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Industry Funding of Medical Education

Report of an AAMC Task Force

June 2008

Association of
American Medical Colleges

The AAMC gratefully acknowledges the Josiah Macy, Jr Foundation for its generous award that supported the work of this Task Force.

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Executive Summary[1]

Introduction

An effective and principled partnership between academic medical centers and various health industries is critical in order to realize fully the benefits of biomedical research and ensure continued advances in the prevention, diagnosis, and treatment of disease. Appropriate management of this partnership by both academic medical centers and industry is crucial to ensure that it remains principled, thereby sustaining public trust in the proposition that both partners are fundamentally dedicated to the welfare of patients and the improvement of public health.

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.

The Association of American Medical Colleges (AAMC) embraces the obligation of the profession to manage, through effective self-regulation, all real or perceived conflicts of interest. Accordingly, in 2006 AAMC charged a special Task Force on Industry Funding of Medical Education (hereafter referred to as Task Force) with forging consensus principles to guide the AAMC and the leaders of medical schools and teaching hospitals in developing policies and procedures to manage industry gifting practices and financial support of their programs of medical education for students, trainees, faculty, and community physicians. This report is the product of the Task Force's efforts.

The Report acknowledges the new policy directions being implemented in many medical schools and teaching hospitals to address industry support of medical education, and it urges all academic medical centers to accelerate their adoption of policies that better manage, and when necessary, prohibit, academic-industry interactions that can inherently create conflicts of interest and undermine standards of professionalism. Although the charge to the Task Force was focused on funding from the pharmaceutical and device industries, institutional policies on conflicts of interest should be comprehensive and encompass providers of equipment and services as well. Concomitantly, industry should voluntarily discontinue those practices that compromise professionalism as well as public trust.

[1] The Task Force report and recommendations have been approved unconditionally by all Task Force members, with the exception of Jeffrey B. Kindler (Pfizer), Kevin Sharer (Amgen), and Sidney Taurel (Lilly). Mr. Sharer supports the "explicit recommendations" of the Task Force, but "is not in a position to endorse the text" of the report. Mr. Sharer further states that "It is understandable that industry and academe will not agree completely on the final wording of any report given our differing roles in health care." Mr. Kindler and Mr. Taurel support all but one of the Task Force recommendations, noting that "We do so without endorsing all of the supporting arguments used in the body of the report." The recommendation of concern, in Chapter 2 under the heading of "Industry-Sponsored Programs," actively discourages academic physicians from participating in industry-sponsored, FDA-regulated speaker programs. Mr. Kindler and Mr. Taurel further state that "We believe the reasoning for many of the recommendations is directionally correct, but more often than not the potential issues addressed reflect perceptions rather than proven consequences." The full statements from these Task Force members are presented in Appendix B.

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Chapter 1. Professionalism and Medical Education

Professionalism lies at the heart of medicine, and inculcating the values associated with it in future generations of physicians is a primary responsibility of academic medicine. In order that its interactions with industry consistently reflect the principles of professionalism, academic medical centers should take pains to impart the qualities of professionalism both through teaching and through the professional behaviors of faculty and staff. Professional standards should also be reflected and continuously reinforced in each institution's policies and practices in the areas of education, clinical practice, and research.

Institutional Policies and Practices

- Academic medical centers should adopt and implement policies that address specific interactions between academic medical personnel and industry and are consistent with recommendations contained in Chapter 2. These policies should reinforce and uphold institutional and individual efforts to promote a learning environment that supports professionalism and eliminates activities that undermine this objective.
- Academic medical centers should make clear to their faculty, students, and staff that to the extent certain interactions with industry are prohibited within academic medical centers, they are also prohibited off-site.
- Similarly, academic medical centers should 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.
- Industry should not invite academic medical center personnel to participate off-site in practices prohibited on-site.

Education for Professionalism

- Educational programs should be developed to raise the awareness among students, trainees, and faculty of challenges to professionalism presented by certain interactions with industry and to provide opportunities that help them build critical evaluation skills that reinforce high individual standards, norms, and behaviors. Specifically, the Task Force recommends a follow-on Medical School Objectives Project (MSOP) that focuses on developing learning objectives regarding professionalism and industry interactions.

Chapter 2. Benefits and Pitfalls

Substantive, appropriate, and well-managed interactions between industry and academic medicine are vital to public health, but they must be conducted in a way that is principled and upholds the public trust. Clear and well-thought-out guidelines will optimize the benefits inherent in the relationship between academic medicine and industry and minimize the risks.

Gifts to Individuals

- Academic medical centers should establish and implement policies that prohibit the acceptance of any gifts from industry by physicians and other faculty, staff, students, and trainees of academic medical centers, whether on-site or off-site. Such standards should encompass gifts from equipment and service providers as well as pharmaceutical and device providers.

Pharmaceutical Samples

- The distribution of medications in academic medical centers, including samples (if permitted), should be centrally managed in a manner that ensures timely patient access to optimal therapeutics throughout the health care system.
- If central management is not thought to be feasible, or would interfere with patient access to optimal therapeutics, the academic medical center should carefully consider whether or not there are alternative ways to manage pharmaceutical sample distribution that do not carry the risks to professionalism with which current practices are associated.

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 nonpatient 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.

Continuing Medical Education (CME)

- Academic medical centers offering CME programs should develop audit mechanisms to assure compliance with the standards of the Accreditation Council for Continuing Medical Education (ACCME), including those with respect to content validation and meals.
- Academic medical centers should establish a central CME office through which all requests for industry support and receipt of funds for CME activity are coordinated and overseen.
- To the extent that educational programs for physicians are supported by any commercial entity, including pharmaceutical, device, equipment, and service entities, the programs should be offered only by ACCME-accredited providers according to ACCME standards.

Participation in Industry-Sponsored Programs

- With the exception of settings in which academic investigators are presenting results of their industry-sponsored studies to peers and there is opportunity for critical exchange, academic medical centers should strongly discourage participation by their faculty in industry-sponsored speakers' bureaus.
- To the extent that academic medical centers choose to allow participation of their faculty and staff in industry-sponsored, FDA-regulated programs, they should develop standards that define appropriate and acceptable involvement.
    1. Academic medical centers should require full transparency and disclosure by their personnel to the centers and when participating in such programs; and
    2. Academic medical centers should require that payments to academic personnel be only at fair market value.
- Academic medical centers should prohibit their faculty, students, and trainees from:
    1. Attending non-ACCME accredited industry events billed as continuing medical education;
    2. Accepting payment for attendance at industry-sponsored meetings; and
    3. Accepting personal gifts from industry at such events.

Industry-Sponsored Scholarships and Other Educational Funds for Trainees

- Academic medical centers should establish and implement policies requiring that:

    1. All scholarships or other educational funds from industry must be given centrally to the administration of the academic medical center;
    2. No *quid pro quo* be involved in any way; and
    3. The evaluation and selection of recipients of such funds must be the sole responsibility of the academic medical center or of a nonprofit granting entity, with no involvement by the donor industry.

Food

- With the exception of food provided in connection with ACCME-accredited programming and in compliance with ACCME guidelines, institutions should establish and implement policies stating that industry-supplied food and meals are considered personal gifts and will not be permitted or accepted within academic medical centers.
- Policies should make clear that the same standard of behavior should be met off-site.

Professional Travel

- Academic medical centers should prohibit their physicians, trainees, and students from directly accepting travel funds from industry, other than for legitimate reimbursement or contractual services.

Ghostwriting

- Academic 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.

Purchasing

- Academic medical centers should establish and implement policies that require their personnel with any financial interest (as defined by the medical center's conflict of interest policy or applicable purchasing conflict of interest policy) in any particular manufacturer of pharmaceuticals, devices, or equipment, or any provider of services, to disclose such interests according to institutional policies and to recuse themselves from involvement in purchasing decisions relevant to the conflicting interests.
- To the extent an individual's expertise is necessary in evaluating any product, that individual's financial ties to any manufacturer of that or any related product must be disclosed to those charged with the responsibility for making the decision.

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Chapter 3. Unmet Needs and Opportunities

Academic medical centers and industry have the obligation to create a healthy platform for cooperation and collaboration that protects academic integrity in education, research, and patient care; can withstand public scrutiny; and builds toward the future.

