Principles to Guide the Relationship between Graduate Medical Education, Industry, and Other Funding Sources for Programs and Sponsoring Institutions Accredited by the ACGME

The Accreditation Council for Graduate Medical Education (ACGME) establishes educational accreditation standards and periodically monitors compliance with them for more than 8,800 residency programs and nearly 700 institutional sponsors of graduate medical education (GME) in the United States.[1] In 2002, the ACGME published "Principles to Guide the Relationship between Graduate Medical Education and Industry" to provide guidance for managing relationships between GME and industry at the program and institutional levels. Nearly 10 years later, GME exists in a setting where an escalating number of U.S. citizens are graduating from medical schools to meet the predicted shortage of domestic physicians available to serve the public. These physicians require completion of GME programs in order to meet the public's needs.[2] However, at present, the future of GME funding primarily through Medicare is being seriously questioned. The ACGME recognizes that removing the substantial sources of support for GME may stimulate responses by programs and institutions that bear unintended negative consequences.[3]

In this context, the ACGME has determined the need to update and expand the 2002 set of guiding principles. The intent of this revision is to support efforts of those who are responsible for residents' and fellows' learning and working environments at a time when availability of industry and other potential funding sources may be critical to the survival of GME programs. By promulgating these principles, the ACGME strives to improve health care by providing guidance to sponsoring institutions and programs in helping to form residents and fellows as physicians who exemplify professionalism by serving the best interests of patients in a consistently ethical manner. (Note: These principles constitute guidance; they are not accreditation standards.)

The Practice of Medicine and the Business of Industry

Over the past 10 years, industry has been an influential source of funding of GME. (For the purpose of this paper, the term "industry" includes pharmaceutical companies, manufacturers of medical devices, and biotechnology companies.) Major benefits often accrue to patients from industry collaboration with teaching hospitals through research and development. However, studies have confirmed that conflicts of interest in medical education, research, and physician practice result from promotional marketing and research funding by industry.[4] These practices, therefore, present a threat to the professionalism of physicians and of the institutions that sponsor GME programs.[5]

In their broadest context, the goals of the medical profession and industry are aligned around efforts to improve human health through a direct and positive effect on patient care. Benefits to patients result from services provided by both physicians and industry. Closer scrutiny, however, of the core relationships maintained by each reveals an irreconcilable difference. The relationship of a company to its shareholders defines values and influences behaviors held by industry. Thus, for example, the responsibility of a pharmaceutical company must be to act in the best interests of its shareholders by maximizing their return on investment. In contrast, the altruism and stewardship responsibilities expected of medical professionals dictate that physicians put patients first.[6,7,8] The physician-patient relationship, with all its ensuing values, is the foundation of medical professionalism; the good of the patient must be preeminent.

The Ongoing Challenge for Graduate Medical Education

This conflict between the professional responsibilities of the physician and the business objectives of industry is apparent in the conduct of industry's promotional activities. Industry engages in advertising campaigns and associated marketing activities because they work; successful promotion increases shareholder value.[9] It is the chief means by which industry relates to physicians, residents, and medical students. Promotion by industry frequently occurs through financial support for a broad array of educational programs, industry-sponsored research, and social events.

Faculty members, residents, and fellows alike communicate professional values through the learning and working environment created by sponsoring institutions and residency programs. The structured curriculum, i.e., conferences, grand rounds, and other formal learning activities, is the most obvious of the contexts in which transmittal of values occurs. While less apparent, though with equal and sometimes even greater intensity, the hidden or informal curriculum communicates values at the level of organizational structure and culture, influencing such areas as policy development, evaluation, resource allocation, and institutional jargon.[10] Transmittal of values thus becomes a pervasive component of the educational process relative to all manner of professional relationships within the sponsoring institution and the individual program. Residents and fellows learn to relate to industry in much the same manner they develop other professional relationships, by observing administration and faculty behavior. The learning and working environment, therefore, has a direct bearing on the "learned" professionalism of the residents and fellows training being educated within it.[11] Regrettably, with regard to support from industry, the learning environment sometimes manifests an "entitlement to largesse of drug companies."[12]

