Industry Relations With Emergency Medicine Graduate Medical Education Programs

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Abstract

A panel of physicians from the Society for Academic Emergency Medicine (SAEM) Graduate Medical Education (GME), Ethics, and Industry Relations Committees were asked by the SAEM Board of Directors to write a position paper on the relationship of emergency medicine (EM) GME with industry. Using multiple sources as references, the team derived a set of guidelines that all EM GME training programs can use when interacting with industry representatives. In addition, the team used a question–answer format to provide educators and residents with a practical approach to these interactions. The SAEM Board of Directors endorsed the guidelines in June 2009.

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Pharmaceutical, biologic, and device manufacturers (industry) have been involved with graduate medical education (GME) for many years in a variety of forms, including disseminating information regarding drugs and devices, providing educational materials, sponsoring continuing medical education (CME) and speaker programs, funding travel to educational programs, and funding research, among others. Physicians and industry share a common goal of providing the best possible care for their patients. However, industry has the added responsibility of promoting their own products in an effort to maximize their returns on investment and thereby please share holders. This divergence in goals has the potential to create a conflict of interest or values.[1,2]

Industry invests billions of dollars annually to discover new medications.[3] To remain financially viable, they must sell their products to realize a return on investment. To accomplish this goal they must promote their products, and they do so through the aforementioned means. This establishes the relationship with physicians and GME programs. In 2000, the pharmaceutical industry spent nearly $8 billion on product promotion and marketing in the first 6 months of the year.[4] These billions of dollars equate to $8,000 to $13,000 being spent directly or indirectly on each physician per year.[5,6] Physicians frequently are not fully aware of the influence promotional activity has on their medical decision-making.[7,8]

At the heart of the matter is the notion that physicians must act ethically, responsibly, and professionally at all times to care for and protect their patients.[9] Students and residents frequently have their first interaction with industry representatives at their educational institutions. Professionalism is deeply influenced by their experiences at these institutions, as well as what they are taught by their faculty.[10] It has been shown that pharmaceutical industry influence potentially jeopardizes the professionalism of physicians and the institutions that sponsor their educational programs.[11,12]

The issue of proper interaction of industry with physicians, medical organizations, medical schools, sponsors of CME, and GME became an important topic earlier this decade. In an effort to provide direction for

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Society for Academic Emergency Medicine Graduate Medical Education, Ethics, and Industry Relations Committees Memberships are listed in Appendix A.

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T. Kowalenko acknowledges he is related to an individual employed by a big pharmaceutical company.

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GME and physicians, a number of professional organizations, including the pharmaceutical industry, created guidelines regarding the interactions. Notable among these guidelines were the following:

- ''Gifts to Physicians From Industry''—American Medical Association (AMA) Code of Medical Ethics (2001);[13]
- ''Physicians and the Pharmaceutical Industry''—American College of Physicians–American Society of Internal Medicine (ACP-ASIM; 2002);[14,15]
- ''Physicians and the Pharmaceutical Industry''—Canadian Medical Association (2002);[16]
- ''Standards for Commercial Support''—Accreditation Council for Graduate Medical Education (ACGME; 2001);[17]
- Association of American Medical Colleges (AAMC) Task Force on Financial Conflict of Interest in Research Statement;[18]
- Pharmaceutical Research and Manufacturers of America (PhRMA) ''Code on Interactions with Healthcare Professionals'' (2002);[19] and
- ACGME ''Principles to Guide the Relationship Between GME and Industry'' (2002).[20]

Shortly thereafter, the Council of Emergency Medicine Residency Directors (CORD) Board of Directors issued a position paper endorsing the ACGME guidelines.[21] In 2007, the Society for Academic Emergency Medicine (SAEM) issued a position paper on the ethical relationships with the biomedical industry.[22] Over the past several years, there has been intense interest and scrutiny placed on physicians and industry, especially by the public, who generally feel that pharmaceutical industries should be regulated more stringently.[23] This resulted in the ''Report of the American Association of Medical Colleges (AAMC) Task Force on Industry Funding of Medical Education'' to the AAMC Executive Council.[24] This, along with the AMA Report of the Council on Ethical and Judicial Affairs (A-08) ''Industry Support of Professional Education in Medicine,''[25] also published in 2008, established guidelines specifically addressing the interactions of academic medical centers with industry. PhRMA then revised their guidelines in July 2008,[19] and these guidelines took effect January 2009. In addition, the Institute of Medicine (IOM) issued recommendations regarding conflicts of interest, specifically addressing the relationship of industry with medical education.[26]

