REPORT 1 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (A-08)
Industry Support of Professional Education in Medicine
(Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

Objective: To provide ethical guidance for physicians and the profession with respect to industry support for professional education in medicine.

Methods: Literature review; ethical analysis of issues in professionalism raised by industry support for undergraduate, graduate, and continuing medical education; and feedback from key stakeholders within the AMA.

Results: Medicine's autonomy and authority to regulate itself depends on its ability to ensure that current and future generations of physicians acquire, maintain, and apply the values, knowledge, skills, and judgment essential for quality patient care. To fulfill this obligation, medicine must ensure that the values and core commitments of the profession protect the integrity of professional education. It must strive to deliver scientifically objective and clinically relevant information to individuals across the learning continuum. To promote continued innovation and improvement in patient care, medicine must sustain ongoing, productive relationships with the pharmaceutical, biotechnology, and medical device companies. However, industry support of professional education has raised concerns that threaten the integrity of medicine's educational function.

Conclusions: Existing mechanisms to manage potential conflicts and influences are not sufficient to address these concerns. Recognizing the profession-defining importance for medicine of achieving its educational goals, the Council recommends that:

- Individual physicians and institutions of medicine, such as medical schools, teaching hospitals, and professional organizations (including state and medical specialty societies) must not accept industry funding to support professional education activities. Exception should be made for technical training when new diagnostic or therapeutic devices and techniques are introduced. Once expertise in the use of previously new devices has developed within the professional community, continuing industry involvement in educating practitioners is no longer warranted.

- Medical schools and teaching hospitals are learning environments for future physicians at a critical, formative phase in their careers and have special responsibilities to create and foster learning and work environments that instill professional values, norms, and expectations. They must limit, to the greatest extent possible, industry marketing and promotional activities on their campuses. They have a further responsibility to educate trainees about how to interact with industry and their representatives, especially if and when trainees choose to engage industry in varying capacities after residency and fellowship training.

- The medical profession must work together to identify the most effective modes of instruction and evaluation for physician learners. It must then more efficiently develop and disseminate educational programming that serves the educational needs of all physicians. The profession must obtain more noncommercial funding of professional education activities.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-A-08

Subject: Industry Support of Professional Education in Medicine

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Referred to: Reference Committee on Amendments to Constitution and Bylaws (Raymond G. Christensen, MD, Chair

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The practice of medicine is inherently a moral activity, founded in a "covenant of trust" between patient and physician.[1,2,3] The status of medicine as a profession rests above all on its commitment to fidelity and service in that relationship. As a profession, medicine must instill core professional values and provide clinical training which ensures that current and future generations of physicians are competent and caring. In return, society grants medicine considerable authority to set the ethical and professional standards of practice and the autonomy to educate its practitioners.[4,5]

Today, medicine is also engaged in multiple relationships with industry, defined as pharmaceutical, biotechnology, and medical device companies, that are both engines of innovation and significant sources of financial support for professional education. Commercial support now accounts for approximately half of all income to nationally accredited providers of continuing medical education (CME).[6] The extent of industry support of undergraduate and graduate medical education is less well documented, but industry spends considerable funds in support of the educational mission of medical schools and teaching hospitals. For example, industry supports educational travel grants for medical students and residents, provides free lunches at grand rounds and similar events, and helps fund residency positions.

While industry and medicine share the overall goal of improving health, their interests and obligations diverge in important ways. Commercial entities have a responsibility to their shareholders and other vested stakeholders to thrive as businesses and maximize returns on investment. Medicine has a responsibility to put the needs of patients first. As relationships between medicine and industry continue to expand, there is growing concern about the impact of industry funding on the integrity of professional education and its implications for public confidence in medicine as a profession.

While the scope of medicine-industry relationships spans a wide spectrum from biomedical research to clinical care, this Report focuses only on industry's support of professional education in medicine, and provides ethical guidance on how individual physicians and the profession as a whole should address this critical issue.