Instances of inappropriate relationships with industry and its "largesse" are often found in the expectations for outside support demonstrated by residency programs and sponsoring institutions. Examples that remain all-too-familiar practices include: "drug lunches" with obvious promotional intent; industry-sponsored lectures with negative results of clinical trials given less or no attention; social functions attached to "information sessions" having a clearer marketing objective than scientific purpose; and promotional activity in which residents and even medical students receive slides, lecture materials, and honoraria, and subsequently act as "experts," delivering the packaged information at continuing medical education events. A more subtle promotional activity involves funding of fellowships established by some pharmaceutical companies that retain their companies' names. Thus, a fellowship program and/or an individual fellow supported by a particular pharmaceutical company is indelibly tied to the company.[13] The risk of compromising professional judgment resulting from these and other activities can be egregious, and both the profession and the public express concern over blatant misuse of industry support.[14,15,16] Promotional support has been proven to influence medical decision-making, and studies find that decision makers are unable to recognize its impact.[17,18]

Over the last several years, some residency programs, fellowships, and sponsoring institutions have adopted policies that curtail these promotional activities relating to their GME programs.[19] However, the increasingly constrained funding environment under which programs and institutions may operate will likely fuel the temptation to justify increased dependence on industry funding.

Recently, other sources of funding for GME outside of Medicare and other government programs, (i.e., "other sources") have also emerged. Sponsoring institutions occasionally receive requests from parents to fund a son or daughter, or even from foreign governments to fund a group of individuals in a residency program or fellowship. Likewise, individuals may offer to pay their own way through residency or fellowship programs. The influence inherent in such instances

does not directly undermine values and influence behaviors of individuals as in the case of industry. However, these often well-meaning gestures have the potential for compromising the recruitment, selection, and promotion policies of sponsoring institutions, creating class differences among peer residents and fellows, causing relaxation of acceptance standards for particular individuals, or developing unequal expectations for satisfactory completion of programs.

Guidance from Related Resources

The ACGME and other groups have published guidelines and resources to inform physicians and organizations about conflicts of interest in medical education, particularly regarding gifts and support from industry. Among these are: the ethical opinion "Gifts to Physicians from Industry" in the American Medical Association's Code of Medical Ethics;[20] "In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making"[21] and "Industry Funding of Medical Education"[14] by the Association of American Medical Colleges; the Accreditation Council for Continuing Medical Education's Standards for Commercial Support;[22] and "Code for Interactions with Companies" by the Council of Medical Specialty Societies.[23] The Association of American Medical Colleges has addressed issues regarding financial conflicts of interest in research through its Task Force on Financial Conflicts of Interest in Research.[24] In addition, the Institute of Medicine published an extensive report with recommendations on "Conflict of Interest in Medical Research, Education, and Practice," with a chapter devoted specifically to "Conflicts of Interest in Medical Education."[25]

These guidelines and resources outline what constitutes ethical behavior for both physicians and their related organizations. Without exception, they establish that it is unethical for physicians to accept gifts or support in any form that results in prescription or recommendation of a particular drug or product, or delivery of particular clinical action.

The Role of ACGME: The General Competencies

In 1999 the ACGME identified six general physician competencies in its program and institutional requirements. These competencies--Patient Care, Medical Knowledge, Practice-based Learning and Improvement, Interpersonal and Communication Skills, Professionalism, and Systems-based Practice--serve as organizing principles around which all GME residency and fellowship curricula should be developed.[26] Residents and fellows must demonstrate achievement in these competencies during and upon completion of their programs through appropriate educational outcomes. ACGME-accredited residency and fellowship programs must demonstrate improvement based upon the outcomes identified through assessments of learning activities organized around the competencies.

The competencies are not prescriptive rules; instead, they are a conceptual framework within which the institution and program define educational curricula and evaluation, as well as program and institutional policies regarding all professional relationships in GME. At present, ACGME accreditation standards do not directly address the nature of the professional relationships that exist between residency and fellowship programs, their sponsoring institutions, and industry. However, these standards do shed light on behaviors appropriate to the integrity and objectivity that must be maintained within the GME learning and working environment. Using a framework shaped by the general competencies, the principles that follow should guide conduct of the relationships maintained by ACGME-accredited programs and sponsoring institutions with industry, and inform policies of sponsoring institutions related to acceptance of funding from other sources as well.