The Educational Experience

- Medical schools and teaching hospitals should design curriculum standards and teaching materials for all phases of medical education—from medical school to residency to continuing medical education—that provide tools to educate students, residents, and faculty about the processes and disciplines of drug discovery, development, clinical testing, safety, therapeutics, and regulation.

Content Validation of Continuing Medical Education

- The AAMC should collaborate with ACCME to create a process by which CME offerings would be externally spot-reviewed or audited for consistency with applicable guidelines and for the presence of inappropriate influence.
- The AAMC should participate with key national medical organizations, such as the American Medical Association (AMA), the ACCME, the Society for Academic Continuing Medical Education (SACME), and other professional societies in an initiative to define the processes and structure that would best ensure the provision of sound, timely, scientifically objective CME that meets the educational needs of physicians.

Development of Information Portals

- The AAMC should convene representatives of academic medicine and industry in a cooperative effort to develop optimal information systems, including Web-based technologies, for disseminating information on new products.
- The AAMC should convene an expert panel composed of academic and industry representatives to explore new opportunities and identify best practices in information exchange between academic medicine and industry that are transparent, rely on rigorous evaluation of evidence, and are consistent with standards of professionalism.

Industry Funding of Medical Education

Report of an AAMC Task Force

Introduction

An effective and principled partnership between academic medical centers and various health industries is critical in order to realize fully the benefits of biomedical research and ensure continued advances in the prevention, diagnosis, and treatment of disease. Examples of the health benefits derived from the close working relationship between academe and the pharmaceutical and device industries are legion and well recognized. In aggregate, they validate the wisdom of public policies that encourage close collaboration. Both academic medical centers and industry require public confidence and trust and must be mindful to avoid conduct that creates or appears to create conflicts of interest. However, given the fundamental differences between the missions, fiduciary obligations, and cultural norms of academic medical centers and those of commercial enterprises, it is inevitable that potential conflicts of interest will arise in the course of their interactions. Identification and appropriate management of those conflicts by both academic medical centers and industry are crucial to ensure that the relationship remains principled, thereby sustaining public trust in the proposition that both partners are fundamentally dedicated to the welfare of patients and the improvement of public health.

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. The validity of these concerns is supported by a robust body of psychosocial evidence and an emerging body of neurobiological evidence regarding the effects of establishing interpersonal relationships and gifts on recipients' choices and decisions. The potential for influence engenders public skepticism, not only in the commitment of medical schools and teaching hospitals to their primary public purpose, but also in the commitment of academia and industry together to promote the public's interest by fostering the most cost-effective, evidence-based medical care possible.

The Association of American Medical Colleges (AAMC) embraces the obligation of the profession to manage, through effective self-regulation, all real or perceived conflicts of interest. Accordingly, in 2006 AAMC charged a special Task Force on Industry Funding of Medical Education (hereafter referred to as Task Force) with forging consensus principles to guide the AAMC and the leaders of medical schools and teaching hospitals in developing policies and procedures to manage industry gifting practices and financial support of their programs of medical education for students, trainees, faculty, and community physicians.

Specifically, the Task Force was asked to undertake the following:

1. Review the range of policies and procedures currently in place in medical schools and teaching hospitals for managing industry support of educational activities and industry gifting practices directed at students, residents, faculty and staff;

2. Evaluate the benefits to be gained and pitfalls to be avoided in the relationships between industry and academic medicine;

3. Develop general principles to guide academic medical institutions in optimizing the benefits and minimizing the pitfalls of industry support of medical education;

4. Identify educational strategies currently used by academic medical centers to raise awareness about the benefits and pitfalls of industry support of medical education and determine whether any of these strategies have been shown to be effective; and

5. Suggest the scope of ongoing work that the AAMC might undertake to help its members operationalize the general principles articulated by the Task Force.

This report is the product of the Task Force's efforts.

April 2008

Chapter 1. Professionalism and Medical Education

Professionalism lies at the heart of medicine, and inculcating the values associated with it in future generations of physicians is a primary responsibility of academic medicine. The prevalence of industry funding for many aspects of the current medical education experience therefore deserves careful attention. There is considerable benefit to be derived from a critical examination of the patterns of support and the identification of any challenges to professionalism that may be imbedded in them. This review must encompass medical education in general as well as the implications of professionalism for each player in the medical education environment: the institution, faculty, and students and trainees. Its scope includes the unspoken messages imparted through the interactions that students and trainees witness between faculty and industry representatives, the implications of institutional policies and practices and the subjects on which they are silent, and the need for formal education in professionalism. Only through a conscientious review of current practice and its implications can each medical center respond appropriately to the challenges of deciding how best to meet the highest standards of professionalism while preserving the valuable interactions between academic medicine and industry consistent with their shared goal of improving the public's health.

A. The Issue in Context

From the many efforts to define "profession," "professional," and "professionalism" in the medical and social science literatures, a broad consensus has emerged. A profession is a collectivity of practitioners who are trained in expert knowledge generally not available to their clients or to the wider public. This endows them with a special power and obligation to practice and advance this knowledge responsibly. Frequently, the basis of this knowledge is scientific, as in the case of the practice of medicine. Professionals are also responsible for training future generations of practitioners. In varying degrees professionals are self-regulating, abiding by the ethics of their profession. Thus, physicians are expected to employ independent, objective judgment in their decisions, based on their understanding of best practices and the best interests of their patients, and not act out of personal self-interest or at the behest of interested others. Professionalism implies a set of ethical standards and motivations on the part of individual practitioners. Among medicine's ethical principles are autonomy, objectivity, altruism, and the avoidance of conflicts of interest.

Two contextual realities of modern medicine can seriously compromise medical professionalism. The first is that most of the therapeutics and technologies of modern medical practice are not produced by medical practitioners themselves, but by private industry. This means that in order for patients to benefit from advances in medical science as soon as possible after regulatory approval, industry must market these products and disseminate product-related information. The second is that within academic medical centers the primary targets for marketing are medical practitioners, not the ultimate consumers, patients. This is true largely because practitioners are the legally mandated distributors of prescription medications and play a key—if not exclusive—role in the selection of most medical devices.

Industry has an important role to play in educating and informing health care professionals about the availability, value, and proper use of novel medications and vaccines, new uses of existing products, and the new science that significantly bears on the therapeutic or economic value of products. Accordingly, creating platforms for appropriate scientific and medical interactions is essential. However, industry has developed and refined many practices designed to influence the behavior of physicians, including physicians working in academic medical centers. These centers provide a learning environment in which students and trainees are arguably at their most impressionable. Some patterns of interaction that have evolved are, and others may be, inappropriate from the standpoints of medical professionalism and the best interests of patients. These include providing gifts to individuals (even when these gifts have educational or practice-related utility); distributing samples directly to practitioners; providing food, meals; or travel expenses; establishing speakers' bureaus; and ghostwriting.[2]

These commonplace patterns of interaction can create conflicts for the affected physicians, and therefore for their institutions, between their duty to exercise independent medical decision making in the best interest of their patients and the biasing influence of personal gifts and other favors on their decisions.[3] Many practitioner-recipients assert that they are not influenced by gifts, payments, and favors, and that they can act in their own economic self-interest as well as altruistically towards patients. However, the link between self-interest and the erosion of altruism has been demonstrated by multiple studies.[4] Over time, a subtle and insidious change in perception can occur. For many recipients, what were originally experienced as simple gifts come to be seen as privileges, and these privileges evolve further into reliance and a sense of entitlement. This evolution makes these practices and their attendant conflicts more entrenched and difficult to eradicate.

For medicine generally, and for academic medicine in particular, these conflicts can have a corrosive effect on three core principles of medical professionalism: autonomy, objectivity, and altruism. If the promise of professionalism is broken, or has the appearance of being broken, academic medicine loses the public trust as well as its ability credibly to nurture the professionalization of future generations of physicians. Supplementing the robust psychosocial evidence regarding the effect of gifts on physician decision making, recent neurobiological studies document that inherent biological processes cause individuals to respond reciprocally—and typically unconsciously—to relationships involving even simple gifts, sponsorships, or the development of personal relationships.[5,6] Although the

[2] The pharmaceutical industry has adopted a Code on Interactions with Health Care Professionals that addresses some of these practices.