* Reports of the Council on Ethical and Judicial Affairs are assigned to the reference committee on Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

MEDICINE'S DUTY TO EDUCATE

> *Publicly in his oath and privately in his encounter with the patient, the physician professes two things—to be competent to help and to help with the patient's best interests in mind.*[1]— Edmund Pellegrino

The special moral character of the interaction between patient and physician arises from the need—illness—that brings the patient into the relationship. Physicians are granted extraordinary privileges to intervene in patients' lives, to impose harm in the service of healing, to gain access to sensitive information, and to engage in intimate contact with patients that would otherwise be prohibited. Educating current and future generations of physicians to fulfill the responsibilities that flow from the patient-physician relationship is the foundation of medicine's status as a caring and competent profession. Therefore, medicine's ethical duty to educate well is not one that can be delegated to others.

To educate physicians for their roles as healers and members of a "learned" profession, medicine must do two things: instill core professional values and impart clinical knowledge and skills.[1–3,5,7,8] The years of medical school and residency/fellowship training are a critical time in the socialization of physicians as professionals. As trainees, medical students, residents, and fellows solidify values and attitudes that will endure throughout their careers.[2,9] Preserving the integrity of professional education is paramount at this crucial, formative stage in professional development. As lifelong learners, practicing physicians must maintain their clinical knowledge and skills through continuing medical education and other professional development activities. Given the wide array of diagnostic and therapeutic options available today, physicians and the patients who rely on them must be confident that clinical decisions are informed by continuing medical education activities that are pedagogically sound, scientifically valid, and clinically relevant.

To achieve these profession-defining goals, medicine must control the subject matter that is taught and work to ensure the objectivity of educational content and of those who teach it. Yet there is growing concern that medicine's increasing reliance on industry financial support of professional education has undermined its status in society.[10] As one recent commentary noted, "[w]hat is at stake is nothing less than the privilege of autonomy in our interactions with patients, self-regulation, public esteem, and a rewarding and well-compensated career."[11]

INDUSTRY FUNDING & THE INTEGRITY OF PROFESSIONAL EDUCATION

Scope of industry support. Over the past decade, medicine has come to rely significantly on industry funding to support professional education across the learning continuum. Compared to 1998, commercial support of providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) increased by a factor of 300% to $1.2 billion in 2006.[6] According to a 2006 national survey of department chairs at all U.S. medical schools and the 15 largest teaching hospitals, 19% of respondents were paid by industry to participate as faculty or speakers in CME activities; 14% were on company speakers' bureaus; and 16% accepted free or subsidized travel, meals, lodging, and other personal expenses associated with attendance at meetings or conferences related to their specific area of expertise.[12]

The extent of industry support for graduate and undergraduate medical education is less well documented, but undoubtedly it is less than what is currently spent on continuing medical education. In the previously cited 2006 survey, 25% of respondents reported that their departments accepted financial support for residency or fellowship training; 38% accepted food and beverages;

and 22% accepted financial support for travel and meetings.[11] Of note, industry has also started funding new residency positions in at least one specialty.[13,14]

Estimates vary on industry's return on investment (ROI) from its various educational and marketing activities.[15] One study estimated that for every $1.00 industry spent on CME programs and other meetings yielded on average $3.56 in increased revenue.[16,] This ROI is higher than what has been estimated for pharmaceutical detail visits and direct-to-consumer advertising. Based on these estimates, industry support for professional education is unlikely to fall; more likely it will continue to grow for the foreseeable future unless steps are taken to intervene.

Integrity of professional education. Professional education in medicine is fundamentally grounded in the ideal of scientific objectivity—in other words, education that is free of all bias. Given that humans are thinking, feeling beings with strongly held beliefs, this ideal is never fully realized. Nonetheless, articulating this ideal helps physicians gauge the soundness of their individual choices and conduct, while challenging the profession to safeguard the integrity of how it educates its current and future members.

