

## **FREQUENTLY ASKED QUESTIONS**

The following section will address some of the common questions and problems that all GME programs face when dealing with issues that involve interaction with industry. Each question will be followed by a discussion of the benefits, risks, and consensus recommendations.

### **1) How should GME programs deal with product in-servicing prior to the department buying the product?**

**Benefits:** Residents and staff may not be aware of new products that may have the potential to positively impact patient care. Device representatives are specifically trained to be more knowledgeable with respect to the utilization of new devices, and may be able to provide residents and staff with valuable information regarding new technologies and their potential impact.

**Risks:** As salespeople, device representatives have the potential to provide biased information with regard to the usefulness of their products, and may not be forthcoming about alternatives that have equal or better efficacy, or are more cost-effective. Benefits to patients over the current (potentially more cost-effective) standard of care may be overstated.

**Recommendations:** Academic emergency medicine (EM) departments should have a small group of faculty who evaluate new devices and make purchasing decisions based on literature-proven efficacy and cost-effectiveness. Members of this group should be free from conflicts of interest. Residents may be included in this evaluation process as part of their education, and to give them the tools to participate in these decisions as part of their future practice. These recommendations are supported by the guidelines set forth by the AAMC<sup>1</sup> and the AMA,<sup>2</sup> with

the caveat that once expertise in the use of previously new devices has developed, continuing industry involvement in educating practitioners is no longer warranted.

**2) How does GME address the issue of product in-servicing after the department buys a product?**

**Benefits:** Device representatives have an extensive depth of knowledge regarding the use of recently developed and purchased devices. Once a device is purchased, it is important that it be utilized correctly so that the time and resources already invested are not wasted, and that the product is used the way it was intended to provide safe and effective patient care.

**Risks:** As salespeople, device representatives have the potential to provide biased information with regard to the usefulness of their products, and may suggest a broader scope for utilization than is appropriate. Benefits to patients over the (usually more cost-effective) standard of care may be overstated.

**Recommendations:** Academic EM departments should oversee the education of residents with respect to new devices that have been purchased. The indications for use should be clear, and should be developed and presented by the faculty in consultation with the device representative. Ideally, the faculty should be trained by the device manufacturer, and these faculty should instruct the residents. Alternatively, a small group of faculty and residents could receive this instruction and disseminate it to the remainder of the residency. Representative contact with residents, if absolutely necessary, should be limited to instruction regarding correct use of the device. Faculty and residents with an instructional role for new devices should be free from conflicts of interest.

**3) The residency program supports a policy that does not allow industry representatives to interact with residents at the hospital. Residents are invited by an industry representative to attend a company-sponsored speaking program after hours at a local restaurant. Do programs have the right, or obligation to control how the residents spend their personal time by prohibiting their attendance?**

**Benefits:** Company sponsored speaker programs provide the opportunity for health care providers to learn about new, emerging trends, diseases, diagnoses, and treatments. Not infrequently, there are significant delays for the information to be presented at a large national professional meeting (often 1-2 years). The company-sponsored speakers are often prominent physicians who are well educated about the products and can provide specific information about their use in appropriate clinical settings.

**Risks:** Company sponsored speaker programs are not CME programs, and as such, are not held to the ACCME guidelines.<sup>3,4</sup> These programs are frequently conducted by prominent, respected physicians. The information provided may not be fully unbiased. Although the company and speaker provide disclosures, physicians, and in particular residents and students, may not always have the skills to detect overt or covert bias. Residents may not possess the critical appraisal skills required to fully understand the implications of the information provided. Without these skills, residents may be improperly influenced by the information, which could result in improper or potentially, unnecessarily expensive medical treatment. This “influence” may be easier to achieve without faculty presence.

