

ETHICAL PRACTICE GUIDELINES ON FINANCIAL INCENTIVES FROM HEARING INSTRUMENT MANUFACTURERS

DEVELOPED BY THE AMERICAN ACADEMY OF AUDIOLOGY AND THE ACADEMY OF DISPENSING AUDIOLOGISTS

FOR MEMBER REVIEW & COMMENT

American Academy of Audiology Fellows are invited to submit comments and opinions on the following guidelines. Members should submit comments to The Academy Board of Directors and The Ethical Practices Committee at ethicalpracticecomments@audiology.org prior to July 1, 2003.

The guidelines that follow are the culmination of a two-year effort that has involved two separate Task Forces of the American Academy of Audiology (AAA) and active collaboration with the Academy of Dispensing Audiologists (ADA). The Boards of Directors of both associations approved the guidelines. During his presidency, David Fabry put together the Ethics in Audiology Presidential Task Force. The Task Force members were Lucille Beck, David Hawkins, Fred Bess, Patti McCarthy, Gail Gudmundsen, Dennis Van Vliet and was chaired by Brian Walden. David Fabry, Laura Fleming Doyle and I served as *ex officio* members. As the result of recommendations made by this Task Force, the Academy Board appointed Teri Hamill as chair of the Ethical Practice Board, and charged her with appointing a Task Force to develop guidelines on Manufacturer/Audiologist Relationships. The Task Force members were Debra Abel, Fred Fritz, Patricia Gans, Stephen Gonzenbach, David Hawkins, Cathy Henderson Jones, Marilyn Larkin, Louis Siemenski, Thomas Tedeschi with Dr. Hamill serving as Chair. David Fabry, Brad Stach and I served as *ex officio*, and Cindy Ellison and Craig Johnson represented the Academy of Dispensing Audiologists.

For both the ADA and AAA, the work of Task Force members did not entail changes in the existing Codes of Ethics of each association, but rather a renewed commitment to ensuring that members have a clear understanding of the importance of avoiding conflicts of interest in our profession. Three questions were of critical importance in the deliberations of the Task Forces: 1) what does it mean to be a professional; 2) what is a conflict of interest, and 3) why is it particularly important for our associations to examine these issues at this particular time in our profession's history?

What sets professions apart from other occupations? Among the most salient identifiers of a "profession" is that its practitioners are assumed to put their patient's interests ahead of their own financial interests. Because of this assumption, society permits professionals a

high degree of self-government and autonomy and codes of ethics are a primary means of self-government. Patients who seek the advice and services of audiologists must have the assurance that recommendations made for services or products are made solely on behalf of the patients' best interests. If the behavior of audiologists routinely deviates, or appears to deviate, from the rules of practice defined by our Code of Ethics, our profession would be misrepresented.

Professions of all kinds have long described conflicts of interest as an inability to make a professional judgement as someone might who was completely uninvolved. Conflicts of interest are sometimes referred to as "perverse incentives"—incentives that cause, or can appear to cause, a loss of independent judgement, a loss of impartiality or a loss of objectivity. Attorney Kevin McMunigal¹ has suggested that professions can avoid confusion about conflicts of interest by distinguishing between "harm rules" and "risk rules" and uses a basketball example to illustrate the difference. The National Basketball Association does not want its players to be involved in brawls. One way to stop this behavior would be to suspend or fine any player involved in fighting—a harm rule. Another way would be to suspend or fine any player leaving the bench when a fight occurs because this is behavior that increases the chances of a larger brawl—a risk rule. McMunigal states that "a harm rule is about sin; a risk rule is about temptation." Similarly, our efforts were centered on guidelines to reduce the "risk" of conflicts of interest in the complex relationships between audiologists and hearing aid manufacturers. At a time in our professional history where we are actively pursuing important initiatives toward direct access to our services in both government and privately funded health insurance programs, it is particularly critical that we avoid any possibility of misrepresentation.

¹ McMunigal, Kevin. "Distinguishing Risk from Harm in Conflict of Interest," *Perspectives on the Professions*, Center for the Study of Ethics in the Professions (CSEP), Illinois Institute of Technology, Vol. 17, No. 1, Fall (1997).