[3] Marco CA, Moskop JC, Solomon RC, et al. Gifts to physicians from the pharmaceutical industry: An ethical analysis. *Ann Emerg Med.* 2006;48(5):513–521.

[4] Wazana A. Physicians and the pharmaceutical industry, is a gift ever just a gift? *JAMA*. 2000;283(3):373-380.

[5] Association of American Medical Colleges and Baylor College of Medicine, Department of Neuroscience and Computational Psychiatry Unit. *The Scientific Basis of Influence and Reciprocity: A Symposium*. Washington, DC: Association of American Medical Colleges; 2007.

[6] Dana J, Loewenstein G. A social science perspective on gifts to physicians from industry. *JAMA*. 2003;290(2):252-255.

neurobiology is still an emerging area of scientific discovery, and studies have not yet been performed on physician-industry interactions and decision making, studies suggest that the neurobiological processes that engage the brain's reward and decision-making circuitry can operate below the detection and overt control of higher cognition. Thus, although strong motivation and altruistic intent exist in most physician-industry interactions, the intention may be unwittingly undermined when innate reciprocity mechanisms are engaged.

These studies reinforce the necessity for multifaceted solutions to interdict biasing influences. To preserve high standards of professionalism, both individual and institutional "circuit breakers" are necessary. A focus on individual commitment to professionalism is necessary but not sufficient; the constant tension between altruism and self-interest must also be acknowledged and addressed in institutional policies and practices. Professionalism in medicine also requires critical reflection by physicians and other health care providers on the likelihood and potential of their own receipt of gratuities of any value from industry to influence their practice of medicine.

B. Professionalism and Industry Support for Medical Education

Historically, the avenues through which professional expertise in medicine and the attributes of professionalism have been transmitted are academic medical centers. Accordingly, the centers should take pains to impart the qualities of professionalism both through teaching and through the professional behaviors of faculty and staff. Professional standards should also be reflected and continuously reinforced in each institution's policies and practices in the areas of education, clinical practice, and research.

In his comprehensive study of professionalism, *A Flag in the Wind: Educating for Professionalism in Medicine*, Tom Inui observes:

> The opportunities for change that will enhance the modeling of medical professionalism are myriad, but *the most difficult challenge of all may be the need to understand—and to be explicitly mindful of, and articulate about—medical education as a special form of personal and professional formation that is rooted in the daily activities of individuals and groups in academic medical communities.*[7]

These daily activities may include faculty and student participation in industry-sponsored clinical research and accredited continuing medical education (CME) programs offered by the institution. Both activities can exemplify principled and productive interactions between industry and academic medicine. The participation of faculty physicians and biomedical scientists in appropriate industry-sponsored research, both basic and clinical, is critically important to developing new

[7] Inui TS. *A Flag in the Wind: Educating For Professionalism in Medicine*. Washington, DC: Association of American Medical Colleges; 2003.

therapeutics, preventatives, and devices. It also serves the educational purpose of conveying to students and trainees the challenges of drug and device development, the intricacies of clinical research, and the process of new drug and device evaluation. Industry-funded, accredited CME programs presented by academic institutions also offer opportunities to grow professionally.

Moreover, there is a history of generous philanthropy from industry to academic medicine. Such philanthropy is and will continue to be extremely important to academic institutions, provided it is given through a transparent process, supported by appropriate documentation, and in keeping with institutional policies that specify which institutional officers are authorized formally to receive such gifts on behalf of the institution. However, in this formative medical education environment, industry support can take additional forms, such as gifts directly to individuals, meals, and direct provision of pharmaceutical samples (all pervasive at present in most academic medical centers). All of these transactions require acquiescence on the part of individuals or institutions, or both—if not their explicit acceptance—in order to continue.

Such forms of industry involvement tend to establish reciprocal relationships that can inject bias, distort decision making, and create the perception among colleagues, students, trainees, and the public that practitioners are being "bought" or "bribed" by industry.[8,9] These interactions may bring value to the recipients, such as otherwise inaccessible educational experiences or up-to-date information about new therapies. Nonetheless, these transactions can erode public confidence and may in fact directly distort objective decision making in highly visible as well as insidious ways. The fault lies not only with industry; the acceptance, indeed the expectation, of such financial incentives by academic professionals and their institutions has encouraged these practices.

C. Industry Support and Students

Informative literature exists on the interactions between industry and medical students. According to Sierles et al., "Most students perceive that they are entitled to gifts. Many simultaneously think that sponsored educational events are likely to be biased, but are helpful. Most think that their prescribing is not likely to be influenced by these interactions and that their colleagues are more likely to be influenced. This combination of perceptions, along with the high exposure to these interactions that the students reported, suggests that as a group they are at risk for unrecognized influence by marketing efforts."[10]

[8] Wazana A. Physicians and the pharmaceutical industry, is a gift ever just a gift? *JAMA*. 2000;283(3):373-380.

[9] US Senate Finance Committee. Committee staff report to the chairman and ranking member: use of educational grants by pharmaceutical manufacturers. Available at: http://www.finance.senate.gov/press/Bpress/2007press/prb042507a.pdf. Accessed April 9, 2008.

[10] Sierles FS, Brodkey AC, Cleary LM, et al. Medical students' exposure to and attitudes about drug company interactions: a national survey. *JAMA*. 2005;294(9):1034-1042.

Studies such as these strongly suggest the importance of initiatives to reform both the explicit and the hidden curriculum to improve students' working understanding of professionalism, and to create a learning environment in which professional behaviors consistently reinforce that understanding. Students may attend industry-sponsored meetings, dinners, or other functions without appreciating the possibility that marketing activity is an important part of the agenda.

Sierles observed:

> Students manifest the same phenomena as do residents, such as accepting gifts while disapproving of them. This may be due to role model behavior and other components of medicine's "hidden curriculum"—lessons students learn that are not formally scheduled…but rather are learned during informal interactions, ward rounds, and clinical experiences in hallways and cafeterias. Physicians and peers who "teach" this curriculum may be unaware that the behaviors they model influence what students believe.[11]

For example, his study found that "93 percent of the students had been asked or required by a faculty member to attend a sponsored lunch."[12]

The Working Group received several telling examples of the hidden curriculum from students and residents. The following are illustrative:

1. "Our institution does not allow industry representatives on campus during our noon educational lectures and has a very limited fare of sandwiches. One day a week, however, the industry representatives would have a catered lunch at a hotel across the street from the hospital. The residents would take us over there for a better lunch. As a student, I witnessed the very friendly interaction and appreciated the "free" pocket reference book that was quickly provided to me for listening to information on the new drug they were promoting. I felt a little awkward crossing the street, but it quickly became normalized by all the residents doing so and our quickly following suit, wanting the break from sandwiches once a week."

2. "Residents are tremendously influential upon medical students." Many large medical centers that can afford it "have isolated themselves and their students in a large degree from interaction with industry representatives during the non-clinical years. When you begin to rotate in the clinical setting as a medical student, however, you are heavily influenced by the interactions of residents with industry representatives. Since residents have traditionally had long hours and low pay given their level of education, they are often more willing to interact with industry and accept free books, pens, or even samples of drugs."

[11] Ibid., p.1040.

[12] Ibid., p.1040.

3. "An institution teaches a lot to its students and residents by the interaction that occurs on campus or with the faculty and residents. The institution in which I trained was large and had strong limits to the interaction of industry representatives with its students and residents. I did an away rotation, however, at a community hospital with less financial resources. During noon conference there, the first person you were greeted by was the industry representative who gladly handed you promotional material. If I had been trained in this environment, it would have been very natural. This sort of interaction and sponsorship teaches students and residents that it should be the expectation that industry sponsor the educational portion of our training programs and provide us with promotional material and information."

4. "Our department chair encouraged us to attend an industry-sponsored retreat in a beach location where he was speaking. There was a competition to see who could go. It seemed prestigious for those who went."

5. "Another attitude that may develop is one where the student expects to get information on drugs from the industry rep, rather than the literature. This is what he or she sees in several mentors' offices. Students' use of a product will depend on the exposure they've had to it, i.e., how many times the rep has visited to talk and put down the competition."

