

COMMENTARY

# Corporate-physician relationships: A need for education

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Knowledge is lacking among Otolaryngologist–Head and Neck Surgeons (ORL-HNS) regarding basic ethical situations in corporate-provider relationships. A pilot educational program demonstrates the need and potential for improvement by structured intervention. “At risk” areas specifically identified regard acceptable gifts, and payments for meetings and travel. Recommendations are made to educate otolaryngologists in standards for compliant behavior in corporate-physician relationships. Further work to formalize and tailor education to the needs of ORL-HNS is warranted, including continued education through the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF). A checklist is provided here as a first step in enabling more compliant behavior as surgeons engage in corporate relationships.

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Corporate-physician relationships are under close scrutiny today by federal regulatory authorities. Federal actions against health care fraud and abuse (HFA) have garnered more than \$2 billion in the first half of 2008.<sup>1</sup>

Existing guidelines concerning such behavior are readily available, through the American Medical Association (AMA), the American College of Physicians, and the US Office of Inspector General.<sup>2–5</sup> Despite availability of educational programs through professional organizations, health care institutions, and the government, many physicians remain unaware or uncertain of the implications that these recommendations hold for their individual practices. In addition, the illusion of invincibility attributed to surgeons may offer a false sense of security from ethical and legal scrutiny.

Flying in the face of regulatory flak is imprudent, if not outright foolhardy: personal, practice, institutional reputations, and, of course, patient safety may all be compromised by unethical and fraudulent behavior. Physicians are not immune from prosecution. The examples made of the or-

thopedic and psychiatric communities—physicians and industry—should be taken seriously as a legitimate sign of growing federal vigor in prosecuting HFA.<sup>6,7</sup>

The paucity of working knowledge of the recommended guidelines for ethical behavior was demonstrated recently through an anonymous audience response system during an instructional course at the Annual Meeting of the American Academy of Otolaryngology–Head and Neck Surgery, Chicago, Illinois, September 24, 2008.

Audience members were taught to use the system and then queried on their responses to questions based on the American Medical Association’s (AMA) Clarification on Gifts to Physicians from Industry.<sup>2</sup> Questions as we phrased them are listed in the appendix followed by the answers. Statistical review found that descriptive statistics only, rather than inferential statistics, should be applied owing to the small and variable sample sizes of the populations studied.

## RESULTS

### Data

Before intervention, low levels (0%-50%) of correct responses were seen for questions 1, 3, 8, and 9: acceptability of gifts, dinner, and travel expenses for speaker’s bureaus, and support of a golf tournament, respectively (Table 1).

Responses after intervention indicate a change in the percentage of correct responses for all questions, usually with better conformity to AMA recommendations, except for questions 5 and 7: meeting fees paid by a company and reimbursement for focus groups, respectively. A slight increase in the percentage of correct responses was seen for questions 1, 3, 8, and 9 (Table 1).

### Statistical Analysis

Descriptive statistics rather than inferential statistics were used to compare data owing to small sample size and vari-

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**Table 1**  
**Participants' responses before and after intervention**

Question	Correct response based on AMA guidelines	% Correct pre-intervention answers of (n)*	% Correct post-intervention answers of (n)*
1. May physicians accept Gram stain test kits, stethoscopes, or other diagnostic equipment?	Yes	0% (4)	25% (4)
2. May contributions to a professional society's general fund be accepted from industry?	Yes	80% (5)	100% (3)
3. May companies invite physicians to a dinner with a speaker at an expensive steak house?	No	17% (6)	25% (4)
4. May physicians, individually or through their practice group, accept electronic equipment, such as handheld devices or computers, intended to facilitate their ability to receive detailed information electronically?	No	83% (6)	100% (2)
5. May a company or its intermediary send physicians a check or voucher to offset the registration fee at a specific conference or a conference of the physician's choice?	No	100% (4)	75% (4)
6. If the company invites physicians to visit its facilities for review and comment on a product, to discuss their independent research projects, or to explore the potential for collaborative research, may the company pay travel expenses and an honorarium?	Yes	80% (5)	86% (7)
7. May a company compensate physicians for their time and travel expenses when they participate in focus groups?	Yes	100% (3)	80% (5)
8. May travel expenses be accepted by physicians who are being trained as speakers or faculty for educational conferences and meetings?	No	0% (2)	25% (4)
9. May companies donate funds to sponsor a professional society's charity golf tournament?	Yes	50% (4)	57% (7)