GENERAL GUIDELINES

The following general guidelines have been accepted by the Board of Directors of the American Academy of Audiology (AAA) and the Academy of Dispensing Audiologists (ADA):

1. When potential for conflict of interest exists, the interests of the patient must come before those of the audiologist.

Any gifts accepted by the audiologist should primarily benefit the patient and should not be of substantial value. Gifts of minimal value (\$100 or less) related to the audiologist's work (pens, earlights, notepads, etc.) are acceptable. Incentives or rewards based upon product purchases must not be accepted. This would include cash,

gifts, incentive trips, merchandise, equipment, or credit towards such items. No "strings" should be attached to any accepted gift.

Audiologists should not participate in any industry-sponsored social function that may appear to bias professional judgment or practice. This would include accepting invitations to private convention parties, golf outings or accepting such items as theater tickets. Meals and social functions that are part of a legitimate educational program are acceptable. When social events occur in conjunction with educational meetings, the educational component must be the primary objective with the meal/social function ancillary to it.

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2. Commercial interest in any product or service recommended must be disclosed to the patient.

This would include owning stock or serving as a paid consultant and then dispensing that product to a patient.

3. Travel expenses, registration fees, or compensation for time to attend meetings, conferences or seminars should not be accepted directly or indirectly from a manufacturer.

Trips sponsored by a manufacturer that are solely educational may be accepted, provided the cost of the trip is modest and acceptance of the trip does not reward the audiologist for past sales or commit the audiologist to future purchases.

Faculty at meetings and consultants who provide service may receive reasonable compensation honoraria, and reimbursement of travel, lodging and meal expenses.

4. Free equipment or discounts for equipment, institutional support, or any form of remuneration from a vendor for research purposes should be fully disclosed and the results of research must be accurately reported.

All materials, presentations, or articles produced as a result of the investigation should also carry a disclosure of the funding source. Investigators should structure research agreements with industry to insure that the results are represented accurately, and presentation of findings is objective.

FREQUENTLY ASKED QUESTIONS

Q. Why are AAA and ADA reviewing gift giving from manufacturers?

A. Gift giving from the hearing health care industry to audiologists has been a customary practice. Gifts serve two functions. First, they remind audiologists of the name of the product made by that company. Second, they help a company establish a relationship with the audiologist. However, if the decisions made by the professional are, or appear to be, influenced by an incentive or reward, or can be viewed as not being made objectively, then a conflict of interest may be present. The professional's belief that he or she is not personally influenced is not sufficient to avoid the appearance of a conflict of interest.

Our organizations encourage manufacturer/audiologist interactions that serve to improve patient care. However, it is important that gifts do not have the potential to impact professional judgment.

Q. Why would audiologists want to adhere to these guidelines?

A. Audiologists must be committed to the principles of honesty, integrity, and fairness.

The principle of putting patients' interests first is the basis of all healthcare professions. Adhering to these guidelines reflects positively on our profession. All healthcare profession licensure acts set

limits on professional behavior. In return for a license, professionals are obliged to adhere to certain standards of conduct and have the obligation to self-regulate. Additionally, adhering to a uniform code of ethical conduct may prevent the audiologist from unintentionally violating federal and state regulations.

Q. If an audiologist accepts gifts, what are the potential legal consequences?

A. Acceptance of gifts may not only be construed as constituting a conflict of interest; it may also be illegal. Federal laws make it a criminal act for an audiologist who provides services to Medicare, TRICARE, Medicaid and VA patients to solicit or receive "any remuneration (including any...rebate) directly or indirectly, overtly or covertly, in case or in kind...in return for purchasing...or ordering any goods or services..." Medicare already indirectly covers hearing aids through some private Medicare HMO plans. The Office of the Inspector General has recently issued guidelines for gift-giving activities for the pharmaceutical industry and physicians that appear directly analogous to the issues covered for audiologists in this guideline.

Q. Are incentive trips, vacation packages, gift certificates, cruises, and credits toward equipment purchases or cash received from manufacturers allowed?

A. No. The acceptance of such gifts,

whether related to previous purchases or future purchases, raises the question of whether the audiologist is, in fact, holding the patient's interests paramount. There can be no link between dispensing or referral patterns and gifts.

