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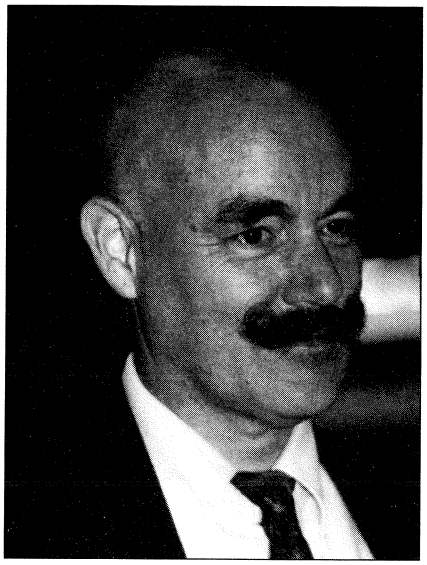

The Adverse Side Effects of FDA's Hearing Aid Proscriptions

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In a recent letter, FDA instructed a hearing aid company that it could not send out reprints of scientific articles published in a leading peer-reviewed audiology journal. The FDA letter stated: "These articles cannot be disseminate [sic] by you at this time. They became [sic] part of your labeling once you distribute them and no claims related to subject performance in background noise have been approved for [your] circuitry at this time."

This ruling is part of a series of FDA actions to regulate the hearing aid industry. According to FDA, scientific articles, peer reviewed for scientific accuracy and published in scholarly, prestigious journals, may now be considered unauthorized labeling unless they pass an additional FDA review. In addition, all hearing aid–fitting software must now be submitted to FDA for approval.

Any claim that a hearing aid can help its wearer hear more clearly in the presence of noise is judged in advance to be misleading. The most recent "Hearing Aids Proposed Clinical Protocol" (undated FDA mailing received March 15, 1994) states: "... FDA finds that misleading claims in labeling are in violation of FDA statutes. An example is the implication that ... the manufacturer's hearing aid will 'deliver speech clarity in the presence of excessive background noise.' " FDA has taken this position despite extensive scientific evidence that almost any modern hearing aid will provide some improvement in clarity, and evidence that the better modern hearing aids, properly fitted, can provide a major improvement in the wearer's ability to understand speech in the presence of noise. FDA's position has no known scientific basis.

How did we arrive at this state of affairs? FDA has created a number of arbitrary and insufficiently justified policies in a well-meaning attempt to restrain misleading hearing aid advertising.

For example, TV ads for hearing aids have claimed that electronic circuits could filter out noise their purchasers didn't want to hear and simultaneously clarify the speech they did want to hear. In fact, no hearing aid circuit can do that (although recently developed hearing aids with detachable microphones or directional microphones can accomplish an equivalent result in many cases).

The FDA response to misleading advertising is akin to using an atomic bomb to kill urban rats.

As a result of these ads, many people—especially older citizens who rely on TV ads for information—purchased hearing aids with which they were extremely dissatisfied. Although in many cases they had the right to return the hearing aids for a refund, they either did not understand that or did not exercise the right because they were unwilling to confront a forceful salesman.

Although the Federal Trade Commission has the authority to restrain false and misleading advertising, FDA has instead attempted to rectify the problem with draconian policy changes, such as the rulings cited above. But these policies are not necessary to prevent misleading advertising (in fact, the advertising in question was stopped without their use). The FDA response is akin to using an atomic bomb to kill rats in the city. Left unchallenged, the fallout from these FDA policies will cause damage to the industry for years.

THE NEW FDA POLICIES

A number of new FDA policies regarding hearing aids will have a widespread effect throughout the industry, especially in the following areas.

Restricting the Flow of Scientific Information to Professionals. The flow of scientific information to scientists, professionals, and consumers is now subject to FDA approval. For years, each time I have given a lecture I have distributed 40 pounds or more of scientific literature to back up the concepts I explain. I have reviewed a set of my most recent handouts; according to the new FDA guidelines, distribution of 7 of the 10 reprints is clearly illegal because they describe benefits for the products I manufacture—including improving the clarity of speech in the presence of noise. Although the conclusions are well documented, it is not acceptable to FDA for me to mention benefits of products I describe.

Restricting the Flow of Information to Consumers. Although FDA has not attempted to control the practice of medicine or audiology, the agency now has suppressed effective communication between professionals and consumers. An August 11, 1993, letter to manufacturers stated: "FDA also recommends that you notify all sales representatives and dispensers of your products, in writing, that oral representations concerning unsubstantiated [as judged by FDA] performance claims may not be made."