As these examples illustrate, the dissonance between what academic medicine preaches about professionalism and what it practices can be dramatic. Through their behavior, faculty and other mentors in the training continuum send powerful messages to students and trainees about how interactions with industry personnel are regarded. In recent years, typical professional career paths have made the behaviors observed during training even more significant. Often, students and trainees follow their formal training in an academic medical center with practice in relatively isolated ambulatory care settings, where there are often few mentors and models for professional behavior. Observations of interactions between faculty and industry during practitioners' formative years may serve as long-term guideposts for their understanding of their professional obligations. Therefore, it is increasingly important that the model provided by faculty and other mentors be intentional, consistent, and in harmony with both professional ethics and institutional policies.

D. Institutional Policies and Practices

In any effort directed at reform, the two critical foci of attention should be:

1. The behaviors of physicians, professional staff, and other teachers and role models in the academic medical center; and

2. The behaviors of the medical centers themselves.

The relationships medical centers maintain with industry, and the role they play in condoning inappropriate behaviors on the part of staff, faculty, residents, and students, have the potential to distort the objectivity of both individual and institutional decision making. The impact may be subtle and insidious; often, it is highly visible.

Even if institutional policies are adopted that prohibit problematic industry funding practices, the way such policies are enforced sends a powerful message. Though federal and state laws and regulations define the legal boundaries of several types of industry funding of institutions and govern many industry interactions with practitioners, these legal imperatives provide only minimum standards of legal acceptability: they do not define standards of professionalism. Institutional policies, on the other hand, can define the context and culture of professionalism. If rigorously enforced, they supplement traditional self-regulating mechanisms of the profession of medicine, not only for education and training but for medical practice.

Faculty may feel they should be exempt in their personal time from institutional constraints on their participation in marketing activities. Narrow acceptance of professional standards of conduct during duty hours and their breach at other times undermine the notion of a profession. Personal conduct unworthy of a professional degrades the perception of a profession, whether it occurs on-duty or off. Accordingly, institutions should not limit prohibitions on the acceptance of gifts, meals, payments, or other inappropriate forms of industry support to the institutional environment alone. Institutional policies should acknowledge that professionalism is ultimately a personal responsibility; that the behaviors of individual faculty members in their personal time are important components of professional conduct; and that faculty choices shape the way trainees and the public view the profession.

The Task Force does not call for institutional policing of the off-site activities of faculty, staff, students, and trainees; however, institutions should make clear that adherence to institutional principles is not reserved for duty hours. Violations on-site and off-site should be prohibited.

Further, academic medical centers should make clear that the absence of policy on any specific industry funding practice implies neither endorsement nor prohibition, and that professionalism, as an individual responsibility, must be the guiding principle for all activities relating to medical education and practice, whether or not there is a stated policy that specifically applies to the situation.

Recommendations:

- *Academic medical centers should adopt and implement policies that address specific interactions between academic medical personnel and industry and are consistent with recommendations listed in Chapter 2. These policies should reinforce and uphold institutional and individual efforts to promote a learning environment that supports professionalism and eliminates activities that undermine this objective.*
- *Academic medical centers should make clear to their faculty, students, and staff that to the extent certain interactions with industry are prohibited within academic medical centers, they are also prohibited off-site.*

- *Similarly, academic medical centers should 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.*
- *Industry should not invite academic medical center personnel to participate off-site in practices prohibited on-site.*

E. Education for Professionalism

Inui observed the following on the subject of formal courses in professionalism in the medical school curriculum:

> Under present circumstances, students become cynical about the profession of medicine—indeed, may see cynicism as intrinsic to medicine—because they see us "say one thing and do another."
>
> Additional courses on "medical professionalism" are unlikely to fundamentally alter this regrettable circumstance. Instead, we will actually have to change our behaviors, our institutions, and ourselves.[13]

Institutional policies can mitigate exposure of professional staff and trainees to potentially biasing relationships with industry, but shielding students and trainees from all marketing activity will not prepare them for coping with the barrage of marketing they face in environments outside the boundaries of the academic medical center and will face when they complete training and enter practice. It is likely that at least partial dependence on industry support for continuing medical education (CME) by providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) and other forms of industry-sponsored educational or marketing events will continue in the foreseeable future. Accordingly, it is the duty of academic medicine to provide students with formal training in professionalism, including training to impart habits of inquisitiveness and skepticism and the skills necessary to assess critically the professional literature and evaluate evidence from all sources.[14]

Many academic medical centers have developed a variety of sophisticated offerings for students and trainees on the subject of professionalism. A recent review of the literature by Carroll et al. suggests that educational interventions can increase skepticism toward industry marketing techniques and influence the intentions and behavior of trainees with respect to their relationships with industry representatives, at least in the short term.[15] However, educational interventions have tended to focus primarily on the explicit curriculum and ignore the learning environment that embodies the hidden curriculum. Academic medicine in

[13] Inui TS. A Flag in the Wind: Educating for Professionalism in Medicine. Washington, DC: Association of American Medical Colleges; 2003:5.

[14] Association of American Medical Colleges. Contemporary Issues in Medicine: Basic Science and Clinical Research. Medical School Objectives Project Report. Washington, DC: Association of American Medical Colleges; 2001.

[15] Carroll AE, Vreeman RC, Buddenbaum J, Inui TS. To what extent do educational interventions impact medical trainees' attitudes and behaviors regarding industry-trainee and industry-physician relationships? Pediatrics 2007;120(6):1528-1535.

general does not appear effectively to teach students and trainees how to think about receiving things of value from industry.

In this regard, it is instructive to examine an AAMC initiative to assist academic medical centers in coping with related challenges. In the mid-1990s, the AAMC embarked on the Medical School Objectives Project (MSOP) to inform the design, content, and conduct of medical education programs with an understanding of "how changes in society's views of health and disease and changes in the organization, financing, and delivery of health care shape expectations of physicians." The initial effort of this project was to develop a "consensus within the medical education community on the attributes that medical students should possess at the time of graduation and to set forth learning objectives for the medical school curriculum derived from those attributes."[16] Four attributes were identified as essential for physicians to meet society's expectations of them in the practice of medicine: physicians must be altruistic, knowledgeable, skillful, and dutiful. Each attribute is accompanied by specific learning objectives "that reflect consensus on the contribution that the medical school experience should make toward achievement of those attributes."[17]

Under the heading "Physicians must be altruistic," one learning objective especially relevant to the challenges to professionalism presented in various interactions with industry is to develop "an understanding of the threats to medical professionalism posed by the conflicts of interest inherent in various financial and organizational arrangements for the practice of medicine."[18] Students and trainees, under physician supervision, should be exposed early in their training to interactions with industry representatives as a part of an integrated curriculum in medical professionalism. The curriculum should focus on evidence-based decision making and be informed by a scientific understanding of the biasing effects of influence and reciprocity on professional decision making.

Recommendation:

- *Educational programs should be developed to raise the awareness among students, trainees, and faculty of challenges to professionalism presented by certain interactions with industry and provide opportunities that help them build critical evaluation skills that reinforce high individual standards, norms, and behaviors. Specifically, the Task Force recommends a follow-up MSOP project that focuses on developing learning objectives regarding professionalism and industry interactions.*

[16] Association of American Medical Colleges. *Learning Objectives for Medical Student Education*, Washington, DC: Association of American Medical Colleges; 1998:1.

[17] Ibid., p.4.

[18] Ibid., p.5.

Chapter 2. Benefits and Pitfalls

Substantive, appropriate, and well-managed interactions between industry and academic medicine are vital to public health. For example, the pharmaceutical/biotechnology industries need access to physicians in order to transmit information on new products. Similarly, the medical device industry depends on physicians and biomedical scientists to help define needs, inform product design, and test and improve devices. Both the interests and responsibilities of each party require that the relationship be maintained in a way that is principled and upholds the public trust. Therefore, it is essential to assess the potential benefits and pitfalls of the relationship so that new and effective models of interaction can emerge. Interactions that must be scrutinized include gifts to individuals, pharmaceutical samples, site access by pharmaceutical representatives and representatives of device manufacturers, Continuing Medical Education (CME) underwritten by industry sponsors, participation in off-site lectures and meetings sponsored by industry but not accredited, industry-sponsored scholarships and other educational funds for trainees, acceptance of food from commercial sources, payments for professional travel, ghostwriting, purchasing decisions by academic medical centers, and the participation of faculty on boards of directors and advisory boards. Acceptable solutions will enable the relationship to flourish within clear and well-thought-out guidelines that optimize its benefits and minimize its risks.