**Recommendations:** Residency programs should develop policies regarding industry representative interaction within the training program or site. Recent guidelines recommend that a single standard be adhered to both in the primary and secondary sites; however, it may be

difficult for programs to control or enforce these rules when a resident is on personal time outside the hospital. This scenario sets up several challenges. Not letting trainees attend events outside of the hospital (controlling what they have access too) may be perceived as paternalistic and may imply that the program leadership does not trust them or their ability to be objective. However, as noted, the risks are great as well. Ideally, residents should not attend company sponsored speaking engagements, especially without faculty who possess the skills to critically appraise the information given, and potentially provide a challenge to the speaker/information. Some institutions have been able to enforce rules pertaining to personal time under the auspices of “professional behavior and expectations.” Because most programs will not be able to enforce rules during personal time, it is critically important that residents be given instruction on the critical appraisal of medical information and the proper professional and ethical interaction with industry representatives and sponsored speakers.

**4) How should GME programs address the issue of industry-sponsored travel to symposia, conferences, etc.? What constitutes legitimate educational opportunity? How far removed must industry be to make the sponsorship “appropriate but not influential”?**

**Benefits:** The cost to attend professional meetings is high, and many programs do not have adequate funding to send trainees to them. This is one way to allow residents to participate in conferences and possibly learn about subjects that are not adequately covered in the program curriculum or are outside the realm of “core” clinical EM. Frequently these sponsored meetings are in the same location and a day before a major medical society meeting, allowing for the travel and one night stay to be funded by the sponsoring company (and therefore not funded by the residency program).

**Risks:** The company-sponsored “educational program” will frequently have some subtle or not-so-subtle commercial bias. Frequently these company-sponsored symposia do not provide CME, and therefore do not need to adhere to the ACCME guidelines. This carries the risk of providing information that is not fully unbiased. As noted above, residents may not possess the skills to adequately critically appraise the information. Even if the program selects the participating resident, that individual will be subject to subtle influence by that sponsoring company, and may feel beholden to it. These risks may be substantially lessened and potentially eliminated if the company sponsorship is to a third party in the form of an unrestricted educational grant.

**Recommendations:** If programs have adequate funding for resident travel they should either not accept travel funding, or consider only accepting if the funding is from a third party that received an unrestricted educational grant from industry. For those programs that are financially challenged with regard to resident travel, the program director should carefully review the material to be presented, specifically paying attention to the content and potential for introduction of bias. In some cases, the program director may need to contact the symposium director for clarification regarding educational content and the relationship speakers have with industry. If deemed appropriate, the program should select the resident participant (this is in adherence with the PhRMA Code<sup>5</sup>). Another option would be to insist that a faculty member accompany the resident to the symposium.

**5) How should GME programs address the issue of paid travel and expenses for residents to attend administrative conferences or other employment recruitment events when sponsored by potential employers (e.g. physician groups), rather than industry?**

**Benefits:** Residents can become familiar with potential future employment opportunities with a particular physician group or geographic region by attending group-sponsored conferences. In addition, the administrative topics presented at such conferences may enhance resident education, especially if these topics are not covered as part of the training program curriculum. Speakers at administrative conferences may have additional expertise and experience in a practice setting that differs from faculty at the training program site.

**Risks:** Because such conferences are often part of employee recruitment, residents may be taken to dinner or given other gifts. If not specifically addressed, this could potentially confuse trainees regarding when receiving a gift creates a conflict of interest. Purely administrative conferences do not create a conflict of interest, as they do not interfere with the physician's ethical responsibility to their patients. However, if clinical topics are covered as part of the conference, then biased information potentially could be presented, especially if ACCME guidelines are not followed.

**Recommendations:** Program directors should review conference invitation letters and brochures to determine if the conference is purely administrative in nature or if clinical material will be presented. Residents should be allowed to attend purely administrative conferences and recruitment events, as they do not present a conflict of interest. Program directors should consider using this opportunity to remind the resident about situations when receiving a gift would create a conflict of interest. If clinical topics will be presented, the program director should determine if the conference is industry-sponsored, and if ACCME guidelines will be followed. For industry-sponsored events, the above recommendations (section 4) would apply.

