REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 2-A-07

Subject: Industry Representatives in Clinical Settings

Presented by: Robert M. Sade, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Richert E. Quinn, Jr., MD, Chair)

INTRODUCTION

Substitute Resolution 726, "Manufacturer's Representatives in Health Care Settings: Their Duties Relative to Patient Care," adopted at the 2005 Annual Meeting, called on the American Medical Association to study the obligations of physicians who allow representatives of device manufacturers to observe patient encounters or to provide technical support.

BACKGROUND

The United States Food and Drug Administration (FDA) defines the term medical devices broadly to include an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.[1]

Manufacturers of medical devices may facilitate their use through representatives (hereinafter "industry representatives") who can play an important role in patient safety by providing information about the proper use of the device or equipment as well as technical assistance to physicians.[2]

Much information is provided through technical brochures, electronic and live demonstrations, and training seminars occurring outside the clinical setting, so that physicians can learn to use new equipment and devices safely and effectively.

In more limited circumstances, industry representatives who possess appropriate qualifications and training sometimes provide assistance in the use of their companies' products within the clinical setting, at the request and direction of a physician.[2,3] In general, representatives are expected to work under the close supervision of the physician and to abide by any specific hospital policies pertaining to their presence and clinical activities.[2]

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Relevant Policy from the American College of Surgeons

Given the likelihood that industry representatives offer information regarding the use of device or equipment related to surgical operations, the American College of Surgeons (ACS) has developed a statement on industry representatives. The statement offers guidelines both to health care facilities and to members of the operative health care team. To facilities, the ACS recommends that all operating room settings should establish written policies on the presence of industry representatives, and cautions that these policies should comply with laws and regulations, as well as policies by credentialing/privileging committees. Moreover, these policies should address the introduction of an industry representative to the entire surgical team; approval by the surgeon; and informing the patient that an industry representative will be present and his or her role.

Additionally, the statement describes the role of the industry representative as advisory. Therefore, such representatives should not engage in the practice of surgery or medical decision making; should not be involved in direct patient contact; and should be monitored by the surgeon or a perioperative nurse responsible for the patient's care.

ETHICAL CONSIDERATIONS

Physicians may invite industry representatives into the clinical setting when doing so is expected to improve the safety and effectiveness of patient care. In such cases, physicians bear the responsibility of ensuring adherence to established standards of ethical conduct. Adequate measures, therefore, must be taken to protect patients' safety, autonomy, and privacy.

The Use of Medical Equipment and Devices

Physicians must study, apply, and advance scientific knowledge to benefit their patients (see *Principle V*). Accordingly, physicians should use new medical equipment and devices when they are medically indicated and when they will promote patients' health and welfare.

Physicians' decisions regarding the utilization of medical equipment and devices should not be influenced by the physician's own financial interests (see E-8.06, "Prescribing and Dispensing Drugs and Devises") and must be free of inappropriate external influences, such as incentives offered by manufacturers (see E-8.061, "Gifts to Physicians from Industry" and E-8.03, "Conflicts of Interest: Guidelines").

Providing Safe and Effective Patient Care

Physicians must promote patient safety by ensuring that they are capable of utilizing medical equipment and devices competently and effectively (see *Principle I* and Opinion E-8.121, "Ethical Responsibility to Prevent Error and Harm"). To accomplish this goal, they should seek adequate educational opportunities and consult with colleagues and other health professionals as necessary (see *Principle V*).

Moreover, physicians may allow appropriately trained representatives to act as consultants within the clinical setting (see E-3.03, "Allied Health Professionals"). Participation by industry representatives should not be a substitute for training of the physician that is necessary for safe and effective use of medical equipment and devices.[4]

When working with industry representatives, physicians remain ultimately responsible for coordinating care (see E-8.043, "Ethical Implications of Surgical Co-Management"). Accordingly, physicians should ensure that representatives understand their roles within the health care team, should adequately supervise the actions of representatives, and should never allow representatives to engage in the practice of medicine.[4]

Patient Autonomy and Disclosure of Material Information

Physicians must enable their patients to make informed treatment decisions (see E-10.01, "The Patient-Physician Relationship," and E-10.02, "Patient Responsibilities"). To do so, physicians must educate their patients about the purposes, benefits, and risks of medical devices, as well as acknowledging any clinical uncertainties and discussing available alternative interventions.

