David B. Hawkins, PhD,
Mayo Clinic, Jacksonville, FL,
Teri Hamill, PhD,
Nova Southeastern University,
Ft. Lauderdale, FL and
Jane Kukula, AuD,
Advanced Audiology Concepts, Inc., Euclid, OH

Ethical Issues in Hearing

In the last five years, the American Academy of Audiology (AAA) and the Academy of Dispensing Audiology (ADA) have made major efforts to educate their members about their respective Codes of Ethics and how they should be interpreted in light of relationships with hearing instrument manufacturers. These efforts began in 2001 when an AAA Presidential Task Force was formed to make recommendations about how the Academy should proceed on a variety of issues related to potential conflicts of interest (COI). Based upon the recommendations of this task force, the AAA Ethical Practices Committee (EPC) and ADA leadership developed a set of guidelines that were endorsed by both AAA and ADA. These guidelines were published in the May/June issue of Audiology Today in 2003 for member comments. Following member input, *The Ethical Practices Guidelines for Financial Relationships with Hearing Industry Manufacturers* was adopted by the AAA and the ADA, thus providing direction for audiologists on these issues. The Guidelines reaffirmed the AAA Code of Ethics, Rule 4c *"Individuals shall not participate in activities that constitute a conflict of profession interest"* and gave some specific examples of conflicts of interest. At that same time, then AAA President Angela Loavenbruck embarked on a series of talks and seminars to educate the membership about the importance of these issues. The AAA EPC also started systematic efforts to inform the membership and raise its awareness of the importance of COI through state and national convention presentations and frequent articles in *Audiology Today.*

The 2001 AAA Presidential Task Force considered the results of a survey of 42 hearing-impaired consumers and 182 audiologists (Hawkins, Hamill, Van Vliet and Freeman, 2002) before recommending that EPC develop guidelines. This survey presented 17 situations and asked the respondents to react to each on a rating scale ranging from "clearly unethical" to "nothing wrong." Given the recent educational efforts to raise awareness of COI issues, the EPC requested that this same survey be administered again to determine if audiologists' views on COI had changed. This article discusses the findings.

METHOD

All active members of the AAA were solicited directly by email in February 2006 and invited to participate in the survey. Participation involved visiting a website, logging in, and spending approximately ten minutes responding to the survey. The survey was completed by 1,633 AAA members. For comparison purposes, the results from the Hawkins et al. (2001) study of 42 hearing-impaired consumers and 182 audiologists will be included.

The 17 situations from the questionnaire given to the audiologists are noted within Figures 1-17. Respondents were asked to rate each of the activities in one of four categories:

1. "I think there is nothing wrong with that practice."
2. "While not unethical, that practice may not be in the patient's best interest. I would be more comfortable working with a professional who did not engage in that business practice."
3. "I think this business practice is highly suspect and certainly borders on unethical."
4. "I think this business practice is clearly unethical."

On the figures that are shown in the Results section, these four categories will be shortened into the following descriptions: 1) Nothing Wrong, 2) Better If Not Done, 3) Borders on Unethical, 4) Clearly Unethical.

The content area of the various questions can be described as falling into one of four areas: 1) business incentives from hearing aid manufacturers, 2) entertainment, small gifts, and visits from manufacturer representatives, 3) CEU events sponsored by hearing aid manufacturers, and 4) business practices. It should be emphasized that inclusion of an activity in the survey does not imply that the EPB considers that activity to be unethical or to place the member in a COI, and in fact some of the activities are considered acceptable given the 2003 guidelines.

RESULTS

The survey results are shown in Figures 1 – 17. A chi-square analysis of each question was performed to determine whether the distribution of responses was significantly different for 1) the

Aids Revisited: A Survey

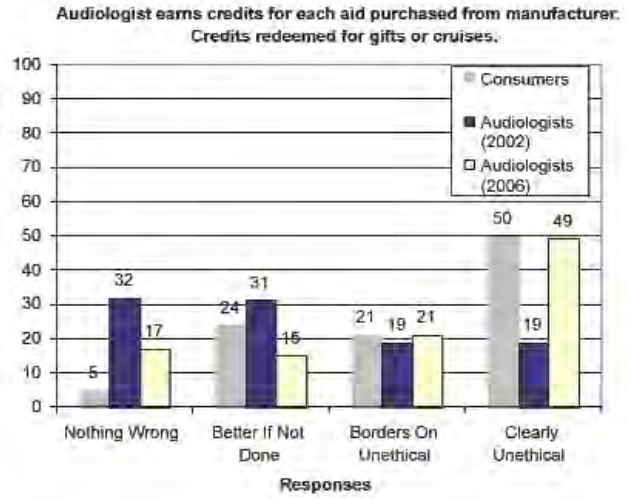
2002 audiologists versus the 2006 audiologists, and 2) the 2002 consumers versus the 2006 audiologists. These results are analyzed below in terms of the groupings of the questions described above.