<u>Professionalism</u>

Professionalism is an expression of the values and norms that guide the relationships in which physicians are engaged.[27] It is, therefore, the competency that stands at the core of how programs and institutions model behavior with regard to relationships with industry. In her review of the literature, Arnold identified those traits commonly associated with professionalism as altruism, respect for others as embodied in humanistic qualities, honor, integrity, ethical behavior, accountability, excellence, a sense of duty, and advocacy.[28] Ginsburg, et.al., described these traits as context-dependent, that is, demonstrated through behaviors that occur in particular circumstances, often manifesting themselves in conflicts between values.[29]

Professionalism demands that program and sponsoring institution policies must guide action in light of particular differences in objectives between industry and the medical profession and also inform the acceptance of funding from other sources. The following principles promote Professionalism in programs and sponsoring institutions with regard to funding:

1. Ethics curricula include instruction in and discussion of published guidelines regarding gift-giving to physicians. Among these guidelines are the ethical opinion “Gifts to Physicians from Industry” in the Code of Medical Ethics of the American Medical Association[20] and the ethics statements of various medical specialty societies.
2. All program- and institution-sponsored events require full and appropriate disclosure of sponsorship and financial interests, above and beyond those already governed by the Standards for Commercial Support promulgated by the Accreditation Council for Continuing Medical Education.[22] Likewise, full disclosure of research interests are published in keeping with the local policies of institutional review boards and following the recommendations of the Association of American Medical College’s Task Force on Financial Conflicts of Interest in Research.[24]
3. Programs and sponsoring institutions determine, through policy, which contacts, if any, between residents, fellows, and industry representatives may be suitable, and exclude occasions in which involvement by industry representatives or promotion of industry products is inappropriate.
4. Sponsoring institutions ensure that residents, fellows, and programs are not identified publically by their funding sources.[25]
5. Sponsoring institutions maintain policies that ensure non-preferential treatment of residents and fellows in the learning and working environment, based upon sources of funding for their positions.

Practice-based Learning and Improvement and Medical Knowledge

Practice-Based Learning and Improvement refers to how physicians apply Medical Knowledge by investigating and evaluating their own patient care, appraising and assimilating scientific evidence, and making subsequent improvements in the care of their patients. The following principles, informed by Practice-Based Learning and Improvement and Medical Knowledge, apply to the relationship between GME and industry:

1. Residency and fellowship curricula include clinical skills and judgment fostered in an objective and evidence-based learning environment.
2. Residents learn how promotional activities can influence judgment in prescribing decisions and research activities through specific instructional activities.
3. Residents understand the purpose, development, and application of drug formularies and clinical guidelines. Discussion includes such issues as branding, generic drugs, off-label use, and use of free samples.

Systems-based Practice

Systems-based Practice includes behaviors that demonstrate an awareness of and responsiveness to the larger context of health care, and the ability to engage system resources to provide care that is of optimal value. The following principles of Systems-based Practice apply to relationships with industry:

1. Residency and fellowship curricula include how to apply appropriate considerations of cost-benefit analysis as a component of prescribing practice.
2. Advocacy for patient rights within health care systems includes attention to pharmaceutical costs.

Interpersonal and Communication Skills

Interpersonal and Communication Skills provide the foundation upon which the satisfactory relationship between doctor and patient central to medicine is established. With regard to relationships with industry, particular aspects of Interpersonal and Communication Skills should be fostered through application of the following principles:

1. Residency and fellowship curricula include discussion and reflection on managing encounters with industry representatives.
2. Communication skills curricula include illustrative cases of how to handle patient requests for medication, particularly with regard to direct-to-consumer advertising of drug.