If industry representatives are present during patient-physician encounters, physicians or their designees must obtain the patient's approval (see E-5.0591, "Patient Privacy and Outside Observers to the Clinical Encounter"). Although this does not require a formal informed consent process, patients should be informed of the role the representative will have in facilitating the care of the patient . (see E-3.03).

The patient may accept or refuse the representative's participation. If the absence of the representative jeopardizes the patient's welfare, the physician must find someone else who is able to provide the necessary assistance. If no alternate is available and the patient persists in refusing the presence of the expert representative, the physician should offer an alternative treatment or cancel the procedure in the interest of patient safety.

Protecting Patient Privacy

Physicians are ethically obligated to maintain confidentiality and to protect patient privacy (*Principle IV)* in all of its forms, including the physical, informational, decisional, and associational aspects of the patient-physician encounter (see E-5.059, "Privacy in the Context of Health Care"). Thus, physicians must ensure that any third parties present within the clinical setting, including industry representatives, understand and are committed to medical standards of privacy and confidentiality.[5]

Quality Assurance

Physicians must promote patient safety and play a central role in identifying and preventing or reducing health care errors, as well as participating in the development of reporting mechanisms

(see E-8.121, “Ethical Responsibility to Study and Prevent Error and Harm”). To achieve quality outcomes, physicians should foster effective communication to promote patient safety. Physicians should include industry representatives in efforts to ensure patient safety, encouraging them to provide advice on appropriate use of the devices or equipment.

CONCLUSION

Physicians may invite industry representatives into the clinical setting when doing so promotes the well-being of their patients. Physicians who facilitate access by representatives to the patient-physician encounter assume the responsibility of ensuring that the representatives adhere to medical ethical standards.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

Manufacturers of medical devices may facilitate their use through industry representatives who can play an important role in patient safety and quality of care by providing information about the proper use of the device or equipment as well as technical assistance to physicians.

Because of their obligation to protect their patients, physicians must strive to prevent industry representatives from breaching patient privacy and confidentiality, and seek to verify that they are properly credentialed and do not exceed the bounds of their training. Physicians may fulfill these obligations by satisfying themselves that the facility has suitable mechanisms in place to accomplish these functions.

Physicians or their designees must disclose to patients the anticipated presence and roles of industry representatives during clinical encounters, and obtain patients' approval. This requires neither disclosure of the representative's specific identity nor a formal informed consent process.

(New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

References are available from the AMA Ethics Group on request.

REFERENCES

[1] US Food and Drug Administration. Is the Product a Medical Device? Available at: http://www.fda.gov/cdrh/devadvice/312.html (Accessed 3-20-06).
[2] Hayes J, Juknavorian R, Maloney J. NAPSE Policy Statement: The role(s) of the industry employed allied professional. *Journal of Pacing and Clinical Electrophysiology*. 2001;24(3) 398-99.
[3] Advanced Medical Technology Association. Code of Ethics on Interactions with Health Care Professionals. Available at: http://www.advamed.org/publicdocs/coe_with_faqs_4-15-05.pdf (Accessed 2-8-06).
[4] American College of Surgeons. *ACS Statement on Health Care Industry Representatives in the Operating Roo*m. Available at: http://www.facs.org/fellows_info/statements/st-33.html (Accessed 2-20-06).
[5] Advanced Medical Technology Association. *AdvaMed Policy Statement on Confidentiality of Patient Information*. Available at: http://www.advamed.org/publicdocs/confidentiality.pdf (Accessed 2-16-06).