Given the recent developments and increasing interest in physician and GME relationships with industry, the SAEM Board of Directors charged the SAEM GME Committee, with input from the SAEM Industry Relations Committee and the SAEM Ethics Committee, to develop a revised set of guidelines for emergency medicine (EM) training programs. What follows is the consensus report on the revised guidelines, and recommendations regarding commonly asked questions (available in Data Supplement S1, available as supporting information in the online version of this paper) as they apply to these guidelines. These guidelines are derived, copied, and or edited/adapted from the aforementioned sources.[13–26]

GUIDELINES FOR BIOINDUSTRY INTERACTION WITH GME

1. Emergency medicine GME programs should adopt and implement policies that address specific interactions between academic medical personnel and industry. 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.
2. Emergency medicine GME programs should make clear to their faculty, students, and staff that to the extent certain interactions with industry are prohibited within their primary academic medical center, they are also prohibited at secondary or off-site rotations.
   a. Emergency medicine GME programs should communicate to secondary training facilities their expectations that the off-site venues will adhere to the standards of the primary site regarding interaction with industry.
   b. Industry should not invite program personnel to participate in practices prohibited at the primary site.
3. Emergency medicine GME programs should establish and implement policies that prohibit the acceptance of any gifts, including food, from industry by physicians and other faculty, staff, student, and trainees, whether at the primary or at the secondary venues. These gifts include gifts from equipment and service providers, as well as pharmaceutical and device providers.
   a. Distribution of medications to EM training programs, including samples (if permitted), should be centrally managed in a manner that ensures timely patient access to optimal therapeutics throughout the health care system. Physicians must avoid distribution of misleading or coercive information.
4. Access by industry representatives to individual physicians, if permitted, should be restricted to private, nonpatient care areas and only by appointment or invitation of the physician.
   a. Involvement of students and trainees in such one-on-one industry-related meetings should occur only for educational purposes and only under the supervision of a faculty member.
5. Emergency medicine GME programs 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 of interaction and critical evaluation. Highly trained industry representatives with MD, DO, PhD, or PharmD degrees are best suited for transmitting such scientific information in these settings.
6. Emergency medicine GME programs sponsoring CME programs should develop audit mechanisms that assure compliance with the Accreditation Council for Continuing Medical Education (ACCME) regulations and policies.

7. Medical centers that sponsor GME programs should establish a central CME office through which all requests for industry support and receipt of funds for CME activity are coordinated and overseen.
8. All educational programs with any support should be offered only by ACCME accredited providers according to ACGME standards.
   a. Bioindustry funding for education should be in the form of unrestricted educational grants.
   b. Industry support of educational events must be acknowledged at the time of the presentation or listed in the event brochure credits and must formally note compliance with the ACCME Task Force recommendations.[17,27]
   c. Educational information should be fair, impartial, and accurate. All presenters must disclose and resolve any financial relationships before presentation.
   d. Presentations should use generic nomenclature of pharmaceutical products. Therapy comparisons should be balanced and represent the spectrum of available agents.
9. 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, EM GME programs should strongly discourage participation by their faculty in industry-sponsored speaker's bureaus.
10. If EM GME programs allow faculty participation in industry-sponsored, Food and Drug Administration–regulated programs, they should develop standards that define appropriate and acceptable involvement.
    a. Require full transparency and disclosure.
    b. Require that payments to personnel be only at fair market price.
11. Emergency medicine GME programs should prohibit faculty, students, and trainees from:
    a. Attending non–ACCME-accredited industry events billed as CME.
    b. Accepting payment for attendance at industry-sponsored meetings.
    c. Accepting personal gifts from industry at such events.
12. Emergency medicine GME programs should establish and implement policies requiring that:
    a. All scholarships or other educational funds from industry be given centrally to administration.
    b. No quid pro quo be involved in any way.
    c. Evaluation and selection of the recipient of such funds must be the sole responsibility of the medical center administration or of the nonprofit granting entity, with no involvement by the donor industry.
    d. With the exception of food provided in connection with ACCME-accredited programming and in compliance with ACCME guidelines, EM GME programs 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.
    e. This should also apply to all secondary training venues.
13. Emergency medicine GME programs should prohibit their physicians, trainees, and students from directly accepting travel funds from industry, other than for legitimate reimbursement or contractual services.
14. Emergency medicine GME programs may allow industry representatives to provide technical training when new diagnostic or therapeutic devices and techniques are introduced. Once expertise in the use of previously new devices has developed within the professional community, continuing industry involvement in educating practitioners is no longer warranted.
15. Emergency medicine GME programs should assist medical schools and teaching hospitals to design curriculum standards and teaching material for all phases of medical education, from medical school to CME, that provide tools to educate students, residents, and faculty about the processes and disciplines of drug discovery, development, clinical testing, safety, therapeutics, and regulation. Residency programs and medical schools should teach recognition, evaluation, and other critical thinking skills to develop a sense of evaluation among students. This education module should include all aspects delineated in the ACGME ''Principles to Guide the Relationships between GME and Industry.''[20]
16. Emergency medicine GME programs should assist in developing optimal information systems, including Web-based technologies, for disseminating information on new products.