A. Principles for Assessing Interactions between Academic Medicine and Industry

Academic medicine and industry share the goal of improving the public health, and that shared goal should ultimately be the guide for evaluating patterns of interaction between academic medicine and industry. From that shared goal, several principles can be derived that should guide any interaction. They include the following:

1. The interactions should serve to enhance the health of the public.
2. The interactions should be transparent.
3. All of the interactions between academic medical centers and industry must reflect high standards of medical professionalism that reach beyond applicable laws and regulations.
4. The interactions should involve reciprocal communications, with knowledgeable parties on both sides of the interactions.
5. The interactions should support and enable the free exchange of information in appropriate settings in a manner adherent to applicable law and consistent with the standards of medical professionalism. Interactions should also be consistent with additional standards that may be established to assure that exchanges of information are evidence-based and free of bias to the maximum possible extent.

6. The interactions must serve both academic medicine and the legitimate missions of industry.

7. Compensation structures and arrangements should be consistent with the foregoing principles.

Each of the areas of interaction addressed in this chapter has been evaluated according to these principles.[19]

B. Gifts to Individuals

Several existing codes define the acceptability of gifts to physicians from industry in terms of dollar amounts, with those below certain thresholds deemed acceptable. Other codes reference the nature or purpose of the gift; for example, they may exempt certain educational or practice-related gifts, some of which, such as texts and anatomical models, carry significant educational value and may enhance patient care. However, there is an extensive body of evidence from the psychosocial sciences and supportive emerging evidence from neurobiology to the effect that gifts of any value affect the objectivity of decision making. Accordingly, "nature," "purpose," or "value" should not determine the acceptability of personal gifts from industry to physicians.

One-on-one gifting relationships of all kinds engender feelings of reciprocity in recipients that can unwittingly bias decision making by recipients in favor of donors' interests. Acceptance of gifts compromises the trust of patients and the general public that physicians' advice is fashioned solely for their patients' benefit and is not conflicted by physician self-interest. Thus, what is at stake here is the objectivity, and the appearance of objectivity, of the physician's decision making.

Recommendation:

- *Academic medical centers should establish and implement policies that prohibit the acceptance of any gifts from industry by physicians and other faculty, staff, students, and trainees of academic medical centers, whether on-site or off-site. Such standards should encompass gifts from equipment and service providers as well as pharmaceutical and device providers.*

[19] These principles are intended to supplement existing federal and state laws and regulations applicable to interactions between medical professionals and industry, including guidance issued by the HHS Office of the Inspector General. Department of Health and Human Services. OIG Compliance Program Guidance for Pharmaceutical Manufacturers. *Fed Reg.* 2003;68(86):23731-23743.

C. Pharmaceutical Samples

The receipt of samples from industry by practitioners in academic medical centers raises many issues. They include bypassing the evaluation, selection, and distribution systems established by the institutional pharmacy and Pharmacy and Therapeutics (P&T) Committee; the potential for the establishment of biasing reciprocal relationships; the timely access to such samples by the needy; and the availability of samples in peripheral teaching sites, such as community practice settings.

Some of these issues are strictly regulated by the Prescription Drug Marketing Act, including management of sample access and distribution. Although appropriate use of samples includes starting patients on therapies when medically necessary and should not be based on income levels, the Task Force acknowledges the long-standing assertion that industry distribution of pharmaceutical samples to physicians in academic medical centers can have social value by providing access to pharmaceuticals to needy patients and enabling them to begin treatment in a timely way. In many health care settings and circumstances, this assertion may be true.

However, a recently published national study revealed that in practice, pharmaceutical drug samples are more likely to be distributed to the wealthy and insured.[20] This conclusion may reflect in part the larger social issues that challenge access to health care by the poor and uninsured in office-based settings. Nonetheless, the primary finding of the study emphasizes that the use of drug samples by the pharmaceutical industry serves as a successful marketing technique as well as, to some extent, a safety net for the poor and uninsured.[21] Providing necessary drugs to the needy can be accomplished in different ways. Some academic medical centers have decided to substitute a voucher system, or to require that samples be left only at the centers' pharmacies where they can be evaluated, like all other proposed new therapeutics, by the centers' pharmacists and P&T Committee. The P&T Committee can then determine whether and how the samples should be distributed within the medical center and its affiliated community sites. In addition, industry has created the Partnership for Prescription Assistance that matches patients with programs that provide free or low-cost prescription medications and may help patients find low-cost medical care.

[20] Cutrona SL, Woolhandler S, Lasser KE, et al. Characteristics of recipients of free prescription drug samples: A nationally representative analysis. *Am J Public Health*. 2008;98(2):284-289.

[21] Ibid.

Adoption of such policies by academic medical centers has both potential advantages and disadvantages. One advantage is that such a policy prevents worrisome gifting relationships between industry personnel and faculty physicians and trainees. The fact that a sample is medically useful and intended for patient care does not remove its potential to affect the objectivity of the physician-recipient; studies show that prescribing patterns are indeed altered when drug samples are made available to physicians and residents.[22, 23, 24] In addition, 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. Education in evidence-based prescribing practices and the use of new drugs should be overseen by expert faculty but could include meetings with scientific liaisons from industry in structured settings.

Because samples may support the effective use of medicines (rapid initiation, trial, titration, adherence), a potential disadvantage of prohibiting direct distribution to physicians is that samples delivered to pharmacies are not immediately available at points of patient service. The Task Force is sensitive to this concern and stresses that when academic medical centers prohibit direct distribution of samples by industry personnel, they must ensure that the needs of patients for drugs in the class of the sample are met in a timely manner wherever care is delivered in the academic health care system.

Recommendations:

- *The distribution of medications in academic medical centers, including samples (if permitted), should be centrally managed in a manner that ensures timely patient access to optimal therapeutics throughout the health care system.*
- *If central management is not thought to be feasible, or would interfere with patient access to optimal therapeutics, the academic medical center should carefully consider whether or not there are alternative ways to manage pharmaceutical sample distribution that do not carry the risks to professionalism with which current practices are associated.*

[22] Adair RF, Holmgren LR. Do drug samples influence resident prescribing behavior? A randomized trial. *Am J Med.* 2005;118(8):881-884.

[23] Chew LD, O'Young TS, Hazlet T, et al. A physician survey of the effect of drug sample availability on physicians' behavior. *J Gen Intern Med.* 2000;15(7):478-483.

[24] Boltri JM, Gordon ER, Vogel RL. Effect of antihypertensive samples on physician prescribing patterns. *Fam Med.* 2002;34(10):729-731.

D. Site Access by Pharmaceutical Representatives

Industry access to medical center premises (or to those of its teaching affiliates to the extent practicable) and to physicians, trainees, and students within these premises may occur for various reasons, some legitimate and educational (for lectures, seminars, and similar gatherings) and others related only to marketing. Access by industry representatives for marketing purposes is fraught with difficulties, including compromises of patient privacy, inappropriate access to restricted areas, security issues, and interference with practitioner schedules. Academic health centers have a wealth of experience with educational presentations by visiting experts and should readily be able to separate legitimate educational opportunities from those involving marketing. Educational opportunities involving industry representatives, if desired, could be scheduled in open group settings and overseen by knowledgeable faculty to ensure opportunity for critical evaluation and interaction.

Industry representatives should not be allowed to have unfettered access to the center. They should gain access only by appointment or when invited by the physician. When invited, they should not have access to individual physicians in either public or patient care areas of the medical center. Academic medical centers should establish central systems to assure that pharmaceutical representatives are registered, provided with identifying name tags, and function within the center according to clearly specified policies and standards. It is important that both academic medical center personnel and industry representatives be made aware of the rules and procedures of the medical center and be held accountable for abiding by them. Therefore, the rules and procedures must be clear, widely publicized, and consistently and fairly enforced.