Business incentives from hearing aid manufacturers

Figures 1 – 4 show the results for the four questions that addressed business incentives from hearing aid manufacturers. There has been a significant shift in opinion from 2002 to 2006 among the audiologists on the question of accepting cruises and gifts from manufacturers. More respondents indicated that it is not appropriate to accept gifts or cruises in exchange for purchase of a certain number of hearing aids (Figure 1, chi-square, p<.0001). For example, 30% more audiologists found this practice "clearly unethical" in 2006 and the percentage who found "nothing wrong" dropped from 32% to 17%. Interestingly, the distribution of responses for the 2006 audiologists and 2002 consumers was not significantly different (p<.20).

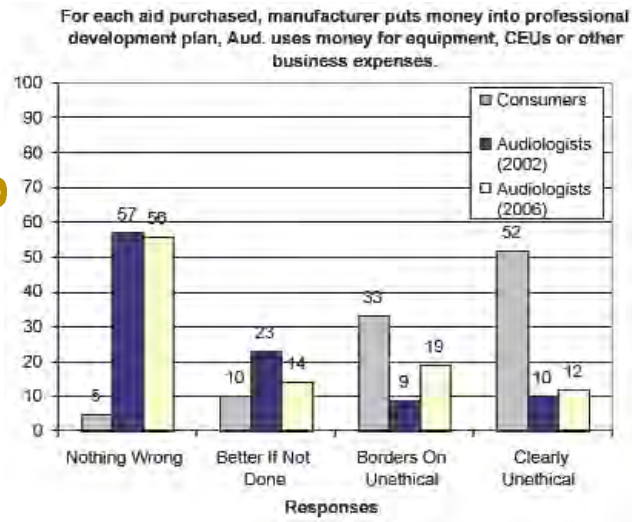
Figure 2 shows that audiologists have a different view when the manufacturer rewards the buying of hearing aids with money deposited into an account to be used for equipment or CEUs or other business expenses. Both today and in 2002, the majority of audiologists found the practice acceptable, while 85% of the consumers had found the practice unethical or bordering on unethical. While over 50% of audiologists retain the view that there is nothing wrong with this incentive, and some 10-12% retain the belief that it is clearly unethical, there was a significant shift in the degree to which the remaining audiologists viewed the practice (p<.001), with more now considering the practice as bordering on unethical. Audiologists consider it more problematic when the incentive is equipment purchase in exchange for agreeing to purchase a set number of aids in the next year (Figure 3). The consumers held similar views for both the reserve account and the agreement to purchase hearing aids to repay the equipment purchase. Again, the distribution of opinions of audiologists changed significantly with more finding it unethical (p<.001) to

Figure 1



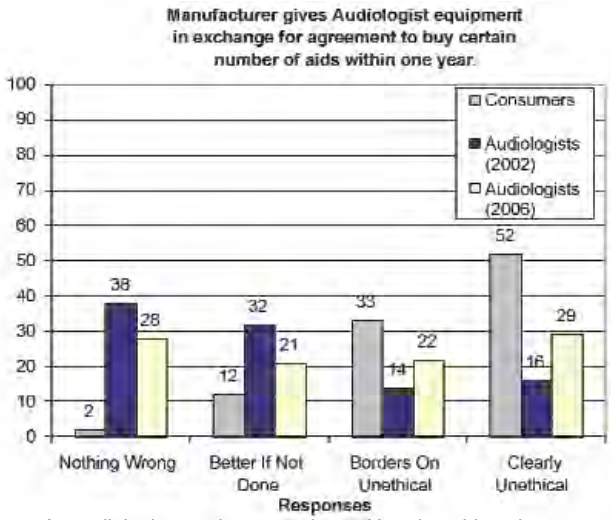
A hearing instrument company has a new promotion. For every hearing instrument sold, the audiologist will earn one "credit". The audiologist can redeem credits for products ranging from those offered in a clothing catalog to a cruise to the British Virgin Islands.

Figure 2



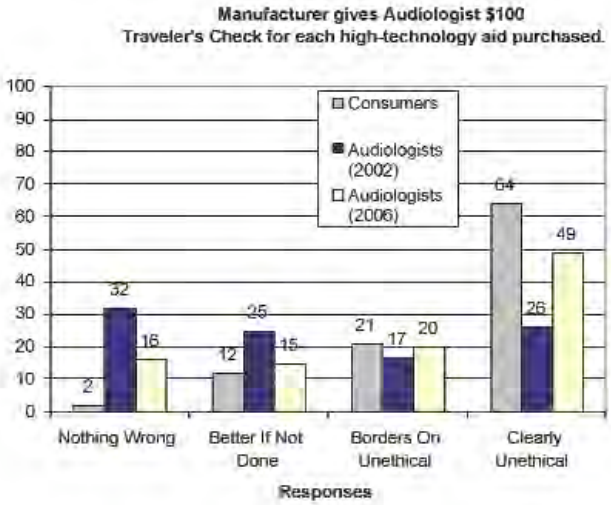
A hearing instrument company has what it calls a "professional development plan." For each hearing instrument sold, the manufacturer places money into an investment account that is redeemable for the purchase of equipment, book, CE workshops or other business-related expenses. The audiologist joins the plan.

