Neither academic programs nor industry are bound by the same ethical framework as members of a professional organization. The purpose of this document is to propose guidelines that could be voluntarily adopted by academic programs and industry. **This article is an opinion editorial developed by the authors listed and has not been endorsed by any organization**.

BY IAN M. WINDMILL, BARRY A. FREEMAN, JAMES JERGER, AND JACK M. SCOTT

It is imperative that both audiology programs and industry work together to identify and manage potential conflicts of interest to ensure that the relationship remains both successful and ethical, and thereby assures that the welfare of the consumer (including students and clinical patients) is paramount in their interactions. he American Association of Medical Colleges (AAMC, 2008) recently published a report titled Industry Funding of Medical Education. The AAMC

> recognized the necessity of an effective relationship between medical schools and industry, and produced a set of guidelines that could be used by member schools to reduce potential conflicts of interest and to establish rules that define appropriate interaction

with industry. The report of the AAMC focuses on issues between clinical faculty and pharmaceutical companies but also includes sections on relationships with manufacturers of medical devices.

Members of professional organizations are subject to codes of ethics and ethical practice guidelines. While individual faculty or employees of industry may be members of a professional organization, and therefore subject to these codes of ethics, neither academic programs nor industry are "members," and thus are not similarly bound to the same ethical framework. Therefore, academic programs and industry must voluntarily adopt guidelines that assure appropriate interaction. In addition, those guidelines should assure that those individual faculty or employees of industry who are members of professional organizations are not placed in positions whereby their individual ethical standing is compromised.

The AAMC report served as a template for the development of these guidelines for the relationship between academic programs in audiology and industry. More importantly, these guidelines were developed with input and consensus of individuals from both academia and industry. The purpose of these guidelines is to provide a framework by which academic programs and industry can continue to work together to advance the diagnosis and treatment of hearing and balance disorders, to provide educational support for future generations of audiologists, and to assure public confidence in the relationship.

Introduction

Over the past 20 years, the relationship between universities and various forms of commercial enterprises has grown substantially. While there are the more obvious partnerships for sponsorship of football stadiums and basketball arenas, there are many more partnerships that have evolved as the direct result of partnering with industry for teaching and research endeavors. In fact, universities are actively engaging business ventures and partnerships both for expanded funding and for increasing academic standing.

Therefore, it is not surprising that partnerships have also evolved between academic programs in audiology and industry. Many of the product development advancements and clinical enhancements realized over the past 40 years would not have been possible without a close working relationship between industry and universities. The emphasis on development of evidence-based clinical practice and research necessarily encompasses a relationship between engineers, scientists, clinicians, and consumers. Those industries that serve the hearing and balance areas are recognized leaders in the development of both new techniques and technologies and partner with universities in product development and validation. Restrictions on these relationships can seriously hamper technological advancements.

In addition, industry often provides economic and other resources for training programs and research within audiology programs. In a broad sense, this partnership is fundamentally necessary to ensure continued advances in the prevention, diagnosis, and treatment of hearing and balance disorders. Examples of some of the health benefits derived from the close working relationships between academe and industry include advances in amplification, cochlear implants, and electrophysiologic test procedures.

The Public Trust

Audiology programs have increasingly sought industry support for many aspects of their core educational missions. While support is most commonly sought for research activities, financial or in-kind support has also been sought for student scholarships, learning labs, guest lectures, teaching equipment (e.g., computers, projectors, software, etc.), clinical equipment (e.g., audiometers, verification systems, etc.), furniture, and even bricks and mortar. This relationship, though common, must be conducted in such a manner as to assure the objectivity and integrity of academic teaching, learning, and practice.

Both audiology programs and industry require public confidence and trust to be successful and, therefore, must be mindful to avoid those activities that may create an apparent conflict of interest. In addition, industry and university relationships should be transparent to students. The university must present an ethical model that can serve as a model for students who will graduate and may have similar relationships with industry in their careers. As there are fundamental differences between academic programs and commercial enterprises in terms of both missions and financial obligations, it is possible that potential conflicts of interest could arise in the course of their interactions. It is imperative that both audiology programs and industry work together to identify and manage these potential conflicts to ensure that the relationship remains both successful and ethical, and thereby assures that the welfare of the consumer (including students and clinical patients) is paramount in their interactions.