Recommendations:

- *To protect patients, patient care areas, and work schedules, access by pharmaceutical representatives to individual physicians should be restricted to nonpatient 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.*

E. Site Access by Device Manufacturer Representatives

The Task Force recognizes that devices can be different from pharmaceuticals in that they are typically not self-administered and very frequently require training, demonstration, ongoing refinement, and maintenance. Representatives of device manufacturers can play an important role in introducing new therapies as well as provide training and support on the proper use of devices by practitioners. Frequently, their presence is essential when devices are initially used. Nonetheless, there is urgent need for developing evidence-based good practices in this area because certain interactions with device manufacturer representatives can also carry risks to independence of decision making and professionalism.

Site access for device manufacturer representatives, as for pharmaceutical representatives, should be controlled through well-thought-out, centralized systems (see Section D above). Similarly, both academic medical center personnel and industry representatives must be made aware of and held accountable for abiding by the rules and procedures of the medical center. These rules and procedures must be clear, widely publicized, and consistently and fairly enforced. Student interaction with device manufacturer representatives should be for the sole purpose of education and should take place only under faculty supervision.

Device representatives who are invited to observe interactions between patients and the academic health care team should be identified by the institution as external technology consultants and not as part of the health care team. Such representatives should be credentialed by the institution, and their presence should be fully disclosed and consented to by patients before the representatives are permitted to be present during patient care interactions.

Recommendations:

- *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.*

F. Continuing Medical Education

Given the heavy dependence by academic medical centers on industry funding for CME, it is essential that the centers assure the independence and legitimacy of course offerings and compliance with evolving ACCME standards. There must be professional, academically oriented management of CME programs; the offerings must be open to a variety of viewpoints; and the programs must not serve as marketing vehicles for industry. Under no circumstances should industry be allowed to restrict the content of programs it sponsors or to specify which faculty or other persons should be selected as presenters.

The Task Force acknowledges that ACCME accreditation *per se* does not remove the possibility of bias from CME offerings. Though existing ACCME standards prescribe conditions for accreditation of providers, there is no mechanism yet in place to assure that sponsoring academic medical centers systematically assess whether or not particular programs are carried out according to the ACCME standards and ensure that program content is free of any bias introduced as a consequence of the funding source. Such assurances are essential components of accountability and trust. Institutions should conduct periodic audits of the content and quality of the offerings they sponsor. Such audits should involve examination of course materials, slides, and other items used in the program, with the results made known to the course offerers as well as to the medical center administration. Industry funding sources should be directly acknowledged in all announcements and literature about particular CME offerings, in the presentations themselves as required by ACCME standards, and in all publications about the programs.

Industry funds provided for CME should be coordinated and overseen through a centralized office. In no case should the medical center permit CME funding directly to individual faculty.

Recommendations:

- *Academic medical centers offering CME programs should develop audit mechanisms to assure compliance with ACCME standards, including those with respect to content validation and meals.*
- *Academic medical centers should establish a central CME office through which all requests for industry support and receipt of funds for CME activity are coordinated and overseen.*
- *To the extent that educational programs for physicians are supported by any commercial entity, including pharmaceutical, device, equipment, and service entities, the programs should be offered only by ACCME-accredited providers according to ACCME standards.*

G. Participation in Industry-Sponsored Programs

Optimally, all educational events in which information is transferred between industry and academic faculty and trainees, whether in the academic medical center or off-site, would either be ACCME-accredited or achieve the equivalent of ACCME accreditation by mechanisms yet to be developed. Academic medical centers continue to struggle to assure the quality of their continuing medical education programs and have widely adopted ACCME standards as a means for doing so. Accordingly, they should prohibit the participation of faculty, students, and trainees in nonaccredited programs billed as "continuing medical education."

To be distinguished from continuing medical education, industry seeks to use academic medical center faculty as clinical experts to speak in FDA-regulated, on-label promotional programs in specific diseases or therapeutic areas. Many argue that these programs are intended to benefit the broader physician community and enhance patient care. Some of these programs involve industry speakers bureaus.

The impact of these presentations is greatly enhanced by the reputations of the faculty speakers and the credibility of their academic medical centers. This raises concerns, especially with respect to faculty participation in speakers bureaus, about the misuse of the medical center's reputation (as a consequence of the academic affiliation of the participant), and about the potential for damage to the participant's credibility because of his or her involvement in industry promotional events. It is important to distinguish such FDA-regulated activities from presentations by faculty investigators to peers of the results of their industry-sponsored studies in settings where there is opportunity for critical evaluation and exchange.

Recommendations:

- *With the exception of settings in which academic investigators are presenting results of their industry-sponsored studies to peers and there is opportunity for critical exchange, academic medical centers should strongly discourage participation by their faculty in industry-sponsored speakers bureaus.*
- *To the extent that academic medical centers choose to allow participation of their faculty and staff in industry-sponsored, FDA-regulated programs, they should develop standards that define appropriate and acceptable involvement.*
    1. *Academic medical centers should require full transparency and disclosure by their personnel to the centers and when participating in such programs; and*
    2. *Academic medical centers should require that payments to academic personnel be only at fair market value.*

- *Academic medical centers should prohibit their faculty, students, and trainees from:*

    1. *Attending non-ACCME-accredited industry events billed as continuing medical education;*
    2. *Accepting payment for attendance at industry-sponsored meetings; and*
    3. *Accepting personal gifts from industry at such events.*

H. Industry-Sponsored Scholarships and Other Educational Funds for Trainees

Central institutional, departmental, or divisional administration and oversight of scholarships and other educational funds helps to prevent the establishment of one-on-one relationships between industry representatives and students and trainees and minimizes the possibility that these funds will be perceived or used as direct gifts.

Recommendations:

- *Academic medical centers should establish and implement policies requiring that:*

    1. *All scholarships or other educational funds from industry must be given centrally to the administration of the academic medical center;*
    2. *No* quid pro quo *be involved in any way; and*
    3. *The evaluation and selection of recipients of such funds must be the sole responsibility of the academic medical center or of a nonprofit-granting entity, with no involvement by the donor industry.*

I. Food

With the exception of food provided in connection with accredited CME programming and in conformity with ACCME guidelines, there is no rationale consistent with standards of professionalism that supports the acceptance of industry donations of food by academic medical centers or their personnel. With respect to off-site activities of faculty physicians, trainees, and students, regardless of location, the academic medical center should prohibit receipt of any kind of personal gift, including food. If faculty, trainees, or students choose to dine off-site on their personal time with industry representatives, they should pay for their own meals.

Recommendations:

- *With the exception of food provided in connection with ACCME-accredited programming and in compliance with ACCME guidelines, institutions should establish and implement policies that industry-supplied food and meals are considered personal gifts and will not be permitted or accepted within academic medical centers.*
- *Policies should make clear that the same standard of behavior should be met off-site.*

J. Professional Travel

Direct payments by industry to academic medical center physicians, trainees, and students should not be allowed, other than for reimbursement of direct travel when the physician, student, or trainee is providing a legitimate service for which the travel is necessary and the travel provided is reasonable in relation to the services rendered. To ensure transparency, such services should be rendered in accordance with terms specified in professional services agreements, which may include compensation for services that is customary and reasonable in academic practice. In addition, academic medical centers should allow those commercial entities that wish to do so to provide funds to a central location in the medical center to be used at the medical center's discretion to provide travel assistance to physicians, trainees, and students for professional development.

Recommendation:

- *Academic medical centers should prohibit their physicians, trainees, and students from directly accepting travel funds from industry, other than for legitimate reimbursement or contractual services as described above.*

K. Ghostwriting

"Ghostwriting" is defined as the provision of written material that is officially credited to someone other than the writer(s) of the material. Transparent writing collaboration with attribution between academic and industry investigators, medical writers, and/or technical experts is not ghostwriting. The unacknowledged, undisclosed provision of content should not be permitted under any circumstances.

Recommendation:

- *Academic 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.*

L. Purchasing

Purchasing decisions made by academic medical centers may be sources of major challenges in efforts to prevent the intrusion of financial self-interest and inappropriate bias. Frequently, in the case of the purchase of pharmaceuticals, devices, and equipment, those with experience and information relevant to purchasing decisions may have financial or other ties to the manufacturer or provider. At a minimum, academic medical centers should ensure that each participant in the purchasing process discloses all potential conflicts of interest and is recused from involvement in purchasing decisions relevant to the conflicting interests.