**6) How should programs handle the situation where a faculty member is part of an industry-sponsored speakers' bureau (especially when the training program restricts and/or discourages resident-industry interaction)? Can program faculty be involved in industry-sponsored activity and still retain credibility as training mentors?**

**Benefits:** Many residency program faculty members are, by the very nature of their scholarly activity, "experts," and in a position to provide education and updates to other physicians on topics in which they possess expertise. Pharmaceutical companies frequently look to these individuals to become part of their company-sponsored speakers' bureaus. As members of company's speakers' bureaus, they will have access to some of the most recent developments in their area of expertise and will better understand the industry side of the education process. With this information, they may be better equipped to instruct residents on the benefits and potential risks of obtaining education from a company-sponsored speaker. It might also be hoped that academic center physicians would be held to a higher professional and ethical standard. If they are entrusted to teach residents and medical students, why wouldn't they be appropriate choices to teach community physicians?

**Risks:** Program faculty may, either consciously or unconsciously, lose their objectivity with regard to the areas for which they act as members of company-sponsored speakers' bureaus as a result of their relationships. This may lead to biased instruction or influence on residents. This may also be perceived as hypocrisy by the residents, especially at programs that do not allow any interaction between residents and industry representatives. It should be noted that even if attendings are not part of a speaker's bureau, that does not prevent them from expressing bias, or ensure that what they are presenting or teaching is not biased toward a particular intervention or treatment.

**Recommendations:** The situation alluded to in this example is not uncommon. In a 2006 national survey of department chairs at all U.S. medical schools and the 15 largest teaching hospitals, 19% of respondents were paid by industry to participate as faculty or speakers in CME activities, 14% were on company speakers' bureaus, and 16% accepted free or subsidized travel, meals, lodging, and other personal expenses associated with attendance at meetings or conferences related to their specific area of expertise.<sup>6</sup> Guidelines strongly discourage academic faculty from belonging to industry sponsored speakers' bureaus.<sup>1,2</sup> If an academic faculty member chooses to be part of a speakers' bureau, this should be fully disclosed to the department and residency at least on an annual basis, and for two years following termination of the relationship. The department should have a policy and procedure for individuals to anonymously report any activity by this or other attendings who may appear to be acting in a biased way with regard to patient care activities. In addition, faculty who have any relationship with industry and belong to committees that make decisions on products used by the hospital, or set clinical practice guidelines, must disclose the relationship, and when appropriate recuse themselves from decisions that pertain to companies with which they have relationships.<sup>5</sup> Disclosure alone does not remove the bias or conflict of interest. It forces the audience to make up its own mind. Program faculty have an obligation to put the education and well-being of trainees ahead of themselves. Their most important duty is to be a role model for young physicians.

**7) Should GME programs accept the offer of an industry representative to sponsor a dinner in conjunction with the program's journal club?**

**Benefits:** Programs frequently conduct journal club at restaurants during the evening hours.

These dinners can be quite expensive, and an industry representative paying for the dinner allows



for the program's money to be spent on other residency-related activities. Residents may be exposed to new cutting-edge drugs or devices. Although the representative may have promotional material and may give a brief presentation, faculty are present to critically appraise what is being presented and can challenge information that seems unbalanced or biased.

Exposing residents to industry representatives during their GME training might benefit residents by preparing them for such interactions following training program completion.

**Risks:** As stated earlier, food is considered a gift. Not infrequently, the restaurant is nicer than that typically paid for by the residency. As such, this may consciously or unconsciously oblige the recipient to reciprocate. In addition, multiple organization guidelines prohibit any gift giving, including food.<sup>7</sup> At most programs, journal club is the one forum specifically dedicated for critical review of the medical literature. Industry representative presence at journal club risks introducing bias at this unique forum reserved for high-level, critical appraisal of literature and EM practice. Although faculty members are present, they may feel uncomfortable challenging the industry representative in front of the residents in an effort not to embarrass, especially since the company is paying for the dinner. In addition, industry representative presence may appear to residents to either endorse a product or imply that industry representatives are an important source of medical information.