While the relationship between pharmaceutical companies and physicians has received much attention over the past several years, practitioner relationships with other sectors of industry, including medical device manufacturers, also have the potential for conflict of interest. While pharmaceuticals and medical devices are fundamentally different, there is a risk of inappropriate influence on students and patients if guidelines are not developed to assure a fair and balanced approach to education. Clinical and academic content decisions must be made by university faculty based on student education and clinical training needs rather than on the relationship with the commercial enterprise. Universities must avoid a perception of motivation for financial gain rather than objective, patient-centered practice and clinical education.

Potential Conflicts of Interest

The relationship between academic programs and industry is more complex than that between private practitioners and industry. There are four areas in which potential conflicts of interest may arise for academic programs in their interactions with industry: (1) with academic and clinical faculty; (2) with students; (3) with the clinics associated with the program; and (4) with the program itself.

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The relationship between individual faculty and industry is perhaps the most obvious and common relationship. Faculty often relies on industry to provide funding for research activities and publications, a practice that has occurred for decades. These opportunities for faculty often lead to advancements in the university, including promotion and tenure. Conversely, industry relies on



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faculty to conduct independent research, often with an eye toward verification of findings or development of new strategies that may benefit the commercial enterprises of the company. In this regard, faculty and industry must strive to manage these relationships to ensure the integrity of the results of such ventures.

Beyond the obvious relationship of funding for research, faculty can have other relationships with industry. These include being an invited speaker for continuing education courses, providing consultation with industry, or being an instructor on recently developed technologies. In each of these cases, the opportunities for conflicts of interest arise as they can with the other more historically commonplace practices. Whether it be accepting royalties from a textbook that then becomes a required text in a course taught by the author, or accepting desk copies of textbooks considered for adoption for classes, these activities all present a potential conflict of interest.

Students

Paradoxically, the impressionable nature of students would appear to make them most vulnerable to conflicts of interest from industry, yet they are not, for the most part, in any position to exercise decisions regarding industry. Students could be influenced by gifts, trips, scholarships, and other benefits from industry, but as they are unlicensed and hold no decision-making roles within academic programs or clinics, they are perhaps not in a position to be conflicted, but they certainly may be impressionable. However, the potential does exist that relationships established prior to graduation may carry over to practice after graduation. Therefore, university programs and preceptors have a responsibility to discuss ethical guidelines and to model best practices to students, to assure that students understand the potential impact of relationships that could be established prior to graduation.

Academic Clinics

The one area that would seem most likely to give rise to conflicts is the patient care activities associated with academic programs. While academic programs may operate a teaching clinic as part of their training program, and clinical faculty may provide services in those clinics, it is most often the case that neither the clinic nor the faculty operates as a traditional for-profit business. That is, the purpose of the clinic is not to maximize profits, but rather, to provide a consistent and controlled teaching environment for students. Similarly, faculty compensation is generally not tied to the profitability of the clinic and therefore would be less likely to be influenced by industry or other external forces. However, exceptions do exist, such as faculty practices. These issues will, however, likely pertain to clinical environments external to the university as well as to preceptors within those environments. As it is possible that students may rotate through these clinical environments, preceptors should be advised of their responsibility to model best ethical practices for the students.

Academic Programs

Universities, in general, and academic programs specifically, establish relationships with industry, often with an eye toward funding basic teaching endeavors. Academic programs will solicit donations from industry to fund faculty salaries, continuing education programs, classroom technology, scholarship programs, or teaching laboratories. Industry often provides funding or in-kind gifts in this regard. The question is whether these gifts could influence a program in a way that might influence patient care activities or students. The obvious concern to academic programs in audiology is that the program may exert influence on the clinical entities of the program to make patient care decisions based on these gifts. For example, a gift from a hearing instrument manufacturer for classroom technology may result in patients being counseled toward that particular device or students gravitating toward those manufacturers and their products, rather than other devices that may be available, after graduation.