Figure 3



An audiologist needs a new piece of hearing aid equipment. He or she could borrow the money and arrange a plan through a bank. Instead, the audiologist accepts a hearing instrument manufacturer's offer of this equipment in exchange for buying a defined number of hearing instruments within a year.

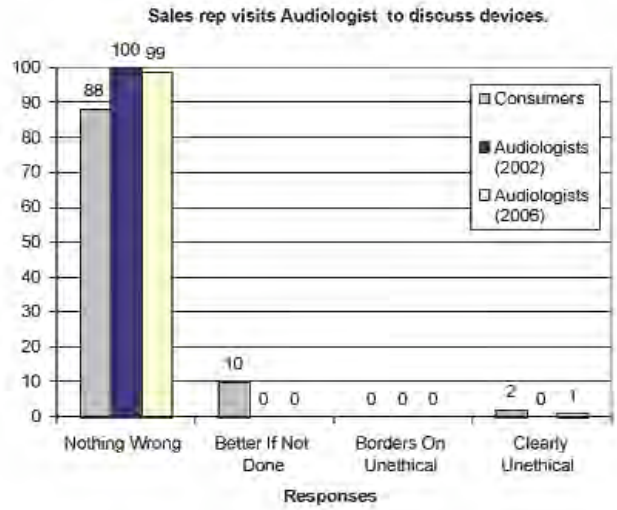
Figure 4



A hearing instrument company offers a promotion whereby the audiologist receives a $100 traveler's check for each high-technology hearing aid that is purchased. The audiologist takes advantage of this offer.

accept equipment for hearing aid purchases; however, the current audiologists' opinions still differ significantly from those of the consumers (p<.001). The perception of the practice of receiving money or a traveler's check from a manufacturer for hearing aids purchased is summarized in Figure 4 and is virtually identical to the answer for the cruise/gift question (Figure 1). The audiologists have clearly become more concerned about this activity as a significant shift has occurred (p<.001) and the opinions of the audiologists in 2006 are now similar to those of the consumers in 2002 (p<.10).

Figure 5



A hearing instruments company sales representative makes a personal visit to the audiologist to discuss the devices that the company sells. The audiologist listens to the salesperson.

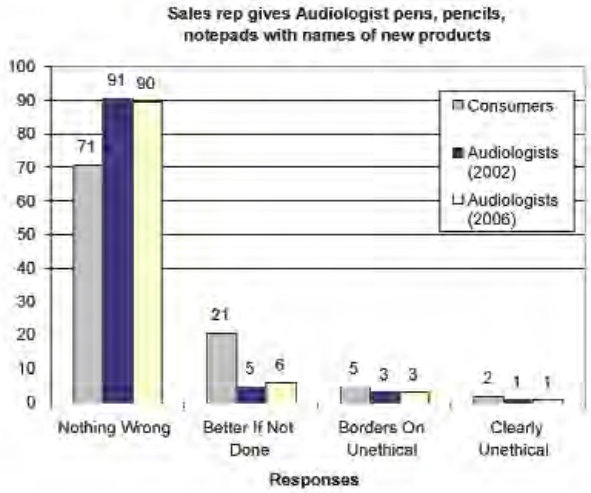
Entertainment, small gifts, and visits from manufacturer representatives

Figures 5 - 10 show the results for six questions that addressed entertainment, small gifts and visits from manufacturer representatives. The results in Figures 5 and 6 show that there is little concern about the practice of sales representatives visiting audiologists and bringing small items such as pens and notepads. There has been no significant change in the opinion of audiologists over the last four years on these two practices (p<.43 and p<.13, respectively). While consumers are also rather accepting of these practices, there is still a significant difference (p<.001) between the consumers and audiologists, with a small minority of consumers showing some reservations about any sales visit.

Similarly, if the sales representative visits and brings lunch or takes the audiologist out to lunch to discuss products (Figure 7), approximately 85% of audiologists see no problem and opinions regarding this practice have not changed significantly from 2002 to 2006 (p<.36). The consumers remain different from the 2006 audiologists (p<.001), with only 45% seeing nothing wrong with the practice. When the audiologist and spouse are taken to dinner and products are only briefly discussed (Figure 8), more concern is seen by all groups. Audiologists have become significantly more concerned since 2002 (p<.001) and the 2006 audiologists are not significantly different from the consumers (p<.051) with respect to this issue.

