

**AMERICAN ACADEMY OF AUDIOLOGY
ETHICAL PRACTICE GUIDELINE FOR RELATIONSHIPS WITH INDUSTRY FOR
AUDIOLOGISTS PROVIDING CLINICAL CARE**

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Preface

The Code of Ethics of the American Academy of Audiology (AAA) is a set of principles intended to specify “professional standards that allow for the proper discharge of audiologists’ responsibilities to those served, and that protect the integrity of the profession” (American Academy of Audiology, 2006, p. xv). Membership in the Academy requires that the member agrees to provide services in a manner that is consistent with the principles of the Code of Ethics. This requirement is important to establish the Academy as a professional society dedicated to the highest standards of patient care, and positions audiologists among health care professionals who subscribe to such standards. Apart from raising the standard of audiology practice, self-governed ethical behavior may obviate costly external scrutiny and regulation.

Principle 4 Rule 4c of the Code of Ethics provides that “Individuals shall not participate in activities that constitute a conflict of professional interest (COI)” (American Academy of Audiology, 2006, p. xvi). In 2003, the American Academy of Audiology and the Academy of Dispensing Audiologists jointly adopted *Ethical Practice Guidelines on Financial Incentives from Hearing Instrument Manufacturers* to define acceptable relationships with industry and specify those relationships that violate Rule 4c. Since then, public scrutiny regarding professional COIs has increased for healthcare and other professions. Peer-reviewed published studies have revealed influences on human behavior resulting from the exchange of gifts (“gift effect”). This body of evidence has fostered a sweeping trend toward more restrictive policies and more transparency in relationships between healthcare professionals and industry. The United States legislature has increasingly become concerned about this issue and has inserted into legislation monitoring and reporting requirements for a variety of professions including but not limited to medicine (H.R. 3590, section 6002; Patient Protection and Affordable Care Act of 2009) and higher education (H.R.4137; Higher Education Opportunity Act). In response, many professional organizations have clarified their approach to the management of COIs. The need to update the guidelines developed in 2003 for the American Academy of Audiology became apparent from this greater awareness that activities previously thought to be benign may actually not be in the best interests of patients or may be perceived negatively by the public.

In general, guidelines are provided by the Academy to assist the professional with interpreting and applying the principles of the Code of Ethics. A guideline is a set of recommended actions or procedures based on available scientific evidence, best practice, and/or expert opinion that has been developed to guide member decision-making. Such guidelines may serve as an ethics compass for the profession that is consistent with current legislative policies and ethical guidelines of related professional organizations.

Although the updated guidelines presented in this document focus on issues surrounding conflicts of interest, it is recognized that while all gifts have the ability to influence decision-making, other factors also affect clinical decisions, including product pricing, durability, features, customer service, patient needs, etc. The practitioner weighs many variables, and thus may feel immune to the “gift effect.” The following guidelines are provided to help the practitioner keep the “gift effect” in mind while making clinical decisions. In combination with evidence-based design of products and evidence-based practice in audiology, such guidelines substantiate the commitment of the members of the American Academy of Audiology to uphold the highest values in patient care in the practice of audiology.

The guidelines provided in this document supersede the previous American Academy of Audiology document *Ethical Practice Guidelines on Financial Incentives from Hearing Instrument Manufacturers (2003)* and provide guidance for relationships between audiologists and industry. The definition of industry in this guideline is expanded to be inclusive of relationships audiologists have with all hearing care manufacturers and vendors, rather than just those with hearing aid manufacturers. Thus, “industry” as referred to in this document includes but is not limited to publishers, hearing aid manufacturers, equipment manufacturers, cochlear implant manufacturers, ear mold labs, hearing aid repair labs, battery and other supply distributors, assistive device distributors third-party administrators, business management organizations, and buying groups. There are many types of buying groups offering a variety of services/options to the professional. Full discussion of such relationships is beyond the scope of this guideline. The member should consider state, federal and ethical guidelines when evaluating a buying group relationship. Each ethical guideline presented defines areas of professional conduct that are inconsistent with Rule 4c of the AAA Code of Ethics. Although these represent the Academy’s guideline, Academy members should be aware that there may be additional guidelines in individual practice settings; therefore, audiologists should insure their behavior is also in compliance with requirements of the facility at which they work as well as state and federal regulations.