Principles for Interactions Between Audiology Programs and Industry

Audiology programs and industry share the goal of educating students to provide quality hearing and balance care to patients, as well as advancing knowledge in auditory and vestibular sciences. The basic principles that should guide decisions regarding interactions between academic programs in audiology and industry include:

- The interaction should serve the interests and legitimate missions of both the academic program and industry.
- From the academic program's perspective, the interactions must serve legitimate educational or research purposes.
- Any interactions should serve to enhance the hearing or balance health of the public.
- All interactions should be disclosed and transparent.

- The interactions should involve open communication between knowledgeable parties.
- The interactions should support and enable the free exchange of information in appropriate settings in a manner consistent with professional behaviors.
- Interactions should not involve any quid pro quo between the program and industry beyond that consistent with fair market value of products used by the academic program and/or clinic and associated services.

General Recommendations for Academic Programs in Audiology

- Audiology programs should adopt and implement guidelines that address specific interactions between faculty, students, clinical sites, and industry. These guidelines should be designed to assure that a principled relationship occurs that promotes the educational mission of programs, enhances the experiences of students, and advances knowledge of hearing and balance disorders.
- Guidelines should be applied with fairness and consistency, keeping in mind that relationships evolve over time. Guidelines should govern all interactions with any sector of industry and should not discriminate based on the size of the company, the financial opportunities involved, or personal relationships.
- "Industry" includes all vendors and/or prospective vendors including manufacturers of diagnostic equipment or treatment technologies, classroom or learning technologies, publishing companies, or other such industries that are related to student education, clinical services, or research.
- Guidelines should adhere to the rules and regulations of the institution of the academic program.

General Recommendations for Industry

- Compensation for services, including reimbursement for expenses, honoraria, or serving in an advisory capacity, should be at fair market value and commensurate with the participation of the faculty or program.
- Industry must recognize their obligation to permit university programs and faculty to make independent

decisions regarding industry products.

- There is a recognized and necessary interaction between manufacturers and practitioners (which includes university faculty), including
 - The collaborative processes in the innovative and creative development of devices;
 - The training, instruction, education, services, and technical support provided to practitioners to assure the safe and effective use of products; and
 - The needed support for research and education provided to develop technologies that better serve the public.

Specific Recommendations for Academic Programs and Industry

A. Gifts to Individuals or Academic Programs

There is a growing body of evidence from the social sciences that gifts of any value may affect the objectivity of clinical decision making. One-on-one gifting relationships of all kinds engender feelings of reciprocity that can unwittingly bias decision making, by recipients in favor of donors' interests. These concerns are particularly targeted at clinical decision making whereby the objectivity of the audiologist in patient care activities could be called into question.

The clinical arm of audiology programs is not immune to the potential of bias in clinical decision making. However, many academic audiology clinics are often operated in a manner that is atypical of for-profit clinics and often rely on a variety of resources to maintain their operations, including direct state funding, grants, in-kind gifts, donations of equipment, and direct or indirect financial gifts. Important in this regard is to separate "gifts" that are provided for legitimate educational purposes versus gifts that potentially induce bias, particularly if the gift is directed at an individual (e.g., clinical audiologists) as opposed to the academic program as a whole. Individuals who provide clinical service, even within this environment, must maintain objectivity in clinical decision making and in regard to the preparation of future clinicians.

Recommendations Regarding Gifts

 Audiology programs should establish and implement guidelines on the type and extent of gifts that may be accepted by faculty from industry. These guidelines should include a definition of what constitutes a gift (e.g., dinner with industry representatives, anatomical models, textbooks, travel grants, etc.), as well as any value limits on those gifts.

- Gifts provided to the academic program in general should serve a legitimate educational purpose. In this regard, such benefits may include, but not be limited to, enhancing the curriculum, expanding service delivery, developing research programs, improving infrastructure, or augmenting faculty development programs.
- Any gift that establishes a quid pro quo should be prohibited.
- All gifts should serve legitimate educational purposes.
- Honoraria for services provided should not be considered gifts but should be equivalent to fair market values for compensation for the services or time rendered.