**Recommendations:** As noted above, multiple organizations that have set forth guidelines regarding industry relations with GME have stated that food is considered a gift, and as such should be prohibited for all the aforementioned reasons. Ideally, the department, independently, should fund any food associated with journal clubs. In addition, the newly published PhRMA Code states:

In order to provide important scientific information and to respect health care professionals' abilities to manage their schedules and provide patient care, company representatives may take the opportunity to present information during health care professionals' working day, including mealtimes. In connection with such presentations or discussions, it is appropriate for occasional meals to be offered as a business courtesy to the health care professionals as well as members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals 1) are modest as judged by local standards; 2) are not part of an entertainment or recreational event; and 3) are provided in a manner conducive to informational communication. These should be limited to in-office or in-hospital settings.<sup>5</sup>

As journal clubs are not informational sessions sponsored by industry representatives, and they do not take place in the hospital (in this example), according to PhRMA Code, they cannot be paid for by industry representatives. In addition, because of the risks noted above, we recommend that industry representatives not participate in journal club.

Some GME programs may desire to expose residents to industry representatives during training, either because the particular representative is believed to have unique expertise or experience with a product, or as an exercise to teach residents about what they will encounter after leaving the GME setting. If a program chooses to allow industry representative participation in journal club, this must be undertaken with great care to ensure unbiased and open discussion of any material presented. Display or distribution of promotional information should not be

allowed, unless the specific purpose is to scrutinize such materials in further discussion (e.g. part of the educational exercise). Because full and open discussion is likely to be inhibited in the presence of an industry representative, some portion of the discussion should occur without the representative present. For example, a program may offer to review the literature regarding a new product as part of the journal club presentation. This affords faculty and residents the opportunity to critically appraise the literature pertaining to this product. The industry representative might be present for the initial discussion of the product and then asked to leave for a “faculty and learners only” discussion. Such expectations should be made clear to the industry representative in advance of the event. If the pharmaceutical company refuses to abide by these guidelines, it should not be allowed to participate in journal club or interact with the residents.

**8) How should GME programs deal with the situation when the primary training site does not allow interaction with industry representatives, but a secondary training site, at which they rotate, does?**

**Benefits:** Although the primary training site may not allow industry representative interaction with residents, the residents may be exposed to industry representatives at secondary training sites. This gives residents an opportunity to learn about new and cutting-edge drugs and devices. This also gives residents an opportunity to start to develop an ethical and professional relationship with industry representatives. They can use what they learn in residency to interact with industry following completion of the training program.

**Risks:** Given that the industry representative interaction takes place at a secondary training site, it would be very difficult for the program director to monitor the activity. As noted in previous

examples, residents may not possess the skills to critically appraise the information provided to them by the industry representative. This could potentially lead to inappropriate behavior or influence.

**Recommendations:** Many EM residencies have residents rotate at multiple facilities. It is not uncommon that these institutions have varying policies regarding pharmaceutical representative interaction. Current guidelines recommend that secondary training sites should adhere to the policies at the primary training site. This poses a real dilemma for program directors. Many have no “control” or influence over the policies or the rules governing pharmaceutical representative interaction at any sites other than the primary site.

The residency programs should develop policies that mandate consistent behavior regarding pharmaceutical representative interaction at all training sites where the residents rotate. If the program cannot mandate a consistent behavior at all sites, the program director should strongly encourage faculty attendance at all functions where pharmaceutical representatives interact with residents.

**9) How should a GME program address the issue of pharmaceutical representatives giving residents free drug samples for personal use?**

**Benefits:** Residents and their families earn modest incomes, and some commonly used medications (frequently over-the-counter [OTC]), are offered to them for personal use by pharmaceutical representatives. One study showed that physicians and their families and staff use approximately one third of the samples provided.<sup>8-11</sup> Many of the samples are safe, effective, available OTC, and are relatively inexpensive.

**Risks:** Samples for personal use are considered “gifts,” and in addition to the fact that multiple organizations have adopted the policy that no gifts should be accepted by physicians, this sets up a feeling of reciprocity that can unwittingly bias decision-making by recipients in favor of the donors’ interest.