Since it is not humanly possible to be free of bias, our perceptions and decisions are inevitably subject to influence in ways we do not perceive.[17,18] Thus it is important to understand what informs and shapes individual and collective decisions. Professional judgment and conduct are dictated by medicine's ethical imperative to put the welfare of patients first. Industry judgment and conduct are driven by the economic imperative to produce products and services that earn a decent return on investment for shareholders. Given the nature of these different imperatives, professional and industry priorities cannot be assumed to be the same or even similar. Sometimes they *are*, but whenever the priorities of medicine and industry are misaligned, and industry promotes its priorities by supporting educational activities, the integrity of professional education is undermined.

The most recent and best available evidence on the improper influence of industry-funded educational activities on physician decision making are legal cases dealing with inappropriate prescribing. In one prominent case brought by the U.S. Department of Justice, the makers of the drug gabapentin (Neurontin™) were charged with using CME presentations as a major method of promoting off-label uses of gabapentin.[19,20] The company was charged with selecting speakers and approving their presentation content specifically to ensure that physicians would be made aware of off-label uses for this drug, despite laws that prohibit pharmaceutical companies from promoting any drug for off-label use. The company ultimately settled the claims for $430 million.

Another case brought against the maker of the drug oxycodone (OxyContin™) charged the company with designing seminars, trainings and educational programs for physicians to serve the same goals as the company's marketing strategies (e.g., detail visits to physician offices).[21] The company's efforts fraudulently promoted oxycodone as being less addictive, less subject to abuse, and less likely to cause withdrawal symptoms than other pain medications. The claims were settled for $634 million.

Additional evidence on the relationship between industry-funded educational activities and inappropriate prescribing is less recent and have small sample sizes. One study worth noting, in part because its research design was quasi-experimental, evaluated whether industry-funded CME led to increased prescribing of the company drug versus non-company drugs in the same therapeutic class. Results revealed that the company drug was prescribed more often by physicians after attending the company-supported CME event as compared to other drugs in the same class.[22]

Another study examined physicians' prescribing patterns of two drugs before and after they attended symposia sponsored by the manufacturers. Findings revealed that participants' usage of both drugs increased significantly following the symposia and this differed significantly from national prescribing patterns of the same drugs for the same time period in comparable clinical settings.[23]

In light of the inherent tension between professional and industry priorities and available evidence, current efforts to ensure the independence of professional education are primarily aimed at improving transparency through financial disclosures; and at mitigating influence through mechanisms that insulate the recipient from direct control by the industry funder.

DISCLOSURE AND MITIGATION

Limitations of disclosure. Disclosing potential conflicts is often seen as an appropriate way to manage them, but disclosure does nothing to eliminate the potential conflict.[24] Rather, disclosure unfairly places the burden of managing the conflict on those to whom the disclosure is made, charging them with determining how skeptical to be about the objectivity of the individual with the potential conflict.[25] It is not reasonable to expect physician learners who are attending an educational event to acquire new knowledge to be in a position to fully discern what "information" provided by the presenter is objective or biased.

In addition, disclosure can have unintended consequences. First, the presenter, confident that the conflict has been managed by his or her disclosure, may feel less of a need to strive for objectivity – encouraging self-interested behavior on the part of the individual making the disclosure. Second, for the learner, disclosure can convey the impression that the presenter is especially honest, and therefore one need not be as skeptical about what is being presented. In other words, disclosure can create a false sense of security about the objectivity of the educational content.[26]

Limitations of mitigation. ACCME Standards for Commercial Support are designed to "ensure the independence of CME activities" by establishing mechanisms that prohibit commercial funders from having control over educational objectives, content, and methods, as well as selection of faculty.[26] The standards also require accredited providers to take steps to resolve any conflicts of interest between funders and individuals who have control over educational content *before* the educational activity takes place.