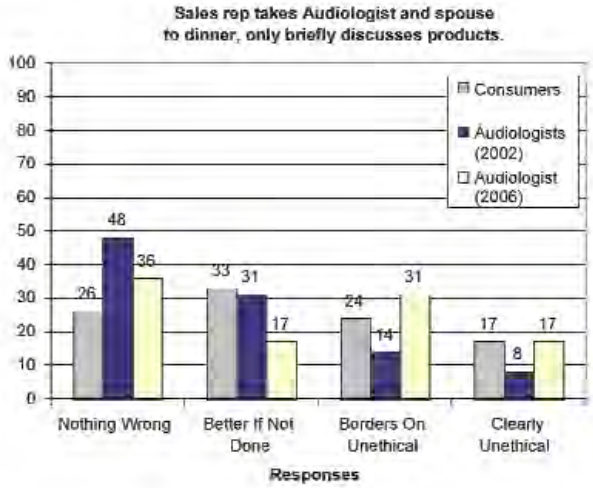
Figures 9 and 10 show the results for the two questions addressing entertainment at conventions. When an audiologist attends a party that is open to everyone (Figure 9), an

Figure 6



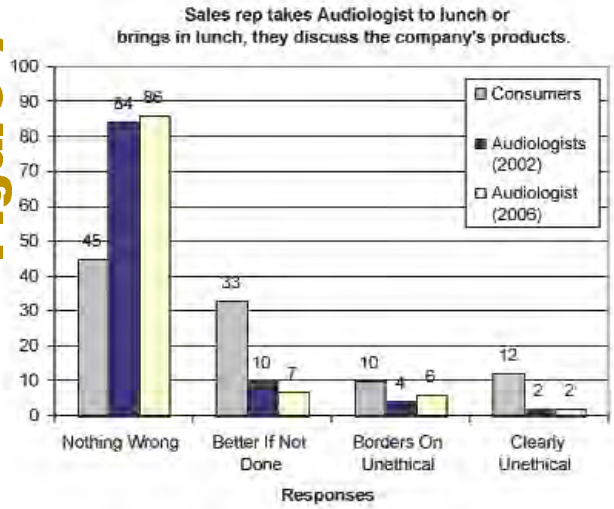
A hearing instruments company sales representative visits the audiologist's office and brings pens, pencils, and notepads with the name of the new product on it. The audiologist accepts.

Figure 8



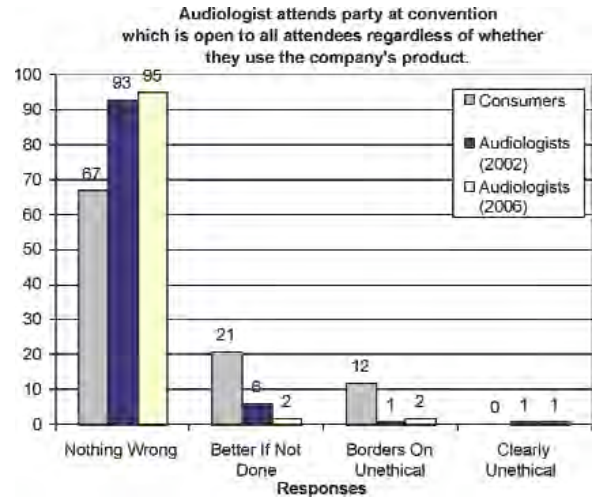
A hearing instruments sales representative takes the audiologist and his/her spouse out for dinner. The sales representative only briefly discusses the company's products.

Figure 7



The hearing instruments sales representative visits the audiologist over the noon hour and takes him or her to lunch, or the representative brings in lunch for the audiologist and staff. They discuss the company's line of products.

Figure 9



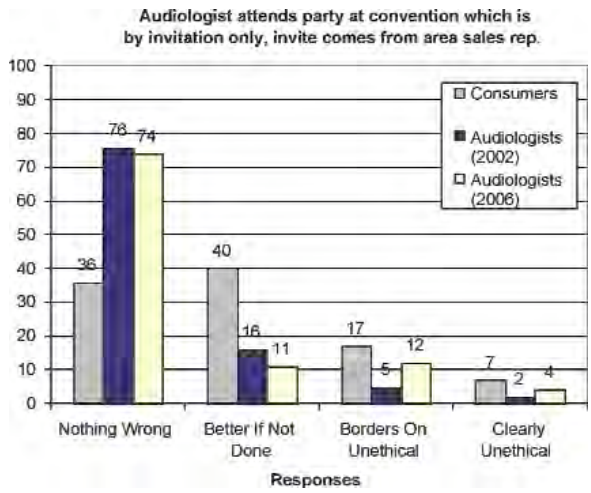
An audiologist goes to a party at a professional convention sponsored by a hearing aid manufacturer. The party is open to all audiologists regardless of whether they dispense that brand of product.

overwhelming 93-95% of audiologists report nothing objectionable. While most consumers seem to approve of this activity as well, the distributions are significantly different ($p<.001$), with 33% of consumers expressing some concern. When the party is by invitation only, the majority of audiologists in 2002 and 2006 still approve (76 and 74%, respectively). Continuing the trend of consumers being more conservative in ethical issues, significantly more concern ($p<.001$) is seen by the consumers on this question as well, with only 36% seeing nothing wrong with this practice. Although the audiologists' change in opinions on the question of parties has been modest, it did reach statistical significance ($p<.01$ for each question.)