B. Site Access by Industry Representatives

Equipment and devices are used extensively in the provision of services to patients with hearing or balance disorders. Representatives of industry can play an important role in introducing new technologies as well as provide training and support on the proper use of devices by practitioners, and thus may have legitimate reasons to be present in the clinics or classrooms of academic programs in audiology. Frequently, their presence is essential when devices are initially used with patients. Also, industry representatives may participate in the educational mission of an academic program through direct or indirect instruction. Nonetheless, there is the potential that certain interactions with industry representatives can also compromise independence of decision making and professionalism.

Recommendations Regarding Access by Industry Representatives

 Access for industry representatives should be based on guidelines and procedures that are well considered, clearly interpreted, and consistently and fairly applied. Faculty, staff, and students of an audiology program, along with industry representatives must be made aware of and held accountable for abiding by the guidelines and procedures in this regard.

- Student interaction with industry representatives should be primarily for the purpose of education.
- Industry representatives who are invited to observe or participate in interactions between patients and the faculty and staff of an audiology program clinic, or participate directly or indirectly in the instructional endeavors, should be identified by the program as consultants and not as part of the faculty. Industry representatives in patient care activities should be sanctioned by the program, and their presence should be fully disclosed and consented to by patients before the representatives are permitted to be present during patient care interactions.

C. Continuing Education (CE) Programs Sponsored by Academic Programs

Industry is a common source of funding or speakers for continuing education activities associated with academic programs in audiology. The credibility of audiology programs requires that CE programs sponsored by the academic program be legitimate, academically oriented, and open to a variety of viewpoints.

Recommendations Regarding CE Programs Sponsored by Academic Programs

- Academic programs and industry should be able to sponsor and/or plan CE programs together. Programs that serve as marketing vehicles for industry should be identified as such.
- Industry funding sources should be directly acknowledged in all announcements and literature about particular CE offerings, in the presentations and forums as required by CE agency standards, and in all publications about the programs.
- Meals, travel, and lodging can be provided for participants so long as those items are consistent to the scope of the program and are offered without expectation of quid pro quo.
- Academic programs offering CE programs should familiarize themselves with standards for continuing education and strive to assure programs with industry sponsorship or participation meet those standards. Approved continuing education credit should be offered when available. Programs not approved for CE credits should be identified as such.

D. Participation in Industry-Sponsored Educational Programs

Industry often takes the lead in the development of new technologies, expanded applications of existing technologies, or advances in the diagnosis and/or treatment of hearing and balance disorders. The dissemination of this information to the audiology community is critical to assuring appropriate understanding and use of these developments. As such, industry has a responsibility to provide educational programs to faculty whose role it is to teach the next generation of practitioners. Educational events in which information is transferred between industry and academic faculty and students, whether at the academic institution or at another location, serves to assure that advances in knowledge and technology are available in a timely manner. Thus, students have the opportunity to learn about the most contemporary developments in hearing and balance health care.

Faculty are often called upon to participate in industrysponsored educational programs due to their expertise or experience. In fact, the credibility of these programs may be enhanced due to the reputations of the faculty speakers and their academic institutions. These programs may provide legitimate educational opportunities to those in attendance. However, faculty should be cautious in participating in industry-sponsored programs whose sole purpose is marketing, the enhancement of the reputation of the company, or for which a quid pro quo is expected. It is important to note that this caution does not extend to programs where faculty present to peers the results of industry-sponsored research provided there is the opportunity for critical review and discussion.

Students can benefit from the expertise, clinical skills, and technology available from industry. To not allow students to attain these benefits is to deny the contributions of industry to auditory and vestibular science. However, students are also vulnerable and impressionable, so it is the responsibility of the faculty, academic programs, and industry to protect students from those situations that could potentially exploit their naïveté.

Recommendations Regarding Participation in Industry-Sponsored Educational Programs

- Audiology programs should develop guidelines that define appropriate and acceptable levels of involvement of faculty and students in industry-sponsored educational programs.
 - Programs should develop guidelines regarding the

appropriate use of faculty names and affiliations for use in industry-sponsored educational activities.

