliminary accreditation in 2008. It does not include accredited Canadian schools or the 20 accredited U.S. schools of osteopathic medicine.

3 These providers are accredited by state medical societies under the rules of the Accreditation Council on Continuing Medical Education.

4 As described by ACCME, "ACCME has two major functions: the accreditation of providers whose CME [continuing medical education] activities attract a national audience and the recognition of state or territorial medical societies to accredit providers whose audiences for its CME activities are primarily from that state/territory and contiguous states/territories" (ACCME, 2005).

5 AMA also authorizes credits for other activities, such as publishing an article in a peer-reviewed journal or achieving and maintaining specialty board certification.

6 The AMSA ratings, the methodology, and other information can be found at http://amsascorecard.org/. The IMAP information can be found at http://www.imapny.org/coi_database/. Both groups use information and policies received in response to a survey conducted under the auspices of the Prescription Project with funding from the Pew Charitable Trust. Some schools did not respond initially, and others refused to supply their policies.

7 ECRI Institute is a technology assessment organization that has a long history of providing advice to health care institutions and government on medical device safety. It is one of the Evidence-Based Practice Centers designated by the Agency for Healthcare Research and Quality and is a Collaborating Center of the World Health Organization.

8 The American Board of Medical Specialties and its 24 member boards have been moving from a process of recertification based on an examination taken once every several years to a maintenance of certification program that emphasizes continuing self-evaluation of practice and knowledge and other activities to maintain competence. Boards may develop self-assessment programs that also offer continuing medical education credit that will meet state licensing board and other requirements.

9 One widely cited analysis estimated that every $1.00 of industry spending on physician meetings and events generated an average of $3.56 in increased revenue (cited in Walker [2001]; see also CEJA [2008] and NAAMECC and Coalition for Healthcare Communication [2008]). Descriptions of the reported analysis do not indicate the relative weight of accredited versus nonaccredited activities in the estimate or whether accredited continuing medical education was distinguished from other types of meetings, such as promotions. Nonetheless, it suggests a rationale for industry support of a range of educational activities.

10 In 1997, the FDA provided guidance on the characteristics of industry-supported educational activities that distinguish them from promotional activities, which are subject to the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act (FDA, 1997). This guidance stresses the role of voluntary oversight, for example, through accreditation; it explicitly disavows an interest in regulating programs.

11 The corporate integrity agreement was signed by Pfizer, which had purchased Warner-Lambert, which, in turn, was the parent company of Parke-Davis, the company named in the case.

Figures

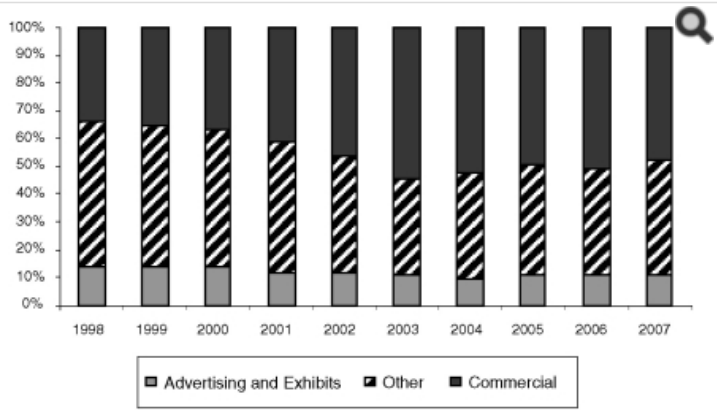

FIGURE 5-1

Sources of income reported by respondents (accredited providers of continuing medical education) to ACCME annual survey, 1998 to 2007. SOURCE: Compiled from ACCME, 2008a.