Q. What is the difference between acceptance of trips, lease arrangements, gifts, or receiving a larger discount level?

A. Establishing any type of savings plan with a specific manufacturer creates the appearance of a conflict of interest. Discount programs, however, are generally protected by the law if they have the potential for benefiting consumers. Discount programs are considered to present ethical issues only if they involve commitments by the audiologist that compromise professional judgment.

Q. Can an audiologist accept a trip to a manufacturing facility for the purpose of training?

A. Obviously, there are times when it is more economical and/or a better educational experience can be provided when audiologists are trained together regionally or at the manufacturer's facility. While it is preferable that audiologists pay their own travel expenses, there are circumstances where it is appropriate to accept tickets and/or hotel accommodations:

- The travel expenses should only be those strictly necessary.

FOR MEMBER REVIEW & COMMENT



Cindy Ellison, Angela Loavenbruck, Teri Hamill and Craig Johnson present at the Ethics Session, Convention 2003 in San Antonio, TX.

- The conference or training must be the reason for the trip.
- Participation must not be tied to any commitment to manufacturers.
- The expense for a spouse or other travel companion may not be compensated by the manufacturer.

Q. Can an audiologist accept a lunch/dinner invitation from manufacturer's representative in order to learn about a new product?

A. Yes, modest business related meals are acceptable.

Q. What are the ethical considerations regarding attendance at sponsored social events at conventions or training seminars?

A. The following criteria should be considered before attending such events:

- The sponsorship of the event should be disclosed to, and open to, all registrants.
- The event should facilitate discussion among attendees.
- The educational component of the conference should account for a substantial amount of the total time spent at the convention.

Q. May an audiologist or a corporation obtain a loan from a manufacturer in order to purchase equipment and then repay a portion of the loan with every hearing aid purchased?

A. Audiologists are encouraged to obtain financing through recognized lending institutions or the equipment manufacturer

to avoid potential conflict of interest. Repayment should include only repayment of the debt plus appropriate interest fees but with no additional considerations or obligations on the part of either party.

Q. May an audiologist "co-op" advertising costs with a manufacturer?

A. If the manufacturer wishes to share the cost of an advertisement that features both the manufacturer's name and the audiologist's name, this is acceptable as long as there are no strings attached.

Q. Is it acceptable for a manufacturer's representative to assist in seeing patients at an 'open house' at the audiologists' clinical facility?

A. Open houses are usually product or manufacturer specific with a manufacturer's representative in attendance. The consumer should be very much aware that the presentation would be focused on the purchase of hearing instruments from the featured manufacturer. However, the audiologist still has the responsibility to utilize the most appropriate instruments.

The audiologist should consider the legal and ethical ramifications involved if a non-audiologist participates in the open house.

Q. Is there a potential conflict of interest if an audiologist joins a network or buying group?

A. Businesses and organizations are free to negotiate prices on products either directly with the manufacturer or by using the purchasing power of a buying group.

Q. If an audiologist is hired by a corporation that provides hearing aids or other related devices and is offered stock options, is there a cause for concern regarding conflict of interest?

A. If the stock is in the corporation the audiologist works for, there is no conflict of interest.

Q. Are there conflicts of interest implications for researchers?

A. One of the researcher's responsibilities is to fully disclose the funding of the research, whether it is in the form of direct grants, equipment grants or other forms of compensation such as a consultantship with a sponsor. This allows the consumer of the research to evaluate the potential for conflicts of interest. Additionally, researchers are ethically responsible for ensuring the rigor of the scientific design of the experiment and the accuracy and integrity of the interpretation.

Q. Will a similar document on ethical practice guidelines be written for audiologists involved in research and academia?

A. Yes. A set of guidelines is in development to address conflicts of interest in research.

Q. How will the ethical guidelines be enforced?

A. Given the increased enforcement of anti-kickback, fraud, and abuse laws, audiologists should stay abreast of changes in regulatory landscape, and establish procedures and protocols that will protect them in their employment settings and practices. These guidelines are not meant to address all possible interactions but are an effort to assist the audiologist in cases of ethical dilemmas. At this point, education of our members is our focus. However, any profession that fails to monitor misconduct and enforce its Code of Ethics invites the loss of autonomy and the loss of trust in the profession. When such activities exist, the profession must have appropriate disciplinary procedures in place. 