The ACGME's Role: Institutional Accreditation

In 2005, several years after the initial principles were published, the ACGME formalized its process for institutional accreditation, which recognizes sponsoring institutions for maintaining an infrastructure to oversee all aspects of the GME learning and working environment. The Institutional Requirements apply both to institutional responsibilities for maintaining a single residency program and to the complexities of managing multiple residency and fellowship programs. These standards specify that sponsoring institutions must provide GME that facilitates residents' professional, ethical, and personal development.[31] In addition, sponsoring institutions must provide the necessary educational, financial, and human resources to support GME.[32] Identified among the responsibilities of the sponsoring institution's graduate medical education committee (GMEC) is the provision of a statement or institutional policy that addresses interactions between vendor representatives, corporations, and residents, fellows, and GME programs.[33]

Consistent with the Institutional Requirements, the GMEC exercises oversight authority of all GME programs sponsored by an institution. Although the current Institutional Requirements do not specify how a sponsoring institution should appropriate funding for its residency and fellowship programs, the authority of the GMEC should logically extend to how the sponsoring institution and its ACGME-accredited programs apply the guiding principles outlined in this paper.

Conclusion

The principles outlined in this paper cannot guarantee individual or institutional professional behavior. Evidence exists, however, that policies relating to sources of educational support appear to affect what physicians believe and how they behave.[34] The value of these

principles, therefore, lies in their ability to inform policymaking and oversight by programs and institutions sponsoring GME programs and to represent to the public the integrity and objectivity of the professional relationships expected by residency and fellowship programs and their sponsoring institutions. The ultimate goal of these relationships is to foster effective Patient Care, the general competency that underlies the mission of medical education.

Promotional activities by industry can seriously compromise the professional relationships that form the substance of medicine. Such compromising activities must not be allowed to continue where they exist. The interests of patients must be paramount and not influenced by the interests of industry to make profits for their shareholders. Residency and fellowship programs and their sponsoring institutions must teach and model core values that are demonstrated by the general competencies. Residents and fellows must be treated non-preferentially, regardless of the source from which the sponsoring institution receives funding for positions. The public and the profession look to GME programs and sponsoring institutions to demonstrate particular clarity around issues of patient advocacy, complete and unbiased medical knowledge, and the application of that knowledge to continually improve the practice of medicine.

References

1 Accreditation Council for Graduate Medical Education. 2009-2010 Data Resource Book, http://www.acgme.org/acWebsite/databook/2009-2010_ACGME_Data_Resource_Book.pdf, Accessed June 19, 2011.

2 Iglehart J. The uncertain future of Medicare and graduate medical education. *N Engl J Med* 2011 Sep 7. http://www.nejm.org/doi/pdf/10.1056/NEJMhpr1107519. 10.1056/nejmhpr1107519 nejm.org. Accessed 09/07/2011.

3 Accreditation Council for Graduate Medical Education. Letter to American Board of Medical Specialties; American Hospital Association; American Medical Association; Association of American Medical Colleges; Council of Medical Specialty Societies: ACGME statement on GME Medicare reimbursement. http://www.acgme.org/acWebsite/home/ACGME_Statement_on_Medicare_GME_Reimbursement.pdf, Accessed 08/10/2011.

4 Brennan TA, Rothman DJ, Blank L, et al. Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. *JAMA*. 2006;295:429-433.

5 Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? *JAMA.* 2000 Jan 19;283(3):373-80.

6 Medical Professionalism Project: ABIM Foundation. Medical professionalism in the new millennium: a physician charter. *Ann Int Med.* 2002;136(3):243-246.

7 American College of Surgeons. Code of professional conduct. http://www.facs.org/memberservices/codeofconduct.html, Accessed 08/10/2011.

8 Adams J, Schmidt T, Sanders A, Larkin GL, Knopp R. Professionalism in academic emergency medicine. SAEM Ethics Committee, Society for Academic Emergency Medicine. *Acad Emerg Med.* 1998;5(12:1193-1199.

9 Association of American Medical Colleges, Baylor College of Medicine. The scientific basis of influence and promotion. Symposium Proceedings. 2007.

10 Hafferty F. Beyond curriculum reform: confronting medicine's hidden curriculum. *Acad Med*. 1998 April 73(4):403-7.

11 Stern D. In search of the informal curriculum: when and where professional values are taught. *Acad Med*. 1998 Oct 73(10 Suppl 1):S-28-30.