Tables

TABLE 5-1 Third-Year Medical Students' Interactions with Drug Companies

Type of Event	No. of Students. (N = 826)	No. (%) of Students Who Received a Gift or Participated in at Least One Event	Exposure Frequency per Month[a]	
			Mean (SD)	Range
A lunch provided by a drug company	793	768 (96.8)	1.08 (0.76)	0–4.2
A small, noneducational gift (e.g., pen or coffee mug)	801	754 (94.1)	0.87 (0.69)	0–3.5
A journal reprint or a glossy brochure from a pharmaceutical representative	800	716 (89.5)	0.53 (0.52)	0–3.5
A snack (e.g., donut, candy, coffee) provided by a pharmaceutical representative	800	713 (89.1)	0.75 (0.72)	0–8.5
A grand rounds sponsored by a drug company	798	690 (86.5)	0.54 (0.57)	0–2.4
A dinner provided by a drug company	801	405 (50.6)	0.13 (0.21)	0–2.4
A drug sample from a pharmaceutical representative	799	435 (54.4)	0.10 (0.20)	0–2.1
Another social event (e.g., party) sponsored by a drug company	799	272 (34.0)	0.06 (0.11)	0–0.8
A book donated by a drug company[b]	826	421 (51.0)		
Attendance at a workshop sponsored by a drug company[b]	826	214 (25.9)		
Registration fee for a conference paid for by a drug company[b]	826	37 (4.5)		
Participation in a market survey sponsored by a drug company[b]	826	29 (3.5)		
Participation in a research project sponsored by a drug company[b]	826	22 (2.7)		
Travel expenses for a conference paid for by a drug company[b]	826	15 (1.8)		
Nominated for an award sponsored by a drug company[b]	826	5 (0.6)		
Obtained a fellowship sponsored by a drug company[b]	826	4 (0.5)		

a For each student, an exposure index was calculated as the sum of the monthly frequencies for the first eight items.

b Monthly frequency data were not requested.

SOURCE: Sierles et al. Medical students' exposure to and attitudes about drug company interactions: a national survey. *Journal of the American Medical Association* 294(9):1034-1042 (September 7, 2005).

TABLE 5-2 Share of Total Accredited Continuing Medical Education Income, Instruction Hours, Participants, and Activities Accounted for by Major Types of ACCME-Accredited Providers

Provider Organization Type	Share (as %)			
	Total CME[a] Income	Total Hours of CME Instruction	Total CME Participants	All CME-Sponsored Activities
Medical school	17	45	31	30
Publishing/education company	33	9	30	30
Physician membership organization (nonprofit)	35	23	26	20
Other providers	15	23	13	20
TOTAL	100	100	100	100

a CME = continuing medical education.

SOURCE: ACCME, 2008a, Tables 2, 3, 4, 7.

TABLE 5-3 Income, Expenses, and Source of Support as Percentage of Income, by Type of Accredited Provider of Continuing Medical Education, 2007

Organization Type (No. of Organizations)	Total Income	Expenses as % of Total Income	Total Commercial Support (% of Total Income)	Advertising and Exhibits Income (% of Total Income)
Nonprofit (physician membership organization) (270)	$887,181	68	$215,388 (24)	$217,907 (25)
Publishing/Education Company [MECC](150)	830,811	74	594,420 (71)	10,831 (1)
School of medicine (123)	427,668	88	245,790 (57)	23,203 (5)
Hospital/health care delivery system (93)	105,014	95	47,498 (45)	7,407 (7)
Nonprofit (other) (38)	160,397	79	78,412 (49)	11,852 (7)
Not classified (33)	55,188	79	29,263 (53)	2,423 (4)
Government or military (15)	69,452	100	255 (0)	376 (0)
Insurance company/managed care company (14)	3,489	193	318 (9)	35 (1)

NOTE: Monetary data for 2007 are in 1,000s of dollars. Data for a third category of income (other) are not shown here. As categorized by ACCME, other income represents income other than commercial support and advertising and exhibit income. Data for providers accredited by state medical societies are not included, but ACCME survey data show that commercial sources accounted for about 25 percent of their income.
SOURCE: ACCME, 2008a (Table 7).

Boxes

BOX 5-1 AAMC Recommendations on Site Access by Sales Representatives

Site Access by Pharmaceutical Representatives

- To protect patients, patient care areas, and work schedules, access by pharmaceutical representatives to individual physicians should be restricted to non-patient care areas and nonpublic areas and should take place only by appointment or invitation of the physician.
- Involvement of students and trainees in such individual meetings should occur only for educational purposes and only under the supervision of a faculty member.
- Academic medical centers should develop mechanisms whereby industry representatives who wish to provide educational information on their products may do so by invitation in faculty-supervised structured group settings that provide the opportunity for interaction and critical evaluation. Highly trained industry representatives with M.D., Ph.D., or Pharm.D. degrees would be best suited for transmitting such scientific information in these settings.