\*(n) = total respondents

ability in the size of response groups. We can use descriptive statistics to note only the areas of concern—specifically lack of knowledge as detailed above—and that answers for concerning areas changed only slightly after intervention. We cannot, however, attribute this change to the educational intervention, both because we did not have a validated tool for educational intervention for this pilot study, and because we cannot attribute the changes to more than just chance

given the inadequacy of the data set as required for inferential statistical analysis.

### Comment

Individual review of questions is summarized in the [Appendix](#), with each question followed by the recommendations of the AMA guidelines. Questions of particular concern relate to

those areas pursued aggressively at present for fraud and abuse, specifically gifts to physicians, dinner, travel expenses, and sponsorship of charity golf tournament (questions 1, 3, 8, and 9, respectively).

Participants' answers to these ethical questions did not always concur with those recommended in the AMA guidelines, but discussion and data revealed that participants in general were more reluctant to accept corporate contributions compared with the limits permitted by answers to the AMA sample questions.

Respondents' discomfort with accepting "small" gifts intended for patient care, which are permitted by the AMA's guidelines (question 1) as well as funds for a charity golf tournament (question 9) may indicate a wariness for potential conflicts of interest. The willingness however to dine at an expensive restaurant, which the AMA guidelines warn against (question 3) and accept fees as part of "speaker's bureau" (question 8), also a concerning behavior according to AMA, should raise concern regarding a propensity to engage in or permit behavior considered unethical by one standard for organized medicine.

Although the small and variable sample size limited our ability to perform statistical analysis, two generalizations can be made from individual responses and aggregate data: (1) there is a dearth of knowledge of basic issues and (2) educational intervention led in some cases to a few changes in answers. These findings may demonstrate promise for a means by which we can better educate and protect our members.

Variable responses may be due to many different factors, from reticence to commit to an answer while listening and learning, a lack of understanding of the question, or a poorly taught intervention. In the future, continuing medical education credits (CME) can be made contingent upon responses, with responses collected on paper or electronically as with advanced life support certification courses, for example.

We have a concern as leaders of our professional organization that our membership may not be prepared, or willing, to face a very real risk of prosecution for HFA. To this end, in addition to recommending a proactive collaborative and transparent compliance program,<sup>7</sup> we recommend self-regulation by the AAO-HNS, the largest professional organization representing ORL-HNS with over 12,000 physicians and allied health members. "Taking care of our own house" may involve:

1. Establishment of educational needs related to corporate-provider relations through a member survey.
2. Development of a validated educational interventional tool to assess the value of teaching in improving physician's understanding of corporate-provider compliance concerns.
  - a. Tests of best educational interventions (lectures, online tutorials, case studies, home study approach).
  - b. Provide members with educational opportunities with respect to corporate-physician relationships, preferably face to face to allow for interactive interchange with knowledgeable and experienced individuals. Case law,

as medical knowledge, changes rapidly, and is situation-specific, thereby limiting the educational impact of online non-interactive teaching. An online question-and-answer activity could be incorporated into a CME program to permit those unable to acquire knowledge through a live venue to achieve interactive dialogue, thereby enabling an exploration of medicolegal nuances so that they leave the session with a working knowledge of compliance.