CEU events sponsored by hearing aid manufacturers

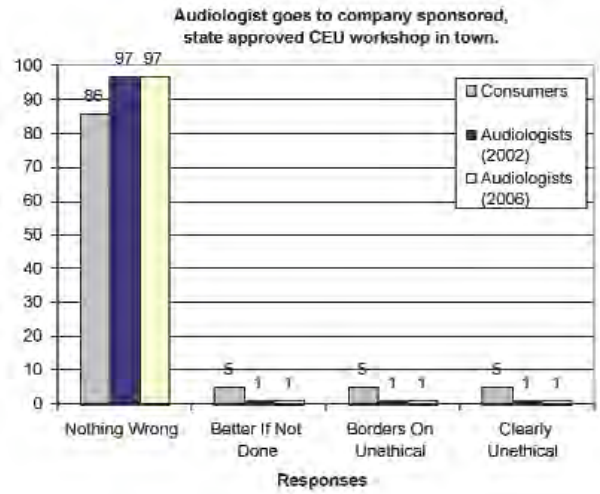
Figures 11 and 12 show the results for two questions related to CEU events sponsored by hearing aid manufacturers in the local town of the audiologist. When the audiologist attends a company-sponsored, state-approved workshop in town (Figure 11), 97% of audiologists see no problem and this view has not changed in the last four years ($p<.62$). When meals are offered along with the CEU events (Figure 12), the consumers are more bothered, as evidenced by the "nothing wrong" percentage dropping from 86% to 64% with the addition of meals. The percentage of audiologists approving when meals are added remains high (92-93%) and has not changed in four years ($p<.95$). Consumers and audiologists remain different in their responses to both questions ($p<.001$).

Figure 10



At the annual audiology convention, the audiologist attends a dinner party that is by invitation only. The audiologist was given the invitation by the area hearing instruments sales representative.

Figure 11



An audiologist goes to a free, state-approved continuing education seminar offered by a hearing aid manufacturer. The seminar covers the features of the company's new products, and instructions on fitting the hearing aid. The seminar is held in town.

All groups expressed more concern when a company-sponsored CEU workshop is out of town and the manufacturer pays the audiologist's expenses to attend. Figure 13 shows the results when the expenses are paid for the audiologist and Figure 14 when a spouse attends as well. When only the audiologist attends with expenses paid, slightly over half of the audiologists see nothing wrong, with the percentage dropping from 66% in 2002. This represents a significant shift for the audiologists ($p<.001$) and again, the consumers are more concerned than the 2006 audiologists ($p<.001$). When the spouse also attends at the expense of the manufacturer (Figure 14), only 16% of the audiologists in 2006 reported seeing no problem with the practice, down from 26% in 2002 ($p<.001$). While the distribution of responses for the audiologists in 2006 and consumers in 2002 are quite similar for this situation, the difference is still statistically significant ($p<.01$).

Business practices

Figures 15 shows the results for the issue of using hearing aids from one manufacturer because of a volume discount when the audiologist believes this brand is a good one. While very few respondents thought this practice was clearly unethical, some reservations are obviously felt by all three groups. The audiologists did change significantly ($p<.01$) from 2002 to 2006, with more seeing a problem with this practice. The consumers again expressed more problems with the practice ($p<.05$).

The results are similar when the practice of purchasing a franchise and dispensing a single line of hearing aids almost exclusively is presented. Figure 16 shows the results and while it is clear that the majority see nothing wrong with the practice, 40-50% of all groups express some concern through their answers. Again, the modest shift in opinion and the difference between 2006 audiologists and consumers reached statistical significance ($p <.001$ and $p<.025$, respectively).

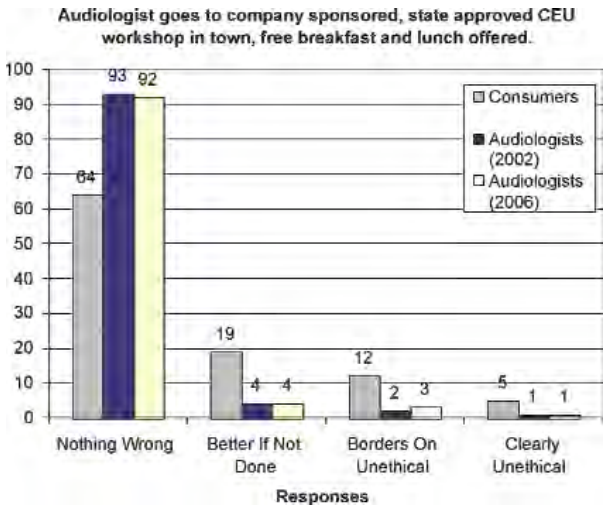
The issue of receiving a commission on the sale of hearing aids is addressed in the remaining question and is shown in Figure 17. The audiologists are not different from 2002 to 2006 ($p<.20$) and while the majority see nothing wrong, 45% see some reason for concern about the practice. The consumers are significantly different from the 2006 audiologists ($p<.001$) and clearly are concerned, as only 10% see nothing wrong with receiving a commission for hearing aid sales.