**Recommendations:** The topic of pharmaceutical samples for resident use causes little to no controversy. Such giving qualifies as a gift to the provider. The AAMC published the increasingly accepted policy on such a gift in their 2008 White Paper on industry interaction.<sup>1</sup> “The SAEM Position on Ethical Relationships with the Biomedical Industry” published in *Academic Emergency Medicine* in 2006, reiterates that gifts to physicians are strongly discouraged.<sup>12</sup>

#### **10) How should GME programs address the issue of pharmaceutical representatives supplying residents with free drug samples for patient use?**

**Benefits:** Industry distribution of pharmaceutical samples to physicians can provide access to pharmaceuticals for needy patients and enable them to begin treatment in a timely fashion and free of charge

**Risks:** Providing samples encourages physicians to prescribe the new product. Research has shown that the physician will write for the same brand of medication after they run out of the free sample.<sup>8,9</sup> Few samples of older or less expensive drugs are typically given to physicians,<sup>13</sup> and this may lead to higher costs. In addition, a recently published study demonstrated that in practice, pharmaceutical drug samples are more likely to be distributed to the wealthy and insured.<sup>14</sup> This may be due in part to the issues of access to health care by the poor and uninsured in the office-based setting. However, it does bring into question the value of samples to the

safety net for the poor and uninsured as compared to the value of sample medications as a marketing technique for the pharmaceutical industry. In addition, studies of patients' attitudes reveal that they tend to disapprove of industry gifts to physicians, including items that they believe might have some value for patients, such as free drug samples.<sup>15,16</sup> Several studies have demonstrated that prescribing patterns are altered when drug samples are made available to physicians and residents.<sup>8,17,18</sup> In addition, the AAMC points out that the acceptance and use of drug samples may send the message to students and trainees that information about samples received from industry sales representatives is sufficient without independent critical evaluation.

**Recommendations:** Industry providing pharmaceutical samples for patient use is a controversial topic. As discussed in the AAMC 2008 White Paper,<sup>1</sup> providing necessary drugs to the needy can be accomplished in different ways. Some medical centers have decided to substitute a voucher system, or to require that samples be left only at the centers' pharmacies. The centers' pharmacists and its Pharmacy and Therapeutics (P&T) Committee can evaluate them like all other proposed new therapeutics. The P&T Committee can then determine whether and how the samples should be distributed within the medical center and its affiliated community sites. This centralized approach may prevent worrisome gifting relationships between industry personnel and faculty physicians and trainees. We must remember that a sample being medically useful and intended for patient care does not remove its potential to affect the objectivity of the physician-recipient. We recommend that if possible the distribution of sample medications (if permitted) should be centrally managed in a manner that ensures timely access throughout the health care system. In addition, 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.

**11) Should the receipt of nominal non-educational gifts (pens, office supplies, etc.) and food be permitted within the context of an EM residency training program?**

**Benefits:** The convenience of a readily available source of supplies or food is undeniable given the hectic schedules and time demands placed on faculty, residents, and staff. Pens, note-pads, reflex hammers, etc. are useful tools when caring for patients and carrying out other professional responsibilities.

**Risks:** The mere appearance of product endorsement can give the casual observer the perception of bias. Accepting even nominal gifts creates a “gift relationship” with a reflexive need for reciprocity that can be both subtle and innocent, while at the same time measurable. Gift-giving helps industry representatives to establish and build personal rapport with physicians.<sup>19</sup> Social scientists have found that the gift is intended to cause the recipient to reciprocate.<sup>20-22</sup> The response to reciprocate takes place at an unconscious level and may not be consciously realized.<sup>23,24</sup>

Accepting any gift may compromise a physician’s professionalism and fiduciary responsibility to his or her patients. Patients tend to disapprove of industry gifts,<sup>15,16</sup> and evidence suggests that patients find gifts less appropriate and more influential than do their physicians.<sup>25</sup> Even small gifts can affect judgment and increase suspicion of conflict of interest.<sup>26</sup>