Such mitigation measures are intended to insulate the educational responsibilities of accredited providers from the marketing influence of industry funders. However, there is evidence that these efforts are not sufficient to guarantee professional autonomy in the identification of topics, selection of speakers, and development of educational content. Companies make educational grants consistent with their overall business strategies and therapeutic areas of interest,[27,18] shifting education toward benefiting funders and away from patient interests.[28] Commercially supported CME programs tend to address a narrower range of topics,[29,18] focus more on drug therapies,[27] and give more favorable treatment to company products[30] than do programs that are not commercially funded.

In one national survey, a large number of department chairs believed that restricted financial support from industry is more likely than unrestricted funding to compromise the ability of academic faculty to provide independent, unbiased education.[10] According to the survey, nearly 60% of respondents believed that restricted funds of greater than $100,000 would have a negative impact on the validity and objectivity of professional education; while almost 40% felt that way about unrestricted funds, which are generally considered to confer the greatest degree of

professional autonomy in the development of educational programming. This study reveals the degree to which many physicians are aware and acknowledge the influence of industry on the objectivity of professional education.

But influence also operates below the level of awareness. Regardless of whether it is possible to clearly differentiate between industry-supported "education" and "marketing," both activities ultimately aim to influence physician behavior. As opposed to industry-supported professional education, successful marketing and promotional practices rely heavily on the ability of industry representatives to establish and build personal rapport with physicians.[31] This is routinely achieved through the offering of gifts that often elicit the desire to reciprocate whether one is aware of it or not.

We must stress that concern about industry influence in professional education is often about subtle bias, not conscious corruption or wrongdoing. Influence is not the result of gullibility or lapse of judgment on the part of physicians, but the inevitable result of how people respond to overtures of perceived benevolence. Financial compensation, gifts, favors, or other benevolent gestures introduce unconscious bias; they distort recipients' decision-making by leading them to emphasize data that support givers' personal views or interests without recipients realizing that they are doing so.[15]

Psychosocial and neurobiological studies indicate that our response to reciprocate what we perceive as a benevolent gesture takes place below the level of conscious intention and independent of the magnitude of the perceived benefit.[15,16] Recall bias may also unintentionally affect physicians' behavior, for example, by unconsciously encouraging them to prescribe a drug that comes first to mind for a condition when they have recently been exposed to detailing, ads, or other promotions.[32] Thus while physicians rightly pride themselves on their scientific training and dedication to objectivity, the human reality is that critical reasoning ability by itself does not guarantee that an individual can predict how interactions with industry affect his or her decision-making.

Finally, with the exception of Food and Drug Administration regulations governing promotion of drugs and medical devices, guidelines addressing relationships between industry and physicians or medical organizations are voluntary.[20] At present there are no mechanisms for proactive oversight or real-time monitoring adherence to existing ACCME standards for commercial support. Further, accredited CME providers themselves have indicated that complying with guidelines is becoming increasingly burdensome.[33]

AN EDUCATIONAL IDEAL

In the history of American medical education, there have been critical moments when the profession has made great strides in meeting its goals to educate and train its members to be caring and competent. Next year marks the 100th anniversary of the publication of the Flexner Report, which transformed how physicians were educated. These "Flexnerian" changes did not occur overnight, but they ultimately established new norms and standards for how we educate and train future generations of physicians.

The current system of professional education in medicine, with industry providing a significant proportion of overall funding, is undermining those gains and the goals of professional education. We are not convinced that attempting to manage industry influence in professional education is a prudent use of resources. Rather, avoiding the influence altogether is essential to ensuring the integrity of professional education. Avoiding influence-creating situations altogether is effective,

simple, and does not place the burden of sustaining objectivity entirely on individual physicians. For example, some specialty societies from their inception have accepted virtually no industry support for their educational activities. Similarly, some major medical centers have decided to accept no industry support for continuing medical education,[35] as have some state physicians' organizations.[34]