Recommendations:

- *Academic medical centers should establish and implement policies that require any personnel who has a financial interest (as defined by the medical center's conflict of interest policy or applicable purchasing conflict of interest policy) in any particular manufacturer of pharmaceuticals, devices, or equipment, or any provider of services, to disclose such interests according to institutional policies and to recuse themselves from involvement in purchasing decisions relevant to the conflicting interests.*
- *To the extent an individual's expertise is necessary in evaluating any product, that individual's financial ties to any manufacturer of that or any related product must be disclosed to those charged with the responsibility for making the decision.*

M. Boards of Directors, Advisory Boards, and Consulting

The Task Force acknowledges the value of permitting academic medical center faculty to interact appropriately with industry. Examples of appropriate interaction include faculty participation on industry boards of directors and scientific advisory boards as well as services provided through professional services agreements and consulting contracts, provided such activities are conducted in full compliance with the policies of the medical center and applicable law, and that compensation reflects the fair market value of the services provided.

Chapter 3. Unmet Needs and Opportunities

Industry contributions to health care are invaluable, and relationships between industry scientists and physicians are necessary to facilitate these contributions. In their educational interactions, academic medical institutions and industry are mutually accountable for maintaining a principled partnership based on the primary goal of providing the highest quality of care for patients. Their interactions should promote the exchange of scientific information that will help the physician learn and apply the latest developments, while diligently assessing and limiting to the maximum extent possible the introduction of any bias that could distort physician's decision making and patient care. Academic medical centers and industry are obligated to create a healthy platform for cooperation and collaboration that protects academic integrity in education, research, and patient care; can withstand public scrutiny; and builds toward the future.

Academic institutions are responsible for inculcating the knowledge, skills, attitudes, and values they expect in their graduates. In this process, high-quality exchange of information between academic medicine and industry is essential. Especially in light of the rapidly changing mechanisms for information transfer, academic medical centers and industry have an unparalleled opportunity to create better educational relationships that build on the principles that both are committed to serving. The Task Force has identified several areas for possible principled collaborations between academic medicine and industry in the continuum of medical education. These include opportunities in the formal educational experience itself, content validation for CME, and developing Web-based platforms or "portals" that facilitate access to reliable scientific information, including information about new products.

A. The Educational Experience

Medical students, trainees, and faculty at all stages of learning must be equipped with the critical skills necessary to assess information and claims made about therapeutics from all sources, including industry, and to evaluate continuously the evidence base that underpins their clinical decision making. Consistent with the recommendations of the AAMC's Medical School Objectives Project (MSOP) report on "Clinical Research in Medical Education," graduating medical students and residents should be inquisitive and skeptical.[25] Arming physicians with a healthy dose of skepticism about whatever they hear is probably one of the most powerful lessons that medical education can instill.

Like most other educational offerings presented in an academic medical center, information on the use of health care products (regardless of their source) should ordinarily occur in a structured learning environment, e.g., rounds, a forum, or a seminar that is supervised by faculty. Whatever the forum, interactions of medical students and trainees with industry representatives should be appropriate to the learners' level of education and clinical experience, and consistent with the values

[25] Association of American Medical Colleges. *Contemporary Issues in Medicine: Basic Science and Clinical Research.* Medical School Objectives Project Report. Washington, DC: Association of American Medical Colleges; 2001.

of the institution. Industry representatives should include M.D.'s, Ph.D.'s, and Pharm.D.'s who understand and can discuss the background of product discovery, clinical testing results, and how a product is used to address a particular problem. There are opportunities for academe and industry to collaborate in developing new forms and models of information exchange that are truly educational and not marketing experiences, and that optimize the potential of modern information technology.

Students often have limited understanding of subject areas important to interactions with industry, including:

- The processes of drug research and development;
- The statutes and regulations that govern these processes;
- The nature of the pharmaceutical and device industries;
- Product marketing and sales;
- The meaning and limitations of FDA marketing approval of a new therapeutic with respect to the safety and efficacy of that therapeutic; and
- The critical role of physicians in supporting the FDA's adverse event reporting system.

As a result, most students are poorly equipped to engage in productive and critical interactions with industry, even though contact with industry representatives will occur throughout their professional careers. Accordingly, one fruitful area of education in which collaboration would be beneficial would be to improve students' and trainees' understanding of the science and processes of drug and device discovery, development, and marketing, of drug and device regulation, and of the principles of safe and effective drug and device therapy.[26]

Recommendation:

- *Medical schools and teaching hospitals should design curriculum standards and teaching materials for all phases of medical education—from medical school to residency to continuing medical education—that provide tools to educate students, residents, and faculty about the processes and disciplines of drug discovery, development, clinical testing, safety, therapeutics, and regulation.*

[26] In a collaborative effort with industry, in spring 2007, the AAMC convened a new Medical School Objectives Project expert panel on "Safe and Effective Prescribing Practices" to develop learning objectives for medical students. The panel report will be published in spring 2008.

In some cases, industry and academe could productively collaborate on the development of these educational materials, with faculty oversight. The goal of such materials would be to provide learners with the information and skills they need to interact knowledgeably and ethically with industry and other interest groups in a manner consistent with standards of professionalism. Potential topics include pharmacology, safety, monitoring, adherence, pharmacogenomics, meta-analysis, clinical guidelines, performance measurement, and comparative effectiveness. Materials developed through such collaborations should be collected, peer-reviewed, and made widely available through an online central resource, such as AAMC's MedEdPORTAL.

B. Content Validation of Continuing Medical Education

Principles that should guide academic involvement in CME include the following:

- The content of CME presentations must be science-based and unbiased, and the content must be determined independently from the source of commercial support.[27]
- As is required by the ACCME, academic medical institutions should monitor the content of CME they sponsor as part of the ongoing effort to ensure the quality and objectivity of education provided to physicians, students, and trainees.[28]
- Academic medical institutions can receive commercial support for evidence-based CME they provide to assist physicians in maintaining competency during their professional careers, to help to address the "knowledge translation block,"[29] and to improve the quality of care.

Academic medical centers are already accountable to ACCME for verifying that CME course content is fair, balanced, and independent of commercial influence, but additional methods of content validation need to be developed—such as external auditing—that are effective, efficient, and realistic. It is important to recognize that assuring that course content is evidence-based is challenging and requires flexible systems that can accommodate emerging science and differing medical perspectives.

[27] The ACCME standard indicates that "CME providers cannot receive guidance, either nuanced or direct, on the content of the activity or on who should deliver that content."

[28] The ACCME standard indicates that "Accredited providers are responsible for validating the clinical content of CME activities that they provide. Specifically: 1. All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. 2. All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis."

[29] The phrase "knowledge translation block" refers to the barriers involved in moving the results of medical research and clinical trials that identify good practice into widespread use in medical practice.

Recommendations:

- *The AAMC should collaborate with ACCME to create a process by which CME offerings would be externally spot-reviewed or audited for consistency with applicable guidelines and for the presence of inappropriate influence.*

  Such a process could be designed to sample appropriately a wide range of offerings on a national basis and provide expert review of them, perhaps through an expert review committee. An expert panel could be appropriately supplemented with content-area expertise to address CME offerings in areas with significant potential for bias, for example, 8 to 10 high-impact, new therapeutic areas where accessible post-marketing information is scant. Questions to be considered include whether national, regional, or local panels would be appropriate for this effort, how they would be funded, and what roles medical schools and teaching hospitals might most appropriately and realistically play.

- *The AAMC should participate with key national medical organizations, such as the American Medical Association (AMA), the ACCME, the Society for Academic Continuing Medical Education (SACME), and other professional societies in an initiative to define the processes and structure that would best be able to ensure the provision of sound, timely, scientifically objective CME that meets the educational needs of physicians.*

  Through this partnership, academic medicine could contribute to the development of new ways to exchange information with their practice communities and to provide CME that is evidence-based, scientifically rigorous, free from bias, and meets ACCME requirements. Since the ultimate goal of CME is to facilitate change at the point-of-care, the structure should leverage new technologies, including health care information technology and Web portals, to provide enhanced levels of learning that will lead to modification of physician behaviors and improved patient outcomes.

C. Development of Information Portals

The Task Force recognizes the critical importance of maintaining and expanding appropriate channels for communication between academic medicine and industry that are consistent with standards of professionalism. It also acknowledges the necessity for changes in the ways information is exchanged between academic medicine and industry. Essential changes encompass content, efficiency, and process.