**Recommendations:** An opinion by the AMA (8.061) Gift to Physicians Workgroup issued June, 1992 stated: “Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).”<sup>27</sup> In April 2003, the Office of the Inspector General (OIG) for the U.S. Department of Health and Human Services issued final federal guidelines for physician-pharmaceutical industry relations that did not directly address

the practice of giving or receiving nominal gifts.<sup>28</sup> The federal guidelines did specifically prohibit any “arrangement or practice” if it has the potential to “interfere with, or skew, clinical decision making,” “increase costs to the federal healthcare programs, beneficiaries, or enrollees,” “increase the risk of over utilization or inappropriate utilization,” or “raise patient safety or quality of care concerns.”<sup>27</sup> In June of 2008, the Executive Council of the AAMC endorsed a report which stated that all “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.”<sup>1</sup> This report included the use of meals as gifts, and called for implementation by July 2009. This view was further supported by the ACP-ASIM Physician-Industry Relations Position Paper:<sup>29,30</sup> In addition, as of January 2009, PhRMA guidelines no longer allow member organizations to provide pens, flashlights, or other nominal gifts to physicians.<sup>5</sup>

The use of nominal gifts (including food) is an effective tool to create brand recognition, facilitate social interaction, and provide an introduction for the physician to novel and emerging therapeutics. It is unlikely that nominal gifts or food sway the average physician, although undoubtedly the social interaction and “face time” purchased by such gifts does both inform and influence clinical decision making. The fact that this “influence” is in the form of education and not the interference prohibited by the OIG does not overcome the appearance of impropriety. The mere appearance of impropriety has been sufficient enough to prompt the AAMC to call for an outright ban on the practice.<sup>1</sup> Taken as a whole, the benefits of convenience, education, and facilitation that the individual physician or physician-in-training receives from this interaction do not outweigh the negative societal impact caused solely by perception.



The acceptance of nominal gifts (including food) should be discouraged within the context of an EM residency training program in accordance with the guidelines recommended by the AAMC.<sup>1</sup>

**12) Should GME programs allow residents to attend industry-sponsored educational activities?**

**Benefits:** Biomedical industries frequently sponsor a variety of educational activities, including continuing medical education (CME), medical school, and GME activities. It has been estimated by the ACCME that industry provided \$729 million for CME courses in 2001, and this accounted for over 60% of total CME funding in that year.<sup>31</sup> These activities can be of very high quality, and strict guidelines by several organizations<sup>1,2,5,29,30,32</sup> significantly reduce the risk of the presented material being unbalanced or biased.

**Risks:** As with any industry sponsored educational activity, even under the aforementioned guidelines, there is a significant potential for introduction of bias or influence. A recent study demonstrated that following an industry-sponsored grand rounds by a pharmaceutical company, a three-fold increase in the use of a particular drug followed, and there was a dramatic increase in the number of prescribers of this particular drug.<sup>33</sup> Another recent study showed that residents who attended sponsored presentations were eight times more likely to choose the sponsor's product, even when it was recommended as a second-line agent.<sup>34</sup>

**Recommendations:** Appropriate management of potential conflicts of interest is essential to the preservation of the integrity of medical education. The AMA policy, "Gifts to Physicians From Industry" addresses this issue,

The Council on Ethical and Judicial Affairs defines a legitimate “conference” or “meeting” as any activity, held at an appropriate location, where a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made. Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.<sup>2</sup>

The AAMC recently published a document entitled "Industry Funding of Medical Education."

This document provides specific guidance regarding funding of CME activities:

- 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. In addition, these programs should be offered only by ACCME-accredited providers according to ACCME standards.<sup>1</sup>
- 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.

The Pharmaceutical Researchers and Manufacturers of American recently enacted its Code on Interactions with Healthcare Professionals.<sup>25</sup> According to this document:

CME, also known as independent medical education, helps physicians and other medical professionals to obtain information and insights that can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. Such financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine.

Accordingly, a company should separate its CME grant-making functions from its sales and marketing departments. In addition, a company should develop objective criteria for making CME grant decisions to ensure that the program funded by the company is a bona fide educational program and that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment.