Site Access by Device Manufacturer Representatives

- Access by device manufacturer representatives to patient care areas should be permitted by academic medical centers only when the representatives are appropriately credentialed by the center and should take place only by appointment or invitation of the physician.
- Representatives should not be allowed to be present during any patient care interaction unless there has been prior disclosure to and consent by the patient, and then only to provide in-service training or assistance on devices and equipment.
- Student interaction with representatives should occur only for educational purposes under faculty supervision.

SOURCE: AAMC, 2008c.

BOX 5-2 Example of a Solicitation of Industry Support (Educational Grants) for a Large Accredited Continuing Medical Education Program

Several support levels are listed below. Please note that educational support is appreciated at any dollar level. Please contact our office for further details. We appreciate that our supporters recognize the need for [the organization] to maintain authority and autonomy in decisions regarding program format, content, and faculty.

Cornerstone Supporter

Total: $195,000

Foundation Supporter

Total: $135,000

Leadership Supporter

Total: $80,000

Satellite Symposia

Open to Cornerstone and Foundation Supporters

1 Breakfast Symposium	Fee: $15,000
1 Lunch Symposium	Fee: $20,000
1 Breakfast Symposium	Fee: $15,000
1 Lunch Symposium	Fee: $20,000
1 Breakfast Symposium	Fee: $15,000

Symposium fee includes:

- Program listing on the [meeting] website, linking to the program provider's online registration site for the satellite symposium.
- Program listing and schedule in the meeting materials distributed to all meeting attendees.
- One complimentary email to the preregistration mailing list for use in promotion of the satellite symposium.
- One time complimentary use of the preregistration mailing list for use in promotion of the satellite symposium (restrictions apply).
- One insert into the delegate literature bag for use in promotion of the satellite symposium.

SOURCE: Excerpted from Oncology Congress, 2008, 2009.

BOX 5-3 Settlements Involving Educational Activities and Speaking and Writing Arrangements

In 2004, Warner-Lambert paid $430 million to settle U.S. Department of Justice charges that the company promoted off-label uses of the drug Neurontin in violation of the Food, Drug, and Cosmetic Act. "This illegal and fraudulent promotion scheme corrupted the information process relied upon by doctors in their medical decision making, thereby putting patients at risk." Tactics included "[paying] doctors to attend so-called 'consultants meetings' in which physicians received a fee for attending expensive dinners or conferences during which presentations about off-label uses of Neurontin were made; … [and sponsoring] purportedly 'independent medical education' events on off-label Neurontin uses with extensive input from Warner-Lambert regarding topics, speakers, content, and participants. … In at least one instance, when unfavorable remarks were proposed by a speaker, Warner-Lambert offset the negative impact by 'planting' people in the audience to ask questions highlighting the benefits of the drug" (DOJ, 2004, unpaged).

In 2007, Orphan Medical, Inc., agreed to pay $20 million and accept a corporate integrity agreement to settle charges that it had illegally promoted the drug Xyrem (sodium oxybate) for off-label uses. Among other charges, the company was accused of using unrestricted "educational grants" as an inducement for off-label use and paying tens of thousands of dollar in speaker fees to physicians for their promotion of these uses. One of these physicians has been charged criminally for his behavior (DOJ, 2007b). The associated corporate integrity agreement required, among other provisions, that the company create procedures to ensure that sponsored continuing medical education and educational activities be independent and nonpromotional (OIG, 2007).

In 2008, in a stipulated agreement filed in Oregon, Merck & Co, Inc., agreed to pay $58 million to 30 states and to end certain deceptive practices used to promote the drug Vioxx (rofecoxib). The stipulation prohibits, among other practices, company use of ghostwriting of published journal articles and the nondisclosure of promotional ties with speakers at independent continuing medical education programs (Oregon DOJ, 2008a).

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