This comprehensive list of guidelines should assist all EM program directors and department chairs by providing the guidance needed when interacting with industry. It has been noted that there is much variability among EM programs with regard to their relationship with industry.[28] These guidelines will, hopefully, help to eliminate some of this variability.

DISCUSSION

The relationship between industry and GME and physician-related education and research is undeniable. The IOM Committee supports further restrictions, but recognizes that ''a goal of $0 contributions from industry'' is not likely.[29,30] Given the financial constraints for many GME programs, it is likely industry will play as big, if not a bigger, role in the future. Industry has provided funding to support residency positions in at least one specialty to date.[31] There is growing concern that medicine's increasing reliance on industry financial support of professional education has undermined its status in society.[32] Commercial support of providers accredited by the ACCME increased by a factor of 300% from 1998 to 2006, to $1.2 billion.[33] In addition, this support accounts for approximately half of all the income to nationally accredited CME providers. A 2006 survey of department chairs revealed 25%

reported their departments accepted financial support for residency or fellowship training, 38% accepted food and beverages, and 22% accepted financial support for travel and meetings.[34] Physicians often do not recognize the financial educational support.[20] GME programs are potentially effective venues for industry marketing and promotion given the educational environment.[20,35]

Physicians and residents frequently do not recognize the influence that industry gifts and services have on them.[36] Several studies have shown that physicians deny industry's influence.[5,37–43] However, research shows a strong correlation between receiving industry benefits and favoring their products.[7,8,44] Physicians and residents feel they are immune to the promotional activities.[45] Sierles et al.[46] reported that students felt that they were entitled to industry gifts and that sponsored educational events were likely to be biased, but helpful. They also observed that students manifested the same behavior as residents, such as accepting gifts while disapproving of them. Although physicians feel immune, the patients perceive industry gifts as inappropriate or influential on medical practice.[37,47,48]

Given that industry is likely to continue to have some interaction and relationship with GME, it is critical not only to develop guidelines, but also to develop educational curricula addressing the interaction as well as developing independent, unbiased sources of information on new drugs and devices. Examples of centralized information sources include peer-reviewed journals, FDA medical reviewers' summary reports on new drug applications that are approved, and information used for submission to regulatory authorities.[24] Carroll et al.[49] reported that educational interventions can increase skepticism toward industry marketing techniques and influence intentions and behavior of trainees with respect to their relationships with industry representatives, at least in the short term. All of the aforementioned guidelines allude to the need for GME programs and faculty within them to develop educational programs and to act as role models.

CONCLUSIONS

Emergency medicine GME programs are likely to have some interactions with industry representatives. Program faculty must act as responsible role models. SAEM has developed guidelines to help program directors deal with issues that may arise when dealing with industry and provide some level of consistency within the specialty. In addition, GME programs have the added responsibility of educating residents and students on the ethical and professional responsibilities of their trainees when interacting with industry.

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SUPPORTING INFORMATION

The following supporting information is available in the online version of this paper:

Data Supplement S1. Frequently asked questions. The document is in PDF format.

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APPENDIX A

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