Since the giving of any subsidy directly to a health care professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the CME provider, which, in turn, can use the money to reduce the overall CME registration fee for all participants. The company should respect the independent judgment of the CME provider and should follow standards for commercial support established by the ACCME or other entity that may accredit the CME. When companies underwrite CME, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines. The company should not provide any advice or guidance to the CME

provider, even if asked by the provider, regarding the content or faculty for a particular CME program funded by the company.

Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty health care professionals attending CME, either directly to the individuals participating in the event or indirectly to the event's sponsor. Similarly, funding should not be offered to compensate for the time spent by health care professionals participating in the CME event.

A company should not provide meals directly at CME events, except that a CME provider at its own discretion may apply the financial support provided by a company for a CME event to provide meals for all participants.<sup>5</sup>

All three of these organizations agree that industry sponsorship of CME events may be done ethically and appropriately, provided the objective is to provide financial support of unbiased legitimate education. If the guidelines are being followed, GME programs may allow residents to attend these educational opportunities.

**13) Should GME programs allow the donation of medically relevant devices to the residents and/or program?**

**Benefits:** Donation of medical devices may provide an important service to patients and health care providers at no additional cost to the GME program. Residents may be exposed to important, cutting-edge devices that the program may have been unable to afford without the donation.

**Risks:** As with any other gift, even if not given to the individual but the program, there is a risk that it will establish the relationship whereby the recipient feels obliged to reciprocate. This may

occur consciously, or unconsciously. This has the potential to influence the judgment and actions of an individual. This can potentially create the perception among colleagues, students, trainees, and the public that practitioners are being “bought” or “bribed” by industry.<sup>35,36</sup>

**Recommendations:** None of the guidelines specifically address the issue of donating a device to a program. It is clear that industry should not donate gifts to individuals based on recommendations from the AAMC, AMA, ACP-ASIM, and SAEM. PhRMA does make the exception with regard to modestly costly (< \$100) educational items and patient education items, such as mannequins. Any donation of a device to a program should exclude residents from the entire process. Senior leadership within the residency should deal with the industry representative directly. It should be made clear that this will not change the previous relationship of the industry representative with the program, and that this will not entitle the representative to have any additional interaction with residents than was previously allowed. The device donation should be treated the same as an unrestricted educational grant. When this is done ethically and all potential conflicts of interest are disclosed, this can be managed appropriately.

**14) Is it appropriate for industry representatives to donate educational materials to residents within a GME program?**

**Benefits:** Educational materials can be very helpful to the overall education of resident. These materials can be expensive, especially for large and/or financially challenged residency programs. These materials may serve as important educational resources, particularly to medical students and residents who may otherwise not have access to those items. Having industry representatives donate these educational materials allows programs to spend precious funds on other needs of the program.

**Risks:** As noted earlier, donation of educational materials may be perceived as gift-giving and set up the reciprocity dynamic.

**Recommendations:** Industry may at times donate helpful educational materials, such as books, DVDs, journals, or subscriptions. The ethical and appropriate donation of educational materials may serve an important role in medical education. According to the PhRMA Code on Interactions with Healthcare Professionals,<sup>5</sup> it is appropriate for companies, where permitted by law, to offer items designed primarily for the education of patients or health care professionals if the items are not of substantial value (\$100 or less), and do not have value to health care professionals outside of his or her professional responsibilities. In general, gifts should be discouraged; however, there may be occasions when industry may be allowed to donate specialized educational materials to the program (through a faculty member) and not to individuals.

Items designed primarily for the education of patients or health care professionals should not be offered on more than an occasional basis, even if each individual item is appropriate.

**15) If residents train at an institution that does not allow interaction with industry representatives, how can program directors and faculty teach their trainees the facts about the effects and influence of industry on physicians' behavior in such a way that they can guide their program graduates in an ethical and professional manner, as well as provide them with a scaffold for thinking about their own interactions with industry and managing future interactions with industry representatives?**

**Benefits:** Programs that do not allow their residents to interact with industry representatives have the advantage of knowing precisely what educational material is being presented to them. They are free of any potential bias an industry representative may impose upon their residents.