In medical schools and teaching hospitals, industry gifts and other marketing activities are so prevalent that it is increasingly difficult to separate these promotional influences from the educational mission of these institutions. At this critical formative stage in their professional development, medical students and resident physicians are exposed to modeling of behavior by their teachers that is often at odds with the core commitments of physicians as professionals.[9] As a result, several medical schools and teaching hospitals have chosen to forgo gifts and meals from pharmaceutical, biotechnology, and medical device companies.[35,36] At the same time, these institutions realize that medical students and resident physicians need to know how to interact with industry and their representatives after they graduate. For example, such education and training may include seminars or other didactic sessions that teach physicians to recognize possible bias in industry-authored materials, and tools for self-study that enhance critical listening and questioning skills. In addition, a number of academic medical centers have moved to significantly curtail and in some cases eliminate outright, industry access to trainees and faculty.[37,38]

Finally, studies of patients' attitudes reveal that they tend to disapprove of industry gifts to physicians, including items that they believe might have some value for patients, such as free drug samples.[39,40] There is also evidence that patients find gifts less appropriate, and more influential, than do their physicians.[41] To our knowledge, no studies have specifically assessed patients' perceptions of industry support for professional education, but surveys over the last decade consistently show that pharmaceutical companies are among the industries the public thinks should be regulated more stringently.[42] While public perception should not dictate the debate about the role that industry should have in professional education, it is important that medicine as a self-regulating profession respond to these public concerns, lest they undermine patients' trust in physicians.

REALIZING THE IDEAL

Divesting the medical profession of industry support for professional education raises two critical questions: what is the best way to educate physicians, and how will it be financed?

To answer the first question, we must systematically examine how physicians learn and then develop and test modes of instruction and evaluation that effectively impart essential knowledge and skills that when applied, will positively impact the quality of care that physicians provide. Many organizations have advocated for some variation of a "professional education research institute" that will create the evidence base that will contribute to positive changes in how physicians learn to care for patients.[43,44] Doing so will require resources, but it is necessary in order to establish that professional education is based on the most effective methods of teaching and learning.

Even as we move to advance the science of adult learning in medicine, we acknowledge that industry involvement in professional education is required when new diagnostic or therapeutic devices and techniques are introduced in medicine. Industry and their representatives are sometimes the only "teachers" qualified to train physicians on how to use devices safely and effectively, especially in the early stages of a device's introduction. It is appropriate and necessary that industry representatives, or physician-innovators whose work led to the innovation, have an

educational role in these learning situations. However, once expertise has developed within the professional community, continuing industry involvement in educating practitioners is no longer warranted. Given the dissemination and adoption patterns of new technological innovations in medicine, it is not possible to determine with absolute certainty when the transition from early adoption to mature clinical practice has occurred. One potential indicator that this educational transition has taken place is when physicians have access to competing devices in the same diagnostic or therapeutic category. Technical assistance or support that industry representatives may provide physicians in the context of patient care (e.g., helping a surgeon in the operating room select the appropriately sized prosthesis component) is considered professional education and is not ethically inappropriate.[45]

To address the second question, we recognize that adopting a policy banning industry support of professional education poses significant resource challenges to some organizations in the immediate term. For many institutions, disentangling medical education from industry support will call for major changes in organizational culture and cultivation of alternative funding streams. A learning environment free of industry influence and that upholds the integrity of professional education cannot be created overnight; such a transformation will demand ongoing, dedicated leadership and committed action at all levels of the profession over the long term.

It should be noted that industry support does not necessarily lead to efficient educational programming. More than half of all commercial support goes to medical education and communication companies, which rely almost exclusively on industry funding but only provide 8% of the total hours of CME instruction. In comparison, medical schools receive 21% of total commercial support, but provide almost half (46.5%) of the total hours of CME instruction.[6] These figures suggest that a significant portion of industry funding does not necessarily result in the development of actual educational programming, regardless of the impact of industry funding on the objectivity of educational content.

