



A Question of Ethics

REAL LIFE LEGAL COMPLICATIONS & CONFLICTS OF INTEREST

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Audiology is not alone in the struggle to guide professionals to avoid conflicts of interest and kickbacks. Two recent news stories reported legal actions against LASIK providers and physicians referring patients for MRI services. Although they involve other professions, these cases highlight some of the ethical and legal pitfalls to which audiologists are also vulnerable.

In the first case, the Federal Trade Commission charged two major LASIK providers with making misleading advertising claims regarding benefits, performance and efficacy of the laser eye procedure according to reports in a consumeraffairs.com article. The 2003 charges were made after LCA Vision and The Laser Vision Institute (LVI) advertised that the refractive eye surgery would eliminate the need for reading glasses, bifocals or glasses for life. The Commission found that the companies could not substantiate the claim with scientific evidence. Additionally, LCA Vision was charged with making an unsubstantiated safety claim by advertising that the surgery was less risky to a patient's eye health than wearing glasses or contacts, and that the company's procedure would eliminate halos and glare at night.

Further, LVI falsely claimed that a free consultation was available to consumers to determine their candidacy for LASIK surgery. Instead, the initial consultation was with non-medical personnel to discuss the cost of the procedure. The complaint alleged that LVI then required consumers to pay a \$300 deposit even before they were told the risks of the surgery or if they were eligible candidates for LASIK. If the patient elected not to have the surgery after the consultation, the deposit was nonrefundable.

The Commission found the companies had engaged in deceptive advertising and proposed consent orders

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to prevent the two companies from engaging in similar practices when advertising their services in the future. The consent order prohibits making any claims about LASIK or refractive surgery without competent and reliable scientific evidence to substantiate the claim. Further, the proposed order permits only device claims approved by the FDA under any new medical device application.

"MRI and CT Centers Offer Doctors Way to Profit on Scans" screamed the May 2, 2005 headline of the *Wall Street Journal*. According to the report, some imaging centers were offering physicians a "per use, non-recourse lease agreement." The imaging center would bill the doctor a flat rate per scan. The doctors would then bill insurers a higher rate for the procedure.

The imaging company charged the physician \$375 per scan, and the physician billed insurers \$706 for the procedure on the "leased" equipment. The salespeople for the imaging center reportedly encouraged physicians to advise insurers that they were providing scans on their own, and to remove the imaging company's name from any insurance billing. One imaging center marketed to physicians by showing that a group practice, referring two patients per day, could make over \$122,000 per year.

Some health care attorneys have advised their clients against entering into this type of per use lease arrangement citing the risk of violating laws barring payment for referral, and the possibility of fraud if doctors falsely claim to provide the leased service within their office. However, the legality of the arrangement has not been tested in court to date. A civil suit was filed in Georgia by a patient arguing the practice violated the state's self-referral law. The case was settled without a judicial ruling on undisclosed terms.

The agency that oversees Medicare and Medicaid, the U.S. Department of Health and Human Services (HHS), is investigating a similar arrangement with a pathology lab offering a per-use fee. A HHS report warned that administrative sanctions could be imposed under the Anti-Kickback Statute.

In the practice of health care, the most important goals should be patient care, wellness and safety. The use of specific procedures and their potential to help the patient should be viewed primarily from a perspective of benefit to the patient and only secondarily as a financial benefit to the provider. Unsubstantiated benefit claims as well as pre-configured agreements with manufacturers which improve the provider's bottom line at the expense of the patient and/or third party payer, will undoubtedly result, at a minimum, in an appearance of a conflict of interest if not an outright conflict. Federal and state laws are enacted to protect the health care consumer from fraud and abuse by providers. Although it is good business practice to negotiate agreements with suppliers on behalf of our patients to enable us to provide high quality hearing healthcare, we must make sure that all professional interactions with patients, suppliers, federal and state agencies and others are first and foremost established to benefit the patient. 