- Audiology programs should require full transparency and disclosure by their faculty with respect to their role in industry-sponsored educational programs.
- Audiology programs should develop guidelines with respect to faculty participation in speakers bureaus.
- Academic programs should assist students in differentiating those industry-sponsored programs that serve a legitimate educational purpose from those that do not. Faculty should also provide insight and advice to students to assure they understand the purpose of their participation.
- Audiology programs should require that payments to faculty for participation in industry-sponsored

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educational activities be only at fair market value and consistent with models of compensation for the services or time provided.

 Meals, travel, lodging, and other trip-related expenses should be at levels that are commensurate with the participation of the faculty in the programs.

E. Industry-Sponsored Scholarships and Other Educational Funds for Students

Industry has historically been a source of financial support for students, most commonly in the form of scholarships or assistantships associated with research endeavors. University programs and preceptors have a responsibility to discuss ethical issues with respect to this financial support to assure that the support is offered without strings attached and serves a legitimate academic purpose.

Recommendations Regarding Industry-Sponsored Scholarships or Other Educational Funds for Students

- Industry should be free to offer financial or in-kind support to academic programs for research funding, student scholarships, or educational funding.
- All scholarships or other educational funds from industry should either be given directly to the audiology program or, if given directly to the student, clearly identified as a scholarship or assistantship to support their academic training.
- Universities that allow students to accept any assistantship, scholarship, or educational fund must assure that there are no expectations of a quid pro quo. Any funding that establishes a quid pro quo should be prohibited.

F. Reimbursement of Expenses

Expenses associated with CE programs, teaching activities, or research endeavors may accrue to faculty, students, or the program in audiology in general. While these may be covered in a professional services agreement with a specific company, many times they can occur with no more than a verbal understanding between industry and the faculty or academic programs.

Recommendations for Reimbursement

 Reimbursement of expenses associated with travel or the provision of services (e.g., copying expenses, teaching material, etc.) when the faculty member, program, or student is providing a legitimate service for which the expenses are necessary should be permitted.

 To ensure transparency, such services should be rendered in accordance with terms specified in professional services agreements, which may include compensation for services that are customary and reasonable in academic practice.

G. Ghostwriting

Ghostwriting is defined as the provision of written material that is officially credited to someone other than the writer(s) of the material. Transparent writing collaboration with attribution between faculty and persons in industry is not considered to be ghostwriting, provided each author legitimately contributes to the endeavor.

Recommendations for Ghostwriting

- Academic programs in audiology should not permit their faculty or students to allow their presentations or publications to be written by others. Faculty and students should not receive credit for work to which they did not substantially contribute.
- Industry should not permit their employees to receive credit for work to which they did not substantially contribute.

H. Purchasing

Purchasing decisions made by audiology programs may present major challenges in efforts to prevent the intrusion of financial self-interest and inappropriate bias. In the case of the purchase of devices and equipment, those with experience and information relevant to purchasing decisions may have financial or other ties to the manufacturer or provider.

Recommendations for Purchasing

- At a minimum, audiology programs should ensure that each participant in the purchasing process discloses all potential conflicts of interest.
- To the extent an individual's expertise is necessary in evaluating any product, that individual's financial ties to any manufacturer of that or any related product should be disclosed to those charged with the responsibility for making the decision.

I. Boards of Directors, Advisory Boards, and Consulting

There is value in permitting audiology faculty to interact with industry, including faculty participation on industry boards of directors and scientific advisory boards as well as through professional services agreements and consulting contracts, provided such activities are conducted with full disclosure and in compliance with the rules and regulations of the parent institution.

Recommendations for Participation on Boards and Provision of Consultative Services

- Faculty should provide full disclosure of participation on boards of directors or advisory boards of industry, or consulting services for industry.
- Compensation for these activities should reflect the fair market value of the services provided.

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Also of Interest

A Model AuD Program: Ensuring Comprehensive Clinical Audiology

by Jennifer M. Simpson, Lata A. Krisman, Kathleen Corbin, Allan. Diefendorf, Robert E. Novak, and Richard T. Miyamoto (*AT* July/Aug 2009): www.audiology.org/resources/ audiologytoday, search the archives.