The scope of the guidelines in this document addresses the relationships between industry and providers of patient care. However, another important special consideration for some audiologists is management of potential conflicts of interest in research relationships with industry. Research and development is crucial for continued advancement in diagnosis and treatment of patients with hearing and/or balance disorders. Productive research relationships between industry and audiologists positively impact the knowledge base and innovation in clinical care. Relationships between industry and audiologists involved in research can be very complex and take multiple forms. Although this is a very important topic, discussion of management of conflicts of interest in research relationships is outside the scope of the guidelines presented here. For guidance on ethical practices in research, please see “Guidelines for Ethical Practice in Research for Audiologists” (Sininger et al., 2003).

Conflict of Interest

A conflict of interest or appearance of a conflict of interest exists when a person or entity in a position of trust has a financial or personal interest that could unduly influence, or could appear to influence, decisions related to a primary interest such as patient care, student education or validity of research. Ideally, COI is best managed by avoiding the situation that produces the conflict. When avoidance is not possible in a clinical care situation, the conflict must be managed by placing priority on the best interest of the patient, such as through evidence-based practice and transparent documentation of services and reason for services. Failure to avoid or manage a COI is a violation of Rule 4c of the Code of Ethics and in some cases may be illegal.

COI may stem from financial incentives or other benefits, including nonmonetary, offered by industry and may take a variety of forms. This document provides guidance for avoiding and managing conflicts that may result from a relationship between an audiologist and industry.

GUIDELINES

1. GIFTS

Ethical Guideline #1.

- a. *Acceptance of gifts of any value by a member of the American Academy of Audiology from any company that manufactures or supplies products that he or she professionally uses or recommends, may compromise, or give the appearance of compromising, the audiologist's ability to make ethical decisions, and should be avoided.*
- b. *A provision for reasonable and necessary meals and travel associated with legitimate product educational/training experiences are covered in Guideline 3.*

Gifts represent a conflict of interest because of the real or apparent influence they may have on audiologists' clinical decisions. Considerable evidence from social sciences research suggests that gifts of even negligible value can influence the behavior of recipients in ways the recipient does not realize (Katz & Merz, 2003). Individual behavior is powerfully impacted by the impulse to reciprocate for even small gifts, and those receiving gifts often lose objectivity (Brennan et al., 2006). Furthermore, a systematic review of gift-giving literature in medicine revealed that accepting gifts from manufacturers had a negative impact on clinical care in an overwhelming majority of cases (Wazana, 2000).

For the purpose of this guideline, "gifts" are defined as anything of value given to individuals by industry for personal use and/or personal profit. These "gifts" would include (but are not limited to) material goods, personal entertainment such as tickets to a play or private social event, cash, non-merit based restricted scholarships provided to recipients selected by industry, and personal rebates such as gift certificates for large

volume purchases. General use business items such as laptops, otoscopes, and general continuing education would be considered gifts and should not be accepted. Uniquely compatible items provided for patient care and education, such as proprietary software, demonstration units, cables, and software needed strictly to dispense a specific product would not be considered a “gift”. Meals and travel deemed as rewards are also considered gifts; however, provisions for necessary and reasonable meals and travel associated with legitimate and necessary product educational/training experiences are not considered gifts, thus are not prohibited, and are covered in Guideline 3.

A special problem is the *Quid Pro Quo* arrangement, which is receiving or accepting rewards in exchange for a purchase, referral, or recommendation. In audiology, this presents in numerous ways including, but not limited to gifts, trips, tuition reimbursement, business support/development programs, advertising and other marketing efforts, and gifts that are tied directly or indirectly to purchases of hearing and balance products. *Quid Pro Quo* arrangements are unethical and prohibited by the Federal Anti-Kickback Statute (AKS). AKS prohibits “any person to knowingly and willfully solicit or receive any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, leasing or ordering (or recommending the purchase, lease or order) of any item or service reimbursable in whole or in part under a federal health care program (except the Federal Employee Health Benefit Program)” (Hahn et al., 2005, p. 34). While gifts, trips and other forms of compensation are not allowed under AKS, one of the Safe Harbor provisions does allow discounts to healthcare professionals. For more information on the Anti-kickback statute and regulatory safe harbors, see <http://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm>.