**Risks:** If residents have no contact with industry representatives during their training, and do not receive explicit teaching about this subject, their knowledge about the issues related to industry support of education and industry interactions with physicians may be severely lacking. This knowledge deficit may leave them unprepared and confused about proper and ethical responses to industry in their future work environments. In addition, residents may not be exposed to new and cutting-edge drugs and devices if the faculty does not educate them on these items.

**Recommendations:** Lack of exposure may not properly prepare them for the industry interactions they may encounter following residency, and they may be “vulnerable” to the potential conflicts of interest that may arise. It is imperative that these programs develop curricula/teaching modules, that at the very least address the ACGME Principles to Guide the Relationship between GME and Industry.<sup>32</sup>

Goals: The goals of this teaching module are to:

- Provide program graduates with a contextual framework in which to consider the effects of industry relations on their future practice, and to make informed judgments about their own responses;
- Provide program graduates with a toolbox of potential resources and methods to manage industry interactions in their future practice;
- Provide trainees and graduates with background information and national guidelines about industry relations with physicians.

**16) Should GME programs accept industry-sponsored unrestricted educational grants?**

**Benefits:** Unrestricted educational grants differ from other sources of funding in that the sponsoring organization does not control either the content of the sponsored activity or how it is conducted. These grants are typically used to fund journal clubs, resident travel expenses to conferences, and resident research projects, allowing trainees to participate in educational activities they might otherwise have missed.

**Risks:** The knowledge that an educational activity is being sponsored by an unrestricted educational grant from a specific company may very well engender some sense of obligation from the individual receiving funding, no matter how far removed the company is from the sponsored activity. This sense of obligation might lead to subconscious future reciprocity.

**Recommendations:** Unrestricted educational grants have typically been allowed by previous guidelines.<sup>37</sup> In addition, only 6% of academic chairs view an unrestricted educational grant less than \$10,000 as detrimental.<sup>6</sup> However, the knowledge that a company has funded an educational activity may still engender an unconscious obligation on the part of the participant. With that in mind, newer hospital-specific guidelines have advocated for the creation of an “Educational Review Board” to review all funding in order to ensure that it is truly without restrictions.<sup>38</sup> Further, the funds will be centrally pooled in and distributed from a hospital-wide “President’s Fund” in an attempt to limit any connection between sponsor and recipient.

Unrestricted educational grants can be accepted but should be reviewed to ensure that they are truly without restrictions. In addition, these funds should be pooled and distributed by institutions themselves, removing any associations with specific sponsors.



**17) Should residents be encouraged to attend marketing dinners endorsed by their residency program?**

**Benefits:** Marketing dinners often involve nationally renowned academicians, giving residents the opportunity to network with prominent figures in emergency medicine. In addition, these dinners may introduce residents to new drugs and devices earlier than they would have otherwise.

**Risks:** More than any other activity, the industry-sponsored marketing dinner is a sales pitch. Although the speakers typically develop their own presentations, they are also typically trained by industry prior to becoming members of the industry speakers' bureau. In addition, industry often supplies slides to the speakers.<sup>5</sup> They run the risk of not being invited again if they do not present the sponsoring drug or device in a promising light.

**Recommendations:** While the AMA discourages physicians from participating in industry-sponsored marketing dinners or speakers' bureaus,<sup>2</sup> a significant percentage still choose to do so.<sup>39</sup> As discussed earlier, residency programs cannot ban attendance at these dinners frequently, especially after work, but should instead provide residents either the tools with which to critically appraise the literature and evidence presented to them, or have faculty members who possess these skills attend as well. However, residency programs that endorse specific marketing dinners are sending a mixed message and risk being seen as endorsing a likely biased presentation that may be aimed more at increasing sales than conveying medical knowledge.

In general, residency programs should not endorse marketing dinners, nor should they encourage their residents to attend such dinners.

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