DISCUSSION

The 2003 *Ethical Practice Guidelines on Financial Incentives from Hearing Instrument Manufacturers* reminds audiologists that the interests of the patient must come before the financial interests of the audiologist. If a business practice has the appearance of conflict of interest, it must be avoided, even if there is no actual conflict of interest. Stated another way, just because an audiologist on introspection believes an incentive does not affect his or her judgment does not mean that it is appropriate to accept that incentive.

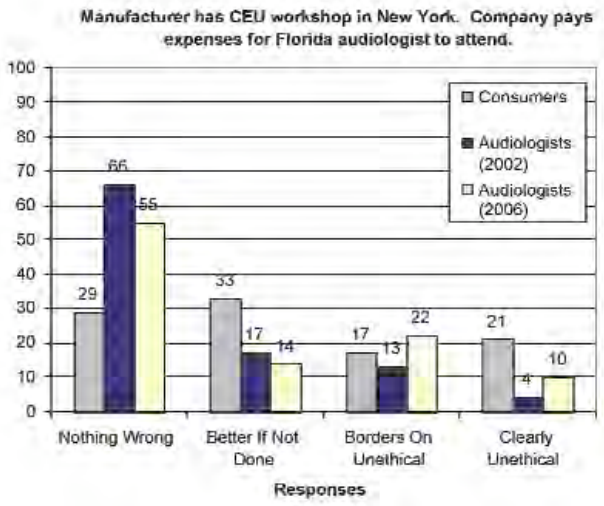
A COI exists when an arrangement has any one of three following three characteristics: 1) a kickback, a quid pro quo arrangement, a gift of money or other item of value tied to the purchase of a product, 2) a gift of value even when not tied to the purchase of a product, and 3) an arrangement which has the appearance of a benefit to the audiologist. An added concern is that under certain circumstances these activities are not only unethical but can be illegal. Hahn et al. (2005) stated "Under the Federal Anti-Kickback Statute…it is a felony for any person (including an audiologist) to knowingly and willfully solicit or

Figure 12



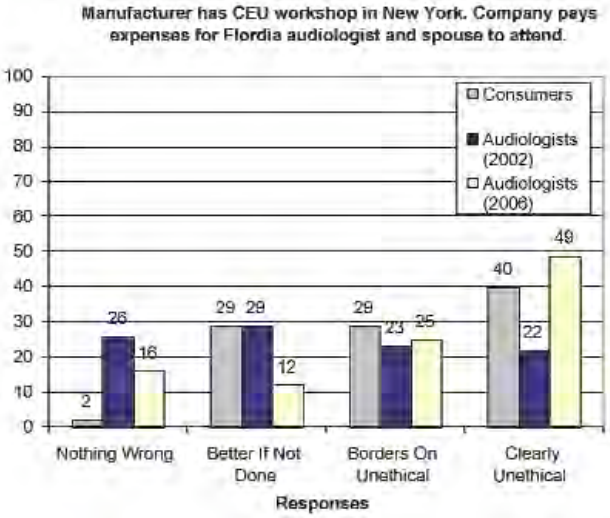
A company offers a free continental breakfast and buffet lunch in addition to a CEU approved course.The audiologist attends and eats the offered meals.

Figure 13



A hearing instruments company sponsors an approved continuing education conference in New York City. The conference discusses the fitting of the company's line of hearing aids, and how to determine which product will help which patient. An audiologist from Florida is invited and attends. The hearing instruments company pays the audiologist's expenses.

Figure 14



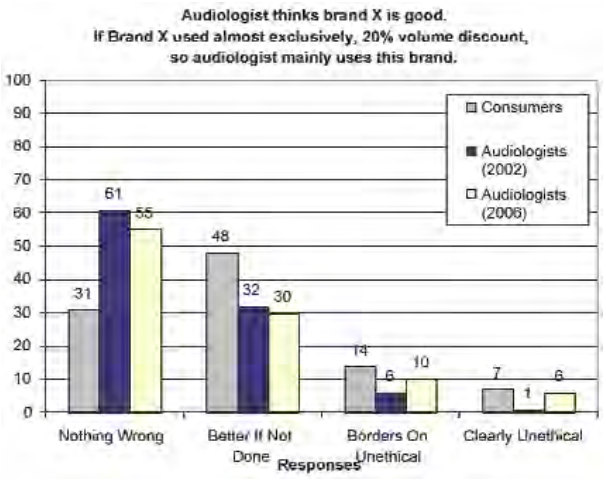
Same situation as above in #13, but this time the company also pays the expenses of the audiologist's spouse, who is not a hearing health care professional. The audiologist and the audiologist's spouse attend.

receive remuneration, directly or indirectly, overtly or covertly, in cash or kind, in return for purchasing, leasing or ordering (or recommending purchase, lease or ordering) of any item or service reimbursable in whole or part under a federal health care program" (p.34).