2. COMMERCIAL INTEREST

Ethical Guideline #2.

- a. *A member of the American Academy of Audiology should avoid ownership interests in a company that supplies or manufactures products that he or she professionally uses or recommends.*
- b. *When this guideline cannot be followed, such as when the member is an employee of the company and receives equity in the company as part of their compensation (e.g., a sales representative to a manufacturer), it is unethical for the member not to provide patients with written and oral disclosure of the conflict of interest.*
- c. *An exception to this guideline is member ownership of shares in the company that are part of a managed portfolio (e.g., a mutual fund).*

An audiologist has a conflict of interest when he or she, or a member of his/her immediate family, has ownership in, or owns stock in, a company that an audiologist

uses in professional business. The commercial interest may influence or appear to influence the audiologist's professional judgment. The conflict arises from the real or perceived increase in value of the stock or ownership that may result from the audiologist's professional use or recommendation of that company's products. In some cases, this type of conflict can be managed by disclosing the commercial interest to the patient. However, recent research indicates that disclosure does not eliminate the behavior or potential negative impact of the conflict of interest (Dana & Loewenstein, 2003; Kassirer, 2004; Surowiecki, 2002).

3. INDUSTRY-SPONSORED EDUCATION

Ethical Guideline #3.

- a. *Members should not attend or participate in educational events where the member or participants are rewarded for conducting business with a specific manufacturer and/or where a Quid Pro Quo relationship exists between the attendee and that manufacturer. Such rewards to be avoided may include but are not limited to discounts on device purchases for attending an event, entertainment, travel to exotic or resort facilities for educational events, and prizes for attendance.*
- b. *Attendees should not accept anything that is beyond reasonable travel expenses, meals, and lodging. Members are encouraged to pay for their own education-related expenses.*
- c. *Members participating as presenters in educational activities should provide participants with a full disclosure of the relationship between themselves and the industry sponsor, which shall include a general description of the relationship and the nature of the remuneration for their participation in the educational event (honorarium, travel expenses, gifts, stock options, etc.). Members should disclose to the audience if any information they are presenting is provided by the manufacturer and not based on the member's own clinical or research experience.*
- d. *It is unethical for a member to knowingly present information that is not accurate and complete.*
- e. *Members who receive remuneration or travel compensation for presenting at company-sponsored educational events in the last 12 months¹ and who utilize that company's products should disclose the relationship to their patients in writing.*

¹ Some states stipulate that non-compete clauses must be limited in scope and time line. 12 months is a commonly used time line used for non-compete clauses and was thus adopted for the purposes of the guideline.

Life-long learning is an important component of being a competent healthcare provider. Industry support is frequently provided for both general continuing education events and product specific training. Careful consideration must be given to the structure of industry involvement in such events. Educational events conducted by industry at industry expense may create conflicts of interest for members who attend the event and for members who teach at the event. A conflict exists when members receive payment, travel expenses, lodging, and meals in association with a company-sponsored event if he or she professionally uses or recommends products sold by the company. In addition, a conflict may exist between the manufacturer and the participant when participants receive incentives to sell products manufactured or sold by the sponsor. Audiologists must make a distinction between necessary and cost-effective educational offerings and those that contain incentives that are not necessary or required for product training, and should not participate in the latter. Receiving travel, lodging and/or meals that is not necessary because training could be obtained without such gifts is covered under Guideline #1. Although necessary and reasonable arrangements for training are acceptable, members are encouraged to pay for their own training-related expenses.