While an unprecedented amount of medically relevant information is available through today's technology, it is difficult to access needed data quickly and reliably. A prime example relates to science-based practice guidelines. The quantity of information about pharmaceuticals, devices, and evolving standards of care that students, trainees, and practitioners must process and understand to stay up-to-date and provide quality care is enormous. Science-based practice guidelines serve an important need: that is, the synthesis of information into succinct recommendations on the standards of care that then support individualized decision making. Yet the guidelines themselves can be subject to bias from several sources, including

source of funding, the opinions of the author or thought leaders, and the objective of the guideline.

The AAMC can assist academic medical centers by leading an effort involving academic medicine and industry to develop portals and other centralized information sources on new products that take advantage of multiple sources of information and that provide tools for assessing the quality of what is available. Examples of such information sources include peer-reviewed journals, FDA Medical Reviewers' Summary Reports on New Drug Applications (NDAs) that are approved, and information used for submission to regulatory authorities.[30]

The entire process for information exchange must be reconceptualized to reflect principles of professionalism, capture the promise of developing science and technologies, and reflect changes in the delivery of health care. The Task Force believes that the AAMC's unique position enables it to assemble representatives of academic medicine and industry to identify new methods for information exchange that will enable objective, critically reviewed information to be disseminated efficiently in ways that maximize the utility of the information for the user and that minimize the intrusion of bias and potential for conflict. The Task Force acknowledges that this is a long-term and challenging goal, but believes that the AAMC is well equipped to initiate and lead the first steps toward its achievement.

Recommendations:

- *The AAMC should convene representatives of academic medicine and industry in a cooperative effort to develop optimal information systems, including Web-based technologies, for disseminating information on new products.*

  These systems would be based on multiple information sources, including highly trained academic and industry scientists, and should be accurate, accountable, transparent, and convenient. Such information systems could be viewed as complementing or as substituting for current methods of communicating scientifically objective information.

- *The AAMC should convene an expert panel composed of academic and industry representatives to explore new opportunities and identify best practices in information exchange between academic medicine and industry that are transparent, rely on rigorous evaluation of evidence, and are consistent with standards of professionalism.*

  Particular areas of interaction should be identified, and targeted projects should be defined that would collectively constitute an initial agenda for developing more credible, transparent, and robust mechanisms for the exchange of scientific information vital to the public's health.

[30] The recently enacted FDA Amendments Act (FDAAA) requires FDA to post their Medical Reviewers' summary reports on all new molecular entities approved for marketing (reviews on other products must only be posted after 3 requests for the information), mandates that all Phase II-IV clinical studies be registered at clinicaltrials.gov (maintained by the National Library of Medicine at the NIH), and requires that summaries of the results of all clinical trials that relate to FDA-approved products be posted at the same site.

Concluding Observations

Examples of the health benefits derived from the close working relationships between academe and the pharmaceutical and device industries are legion and well recognized, and in aggregate validate the wisdom of public policies that encourage their continued close collaboration. However, given the fundamental importance to both parties of maintaining public confidence and trust, diligent and effective management of these relationships by both parties is crucial to ensure that relationships remain principled, transparent, and capable of sustaining intense public scrutiny.

This report, acknowledging the new policy directions being implemented in many medical schools and teaching hospitals to address industry support of medical education, urges all academic medical centers to accelerate their adoption of policies that better manage, and when necessary, prohibit, academic-industry interactions that can inherently create conflicts of interest and undermine standards of professionalism. Although the charge to the Task Force was focused on funding from the pharmaceutical and device industries, institutional policies on conflicts of interest should be comprehensive and encompass providers of equipment and services as well.

Addressing the issues identified in this report will help ensure that medical education occurs in settings in which individual and institutional behaviors continuously inculcate and reinforce the highest standards of professionalism. By implementing these recommendations, academic medical centers can better equip students and trainees with the knowledge, skills, and attributes they need to make responsible and ethical decisions and to optimize their own relationships with industry. Concomitantly, industry should voluntarily discontinue those practices that compromise professionalism as well as public trust. Both parties should work together constructively to develop new paradigms for the vital function of scientific information transfer. Moving forward, the overarching goal for both academic medicine and industry must be to maintain productive relationships in research, education, and patient care that contribute to the health of the public and sustain the public's trust.

Appendix A. Task Force Roster

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Appendix B

David Beier
Senior Vice President
Global Government and Corporate Affairs

AMGEN

555 13th Street, NW
Suite 600W
Washington, DC 20004

April 7, 2008

David Korn, M.D.
Senior Vice President
Association of American Medical Colleges
2450 N Street, NW
Washington, DC 20037

Dear David,

Amgen, one of the leading biotechnology firms in the world, conducts pioneering science to deliver vital medicines to patients with grievous illnesses. We believe that the relationships between health care providers and companies like ours must be based on trust and respect. We support the explicit recommendations of the AAMC Task Force because we share the goal of improving the interactions between our professionals and academic medical providers so that patient's best interests are served and health outcomes improved. We believe that the dissemination of science-based, accurate and timely information from us to professionals who work in academic settings serve important societal interests. We are committed to the highest standards of ethics, education and training for our representatives and medical liaisons. Our goal in interacting with academic colleagues is to advance the human condition by offering meaningful insights into the products we research, develop and provide to patients. Our experience is that medical professionals who work in academic settings are dedicated professionals focused on the delivery of patient care and have not been inappropriately influenced in the manner, or to the degree, represented in this report. Professionals working at Amgen are similarly dedicated and focused on delivery of products and information that further patient care. Amgen has made the commitment to interact with healthcare professionals based on our internal "U.S. Standards for Interactions with Healthcare Professionals", for example we:

- Engage healthcare professionals in appropriate fair market value contractual relationships to participate in FDA Approved Speaker Programs
- Engage healthcare professionals as consultants with appropriate fair market value contractual relationships for defined interactions
- Provide funding for Independent Medical Education to qualified recipients and, per a new policy, disclosing all Independent Medical Education and Healthcare Donations publicly
- Deliver appropriate product and disease information to healthcare professionals via field based Representatives and Medical Liaisons

Amgen agrees that academia should have policies in place to guide interactions with industry and that the AAMC Task Force Report provides a guidepost for individual academic institutions to follow. We are not in a position to endorse the text of the AAMC report, in part, because we have a different view about the accuracy concerning representations about the motives of the participants in industry-academic interactions. It is understandable that industry and academia will not agree completely on the final wording of any report given our differing roles in healthcare.

Sincerely,

David Beier

Dear David,

We believe the work of the AAMC Task Force process has been a very positive experience and we appreciate having had the opportunity to participate and contribute to the constructive discussions that you led.

We are pleased to be able to support all but one of the recommendations in the final report, which we believe are reasonable and appropriate in the particular context of Academic Medical Centers. We do so without endorsing all of the supporting arguments used in the body of the report. We believe the reasoning for many of the recommendations is directionally correct, but more often than not the potential issues addressed reflect perceptions rather than proven consequences. Perceptions are, however, important and we believe that the recommendations of the report will contribute to closing the gap that exists between the reality of the interactions between Academic Medical Centers and industry and the public perceptions of these activities.

We particularly welcome the report's call for enhanced joint participation by AMCs and industry in various activities designed to enhance medical education: physician and patient understanding of the drug discovery and development process; and our shared goal of improving public health.

One recommendation in the report, however, continues to trouble us. We cannot agree with the report's suggestion that AMCs actively discourage academic physicians from participating in the defined speakers programs. While individual academic centers may decide to adopt such a policy—and, in that case, we will, of course, abide by those policies for those centers—we continue to believe that these types of programs, which are subject to clear regulations regarding their content, can be worthwhile educational activities. We therefore must continue to express our disagreement with the provisions of the report that actively discourage academic physicians from participating in industry-sponsored, FDA-regulated speaker programs.

Thank you very much for your tireless efforts in leading this constructive process. We applaud those efforts, and the product of them.

We look forward to continuing to work constructively with the AAMC and its member institutions, and to further strengthening our partnership around education, clinical care and research in the best interests of advancing science and helping patients.

Sincerely,

Jeffrey B. Kindler
Chairman of the Board
Chief Executive Officer
Pfizer Inc

Sidney Taurel
Chairman of the Board
Eli Lilly and Company

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