This survey indicates a large change in audiologists' opinions about the most blatant conflicts of interest: accepting gifts and cruises in return for hearing aid purchase. While half of audiologists find this clearly unethical, which is the position of the Academy, audiologists' opinions on the acceptability of professionally related gifts in exchange for hearing aid purchase has not changed as markedly. Consumers viewed the ethics of accepting cruises or business equipment in exchange for hearing aid purchases similarly. Regardless of whether equipment is purchased from funds deposited into an account as a reward for purchasing hearing aids, or whether a loan is repaid by purchasing a given brand of hearing aids, about half of the consumers find this clearly unethical. Because the consumer could reasonably question whether the motive of the audiologist for selling a brand was to fund office equipment, the conflict of interest guidelines prohibit this practice. Apparently, many audiologists continue to justify the "greater good" of the business-related incentives. The problem that arises is that the "goodness" of the gift, e.g., hearing aid fitting hardware or education, gives an appearance of "goodness" to the transaction but in actuality this can be considered a money laundering scheme. Regardless of the "goodness" of the gift, the audiologist is still accepting a gift that is of value. It is the value to the audiologist, regardless of potential benefit to the patient, that creates the appearance of a COI.

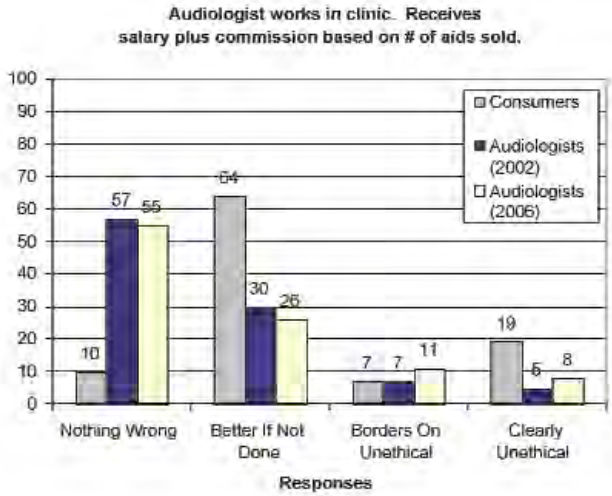
While the Academy strongly supports the use of state-of-the art equipment and the funding of continuing education, it is recommended that the audiologist negotiate up-front hearing aid discounts from manufacturers rather than engaging in covert business arrangements. Discounts should be reflected on the manufacturer's invoices and passed on to those third-party payers who reimburse actual costs. This offers legal protection, as failure to disclose the true cost of goods (e.g., if a Medicaid aid purchase was rewarded) is a violation of the Federal Anti-Kickback statute.

Figure 15



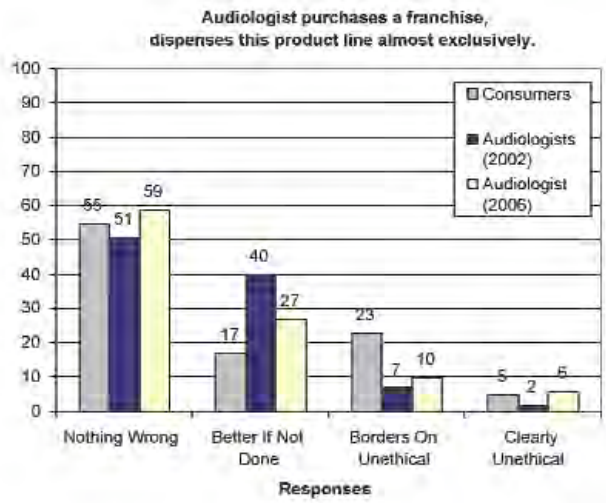
An audiologist finds that Brand X is at least as good as other brands. By purchasing Brand X hearing aids almost exclusively, the audiologist gets a 20% volume discount; therefore, the audiologist predominantly uses this brand.

Figure 17



An audiologist is an employee for a clinic. The audiologist receives a salary, plus a commission based upon the dollar amount of hearing instruments sold.

Figure 16



An audiologist has purchased a hearing aid franchise from a company with a well known name, one that advertises nationally, one that consumers easily recognize. The sign on the door indicates the brand name. The audiologist dispenses this product line almost exclusively. The audiologist only uses another manufacturer's product when there is no franchise product that can meet the client's needs.

Volume discounts are not considered a conflict of interest so long as the discount is not predicated on dispensing a set number of hearing aids. Negotiating a lower price is a widely accepted business practice that permits a practice to be financially successful, well equipped, and ultimately offer lowered costs of goods and services to patients. Practices such as purchasing discount offers with backend discounts, kickbacks and other hidden financial incentives originated from the hearing aid dispenser model and are not appropriate for a professional delivery system. Further, this is illegal in that the audiologist is "covertly" accepting indirect remuneration as described by Hahn et al. (2005).

Audiologists had similar opinions about volume discounts and purchase of a hearing aid franchise. Consumers did not strongly object to either practice, but found the franchise to be more acceptable. This may be because the consumer walking into a franchise has full knowledge that a single brand is dispensed, while volume discounts are not generally disclosed.