When members are hired by industry to teach material that is related to equipment/products manufactured or supplied by the sponsor of the educational program, a real or apparent conflict of interest may occur in two contexts. If the audiologist uses the product clinically, the objectivity of the audiologist's recommendations may be questioned. Additionally, objectivity in the presentation of the educational material may be questioned because of the financial relationship. Audiologists attending the educational event must be made aware of the potential conflict of interest so that they can evaluate the objectivity of the presenter, and patients of the presenter should similarly be made aware of the dual relationship. When considering an offer from industry to teach, the member may want to consider the following guiding questions offered by the U.S. Office of the Inspector General (http://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf p. 25):

1. Does the company *really* need *my* particular expertise or input?
2. Does the amount of money the company is offering seem fair and appropriate for the educational value I will add to the presentation?
3. Is it possible that the company is paying me for my loyalty so that I will prescribe its drugs or use its devices?
4. Does the sponsor prepare a slide deck and speaker notes, or am I free to set the content of the lecture?

In audiology, industry supports a wide range of educational events which benefit audiologists, students and their present or future patients. Nonetheless, the conflict created by the relationship between the company and faculty should be managed by full disclosure to create transparency for the audience attending the event.

4. CONSULTING

Ethical Guideline #4.

- a. *It is considered unethical for a member to serve as a paid consultant when the consulting services are not specified in a contract and/or if the compensation is not based on the fair market value of the work provided.*
- b. *If an audiologist professionally uses or recommends a product manufactured by a company while serving as a paid consultant or on a clinical advisory board for that company within the past 12-months, the audiologist should disclose the consulting relationship to the patient in writing.*

Consulting relationships between industry and audiologists have been important in influencing product development to achieve better clinical outcomes. When a member is a paid consultant for a company whose products the audiologist professionally uses or recommends, a real or apparent conflict of interest exists, and in certain circumstances could violate the Federal Anti-kickback Statute (AKS).

If the company pays the audiologist above-market rates for the work performed, then there is a conflict of interest; the remuneration can be viewed as a reward for the relationship with the company. When a consulting relationship exists, it should be managed in a manner that informs and protects patients. To avoid a violation of AKS, work performed under such a relationship should be specified in a written agreement and compensation should be consistent with the fair market value of the work performed. The consulting relationship should be disclosed to patients for whom products manufactured or distributed by the contractor are professionally recommended. The U.S. Office of the Inspector General offers the following guiding questions when considering a consulting relationship with industry

(http://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf p. 22):

1. Does the company *really* need *my* particular expertise or input?
2. Does the amount of money the company is offering seem fair, appropriate, and commercially reasonable for what it is asking me to do?
3. Is it possible that the company is paying me for my loyalty so that I will prescribe its drugs or use its devices?

CONCLUDING COMMENTS

In the general marketplace, sales and profits are accepted as the natural result of a free-market society and buyers are expected to look out for themselves (*caveat emptor*). But there is a different set of expectations in healthcare. Healthcare professionals are expected to hold paramount the interests of patients before any profit motive. There are a variety of professional and legal sanctions that enforce that expectation. A heightened awareness of real and perceived conflicts of interest that may result from an audiologist's relations with industry has created the impetus for these revised guidelines. Acceptance of and adherence to these guidelines will benefit patients and, thereby, benefit the profession of audiology.

These guidelines are based on current understanding and experience regarding relations between audiologists and industry. Obviously, not all pitfalls potentially resulting in a conflict of interest can be detailed here; therefore, professional judgment and prudence should be exercised in all circumstances. As professionals, audiologists should endeavor to avoid real, apparent, or potential conflicts of interest whether or not they are discussed in this document. In contemplating their relationships with industry, the audiologist may want to consider some guiding questions:

1. *How might my patients feel about my relationship with industry?*
2. *How might patients view my receiving gifts from industry?*
3. *How would independent colleagues view my association with industry?*
4. *Would I be willing to have the details of my involvement with industry made public?*
5. *Could my relationship with industry be viewed as one which may influence my professional judgment in patient care?*

Partnerships between audiologists and industry in the interest of enhancing patient care have and will continue to benefit our profession and our patients. The American Academy of Audiology encourages our industry partners to join us in ensuring that our clinical practices follow ethical guidelines and help us provide the best possible care for our patients.

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