3. Continued educational activities to promote discussion and acquisition of ethical language and behaviors.
4. Development of guidelines to redress the paucity of information as noted by the Accreditation Council for Continuing Medical Education's recent report on conflicts of interest regarding industry support of CME activities.<sup>8</sup>

- Oversight
  - Practice guidelines
  - Institutional policy
  - Professional organizations
    - Medical devices
    - Subspecialty guidelines
  - Federal and State laws
  - Medical licensing requirements
  - Office of Inspector General guidelines
  - Relevant ethical guidelines
- Patient benefit
  - Feedback loop
  - Termination of bad devices
  - Disclosures
- Provider protection
  - Idea
  - Profit
  - Reputation
  - Legal representation

**Figure 1** Compliance checklist.

5. Interim dissemination of a compliance checklist (Fig 1) by which members can frame their thoughts when engaging in corporate-provider relationships. Personal and organizational legal counsel should guide provider decision making, particularly before agreements of “nondisclosure” are signed. Specific details on the checklist may be found in a manuscript submitted for publication (Shah UK, Schmidt RJ, Hussain M, et al. Limiting Legal Risk in Physician-Industry Relationships: Regulatory Guidelines and Case Studies).

## CONCLUSION

Education to clarify recommendations for behavior regarding corporate-physician relationships is recommended on at least an annual basis to protect physicians from HFA prosecution. Interactive discussion is recommended to accommodate for appreciation of nuances of individual cases, as well as changing legal and regulatory environments. Online interactive discussion may be one vehicle if face-to-face meeting attendance is not possible. Professional medical organizations such as the AAO-HNS may provide this education annually as part of a proactive compliance program to better protect patients and the organization’s members.

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## APPENDIX

Questions asked, with paraphrased answers from AMA guidelines<sup>2</sup>

- Question 1: May physicians accept Gram stain test kits, stethoscopes, or other diagnostic equipment?
  - Diagnostic equipment primarily benefits the patient. Hence, such gifts are permissible as long as they are not of substantial value (to date, considered meaning less than \$100 US). In considering the value of the gift, the relevant measure is not the cost to the company of providing the gift. Rather, the relevant measure is the cost to the physician if the physician purchased the gift on the open market.
- Question 2: May contributions to a professional society’s general fund be accepted from industry?
  - The guidelines are designed to deal with gifts from industry, which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

- Question 3: May companies invite physicians to a dinner with a speaker at an expensive steak house?
  - Modest meals, at venues where one may ordinarily dine if not sponsored, are acceptable. Speaker content should be free of bias.
- Question 4: May physicians, individually or through their practice group, accept electronic equipment, such as handheld devices or computers, intended to facilitate their ability to receive detailed information electronically?
  - Although the guidelines recognize that gifts related to a physician's practice may be appropriate, they also make clear that these gifts must remain of minimal value. It is not appropriate for physicians to accept expensive hardware or software equipment even though one purpose only may pertain to industry-related activities of a modest value.
- Question 5: May a company or its intermediary send physicians a check or voucher to offset the registration fee at a specific conference or a conference of the physician's choice?
  - Physicians should not directly accept checks or certificates that would be used to offset registration fees. The gift of a reduced registration should be made across the board and through the accredited sponsor.
- Question 6: If the company invites physicians to visit its facilities for review and comment on a product, to discuss their independent research projects, or to explore the potential for collaborative research, may the company pay travel expenses and an honorarium?
  - If the physician is providing genuine services, reasonable compensation for time and travel expenses can be given. However, token advisory or consulting arrangements cannot be used to justify compensation.
- Question 7: May a company compensate physicians for their time and travel expenses when they participate in focus groups?
  - Yes. As long as the focus groups serve a genuine and exclusive research purpose and are not used for promotional purposes, physicians may be compensated for time and travel expenses. The number of physicians used in a particular focus group or in multiple focus groups should be an appropriate size to accomplish the research purpose, but no larger.
- Question 8: May travel expenses be accepted by physicians who are being trained as speakers or faculty for educational conferences and meetings?
  - In general, no. If a physician is presenting as an independent expert at a CME event, both the training and its reimbursement raise questions about independence. In addition, the training is a gift because the physician's role is generally more analogous to that of an attendee than a participant.
  - Speaker training sessions can be distinguished from meetings ("safe harbor") with leading researchers, sponsored by a company, designed primarily for an exchange of information about important developments or treatments, including the sponsor's own research, for which reimbursement for travel may be appropriate.
- Question 9: May companies donate funds to sponsor a professional society's charity golf tournament?
  - Yes. But it is sensible if physicians who play in the tournament make some contribution themselves to the event.