Manufacturer training on use of products and software is crucial. The conflict of interest guidelines advise audiologists that manufacturer representatives' offers of business related items valued at less than $100, offered when a representative visits a practice to discuss products, can be ethically accepted, as can business lunches. Audiologists' opinions on this have not changed markedly; most agree with the Academy position. Similarly, the Academy views open-invitation parties at convention as ethically acceptable, a view that is also supported by the membership.

Entertainment that has "strings" attached is not considered acceptable according to the conflict of interest guidelines. The example scenarios in this survey were the non-business dinner invitation that includes the audiologist's spouse and the invitation-only convention party. There has been more change in audiologists' beliefs that the non-business dinner with the spouse is unacceptable, with nearly half finding that unethical or borderline unethical. There has been less acceptance of the idea that an invitation-only party for the company's best accounts is an unacceptable reward. The Academy position is that this is a conflict of interest, as it is a reward for past business that is intended to create a social obligation that patients may view as compromising the objectivity of the audiologist.

This same rationale applies to company-sponsored training. The Academy prefers that audiologists not accept travel expenses

if training must be held out of town, but recognizes that manufacturers sometimes will find it educationally necessary and more economical to conduct training in a central location. In those cases, the audiologist is permitted to accept travel expenses and meals; however, it would not be acceptable to permit the manufacturer to provide entertainment expenses or spousal travel. There has been a recent trend among manufacturers to offer training trips outside of the country. Although the Academy views product training as a responsibility of manufacturers and supports regional and national product training activities, there is a problem with product training activities which take audiologists out of the country. While at times a product training trip outside of the country may be as cost effective as in the United States, audiologists still need to be aware that the appearance of extravagance creates a conflict of interest. The survey results show that most audiologists are now in agreement. Almost 75% found it unethical or borderline for a manufacturer to fly the Florida audiologist and spouse to New York for training, which compares to 69% of the consumers who held that view.

The conflict of interest guidelines did not specifically address the practice of audiologists receiving a commission for the sales of hearing aids, but the survey has shown a slight change in how audiologists view this practice. Physician and lawyer Bryan Liang addressed this issue in his invited presentation at AudiologyNOW! 2006 in Minneapolis. He views a sales-volume incentive system as entirely inappropriate and a clear conflict of interest, but believes other forms of incentives can be entirely ethical. Receiving a commission based on a percentage of the sales price creates a conflict of interest because the patient may question the motive behind the recommendation. Receiving a work-based incentive is a more acceptable means of rewarding productivity. That is, if an incentive system rewards all forms of productivity equally, it is ethical. Liang suggested a system where diagnostic testing has value units and fitting/ dispensing has value units (that are not based on the product prices). In such a system, a practice may decide to award more value units to some forms of dispensing, such as to new users or children, because of greater work involvement, but would not be free to reward an activity more simply because it is more profitable, such as selling a high-end digital hearing aid over a mid-range digital aid. Liang counsels that the incentive plan should be arranged in advance and applied equally to all employees, in which case it models the relative value unit incentive plans offered to physicians, which are widely accepted.

CONCLUSIONS

The 2006 survey of audiologist's opinions of the ethics of relationships with manufacturers shows that audiologists are increasingly of the opinion that accepting gifts or cruises is unethical, which was the major focus of the Academy's 2003 guidelines on relationships with manufacturers. While changes were also seen in viewpoints on the more subtle, but still unethical, practices such as the acceptance of equipment in return for hearing aid sales, it is clear that further member education is required. The Academy has recently published *Ethics in Audiology: Guidelines for Ethical Conduct in Clinical, Educational, and Research Settings* and AudiologyNOW! 2006 offered 8.5 hours (.85 CEUs) of continuing education in ethics. These efforts may foster further evolution in the beliefs of audiologists about the impact of conflict of interest on the doctoring profession of audiology.

REFERENCES

American Academy of Audiology. (2003). Ethical Practice Guidelines on Financial Incentives from Hearing Instrument Manufacturers. *Audiology Today, 15*(3), 19-21. (Available online at http://www.audiology.org/professional/ethics/)

Hahn, R., Abel, D., Kukula, J., and Members of the Ethical Practices Board (2005) Audiologists Beware…And Be Aware of Conflicts of Interest. *Audiology Today,* 17(4), 34-35.

Hamill, T., Ed. (2006). *Ethics in Audiology: Guidelines for Ethical Conduct in Clinical, Educational, and Research Settings*. American Academy of Audiology: Reston, VA.

Hawkins, D., Hamill, T.A., VanVleit, D. & Freeman, B.A. (2002) Potential conflicts of interest as viewed by the audiologist and the hearing-impaired consumer. *Audiology Today, 14*(5), 27-33.

Liang, B. (2006). Ethical issues facing audiology: Law and professionalism. Now Session Presentation at the American Academy of Audiology Annual Convention, Minneapolis, MN.