12 Rennie D. Thyroid storm. *JAMA*. 1997 April 16;277(15):1238-43.

[13] Medical and Academic Partnerships: a Pfizer Program. http://www.pfizerfellowships.com/GrantsProgType.aspx?ProgTypeID=3, Accessed 08/03/2011.

[14] Association of American Medical Colleges. Industry funding of medical education. Report of an AAMC Task Force. Washington, DC: Association of American Medical Colleges; 2008;3.

[15] Elliott C, Pharma goes to the laundry. *Hastings Cent Rept.* 2004;34(5).

[16] Nakayama DK, Bozeman AP. Industry support of graduate medical education in surgery. *Amer Surg*. 2009 May 75(9):395-400.

[17] Rothman D. Medical professionalism—focusing on the real issues. *N Engl J Med* 2000 342(17):1284-6.

[18] Kassirer J. Financial indigestion. *JAMA* 2000 Nov 1;284(17)2156-57.

[19] Coleman DL. Establishing policies for the relationship between industry and clinicians: lessons learned from two academic health centers. *Acad Med.* 2008 Sept 83(9):882-887.

[20] American Medical Association. AMA code of medical ethics opinion 8.061: gifts to physicians from industry. http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.page, Accessed July 25, 2011.

[21] Association of American Medical Colleges. In the interest of patients: recommendations for physician financial relationships and clinical decision making. Report of the Task Force on Financial Conflicts of Interest in Clinical Care, Washington, DC: Association of American Medical Colleges; 2010.

[22] Accreditation Council for Continuing Medical Education (ACCME). Standards for Commercial Support of Continuing Medical Education, http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf, Accessed July 25, 2011.

[23] Council of Medical Specialty Societies. Code for Interaction with Companies, http://www.cmss.org/uploadedFiles/Site/CMSS_Policies/CMSS%20Code%20for%20Interactions%20with%20Companies%20Approved%20Revised%20Version%203-19-11CLEAN.pdf, Accessed August 3, 2011.

[24] Association of American Medical Colleges. Task force on financial conflicts of interest in research. Protecting subjects, preserving trust, promoting progress: Policy and guidelines for the oversight of individual financial interests in human subjects research. Washington, DC: Association of American Medical Colleges; 2002.

[25] Lo B, Field MJ (eds) Conflict of interest in medical research, education and practice. Conflicts of interest in medical education (Chapter 5). Washington, DC: The National Academies; 2009.

[26] Accreditation Council for Graduate Medical Education. Common program requirements: general competencies. http://www.acgme.org/outcome/comp/GeneralCompetenciesStandards21307.pdf, Accessed 08/03/2011.

[27] Kuczewski M. Developing competency in professionalism: the potential and the pitfalls. *ACGME Bulletin* 2001 October;3-6.

[28] Arnold L. Assessing professionalism: from concept to construct. *Acad Med.* 2001.

[29] Ginsburg S, Regehr G, Hatala R, McNaughton N, Frohna A, Hodges B, et.al. Context, conflict, and resolution: a new conceptual framework for evaluating professionalism. *Acad Med.* 2000;75 Suppl: S6-11.

[30] Lo B, Field MJ (eds) Conflict of interest in medical research, education and practice. Conflicts of interest in medical education (Chapter 5). Washington, DC: The National Academies; 2009, 139.

[31] Accreditation Council for Graduate Medical Education. Institutional Requirements: I.B.1, http://www.acgme.org/acWebsite/irc/irc_IRCpr07012007.pdf, Accessed 08/03/2011.

[32] Accreditation Council for Graduate Medical Education. Institutional Requirements: I.B.2, http://www.acgme.org/acWebsite/irc/irc_IRCpr07012007.pdf, Accessed 08/03/2011.

[33] Accreditation Council for Graduate Medical Education. Institutional Requirements: III.B.13, http://www.acgme.org/acWebsite/irc/irc_IRCpr07012007.pdf, Accessed 08/03/2011.

[34] McCormick B, Tomlinson G, Brill-Edwards P, Detsky A. Effect of restricting contact between pharmaceutical company representatives and internal medicine residents on posttraining attitudes and behaviors. *JAMA* 2001 Oct 24/31;286(16):1994-99.