The importance of spending every educational dollar as efficiently as possible is especially pertinent for physicians who practice outside large, urban academic settings—for example, those in community hospitals and rural clinics. Smaller and rural institutions in medicine will likely require more time to transition to a point where they no longer rely on industry support for educational activities. Large academic medical centers that have already moved to eliminate industry support of their educational mission must be prepared to help during this transition by developing and disseminating relevant specialty-specific educational programming to colleagues in these practice settings. Medicine might consider following the example of non-medical educational institutions that have made their entire curriculum available free over the Internet.[46]

Many have also argued that ending industry support will decrease CME availability, independent of how efficiently and effectively the resources are spent in producing CME.[47,48] If that is the case, physicians must also advocate for more noncommercial sources of funding for educational activities—the education of physicians is a public good whose burden should not be shared by the profession alone.

Finally, challenges, seen and unforeseen, will undoubtedly arise as the medical profession realizes this educational ideal, but we are confident that none of them are insurmountable. More than 160 years ago, the American Medical Association came into being in response to threats that stood to undermine the integrity of professional education of physicians. Our young organization was then instrumental in promulgating standards for rigorous, systematic, scientifically sound medical education. It was a driving force behind the Flexner Report that transformed the system of

American medical education almost a century ago. It must and will live up to that legacy of leadership to address any risks to the integrity of professional education today.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and that the remainder of this report be filed:

Medicine's autonomy and authority to regulate itself depends on its ability to ensure that current and future generations of physicians acquire, maintain, and apply the values, knowledge, skills, and judgment essential for quality patient care. To fulfill this obligation, medicine must ensure that the values and core commitments of the profession protect the integrity of professional education. It must strive to deliver scientifically objective and clinically relevant information to individuals across the learning continuum—from medical school, into residency and fellowship training, and throughout continuing medical education.

To promote continued innovation and improvement in patient care, medicine must sustain ongoing, productive relationships with the pharmaceutical, biotechnology, and medical device companies. However, industry support of professional education has raised concerns that threaten the integrity of medicine's educational function. Existing mechanisms to manage potential conflicts and influences are not sufficient to address these concerns.

Given medicine's current reliance on industry funding of professional education, implementing the following recommendations will take time. Yet we must recognize the profession-defining importance of ultimately achieving these goals. To that end:

(1) Individual physicians and institutions of medicine, such as medical schools, teaching hospitals, and professional organizations (including state and medical specialty societies) must not accept industry funding to support professional education activities. Examples of such activities include, but are not limited to, industry funding for:

    (a) residency positions and clinical fellowships;

    (b) didactic educational programs, such as live or web-based continuing medical education activities:

    (c) physician speakers' bureaus; and

    (d) travel, lodging, and amenities for participants of clinically relevant educational programming.

(2) One exception to no industry support of professional education is when new diagnostic or therapeutic devices and techniques are introduced. Given the requirement for technical training on how to use new devices, industry representatives may have to play an educational role because they could be the only available teachers. But once expertise in the use of previously new devices has developed within the professional community, continuing industry involvement in educating practitioners is no longer warranted. Technical assistance or support that industry representatives may provide physicians in the context of patient care (e.g., helping a surgeon in the operating room select the appropriately sized prosthesis components) is not considered professional education and is not ethically inappropriate.

(3) Medical schools and teaching hospitals are learning environments for future physicians at a critical, formative phase in their careers. These institutions have special responsibilities to create and foster learning and work environments that instill professional values, norms, and expectations. They must limit, to the greatest extent possible, industry marketing and promotional activities on their campuses. Examples of such activities include, but are not limited to:

(a) free food and other industry gifts for trainees and faculty, and

(b) detailing visits by industry representatives.

Medical schools and teaching hospitals have a further responsibility to educate trainees about how to interact with industry and their representatives, especially if and when trainees choose to engage industry in varying capacities after residency and fellowship training.

(4) The medical profession must work together to:

(a) identify the most effective modes of instruction and evaluation for physician learners, then;

(b) more efficiently develop and disseminate educational programming that serves the educational needs of all physicians, especially for those who have difficulty accessing continuing medical education (such as those who practice in rural areas); and

(c) obtain more noncommercial funding of professional education activities.

(New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

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