FDA also regulates the material that professionals can give to patients. Virtually all consumer literature describing product

benefits other than the FDA-approved claim of amplifying sound has now been recalled. Pretty pictures and fluff remain.

Downgrading the Performance of the Product the Average Consumer Will Receive. FDA has in effect stated: All hearing aids are basically the same. FDA interprets any claim that a hearing aid can help a user understand speech in the presence of noise as a claim that the aid can separate speech from noise.

It is important to understand the difference between these two claims: Hearing aids that help their wearers understand speech in the presence of noise restore audibility to as much of both the speech and noise as possible in order to enable the brain to sort out the speech from the noise.

That approach works; it is how people without hearing impairments process speech in the presence of noise. The attempt to filter out noise doesn't work. Crucial speech information is filtered out at the same time, and the brain is left starved for the information needed to separate speech from noise.

FDA's primary concern in this matter is stated to be whether the device helps users distinguish speech in the presence of noise. The irony is that, by denying manufacturers the right to supply scientific information to consumers, and substituting misleading information in its public announcements (such as FDA Commissioner David Kessler's televised statements indicating that all hearing aids are basically the same), FDA's ruling effectively promotes the lowest-common-denominator hearing aids—those that don't help distinquish speech from noise. Manufacturers and audiology professionals are effectively prohibited from demonstrating with existing scientific evidence that there is a difference among hearing aids.

Discouraging Design Innovation and Improvement. A corollary to the above ruling is that it will take at least a year before manufacturers are permitted to tell the world about the benefits of any new hearing aid development: six months for the required clinical research trials and six or more months for the average, delayed FDA approval (should the promotion of a particular benefit be approved). Such delays may be necessary when approving life-and-death drugs, but they dampen manufacturers' enthusiasm for risking R&D capital in the field of hearing improvement.

The problem will become exacerbated if the proposed new user-fee structure for device approvals is ratified by Congress: A simple 510(k) application for a hearing aid will cost $3200, a PMA supplement with clinical data $7100, and a full PMA $52,000. What's more, recent FDA guidelines indicate that virtually any significant design or software change may require submission of a 510(k). These combined factors increase the already high pressure on manufacturers to stick with older, FDA-approved, lowest-common-denominator devices or products.

My own company provides a case in point. Nine years ago, as a fledgling company, we developed an insert earphone to test hearing, to replace a 40-year-old headphone design in use at the time. We obtained a major order for the new earphones just in time to keep us alive. Such earphones were considered accessories and were not regulated by FDA at the time, so we could start shipping almost immediately. That audiometric earphone has since become a standard in many testing applications in the United States and Europe, and we have introduced other innovative products that are widely recognized in the international scientific community as having made a significant contribution to hearing improvements.

The FDA position effectively discards all previous research as irrelevant.

Nine years ago, my company had only three months of start-up capital left. A recent 510(k) submission took two months to prepare and another six to be approved. Given those timing considerations, it is reasonable to conclude that had we been required to submit a 510(k) for the earphone, we would have had to shut down our operations. Although our international sales now rival our U.S. sales, we would have become one more FDA casualty in the high-technology balance-of-trade effort.

Rejecting All Past Research. In order to stand a reasonable likelihood of obtaining FDA approval for a benefit claim, a hearing aid manufacturer must submit findings based on a minimum of two new clinical studies that follow a proposed FDA research protocol. FDA bases its judgments on whatever new knowledge comes from those studies; its approval process is blind to the decades of scholarly research that preceded them. Claims for benefits to the wearer that flow naturally and inevitably from improved electroacoustic performance will not be considered valid even if based on thousands of hours of prior scholarly research.

The FDA position—that the only claim that can be made for a hearing aid not backed by FDA-approved clinical trials is that it amplifies sound—effectively discards all previous hearing aid research as irrelevant.

Dictating Research Protocols. A reading of the previously mentioned "Hearing Aids Proposed Clinical Protocol" suggests that its authors are more familiar with the requirements of medical device–oriented statistical designs than with those of good hearing aid research.

For instance, one of the many questionable requirements in the FDA protocol for hearing aid research is the one for double-blind studies. The only apparent explanation for this requirement is that it is a rote transfer from drug research, where the placebo effect may be stronger than that of the medication. However, there is no evidence that a positive mental state in a hearing-impaired individual will enable that individual to score significantly higher on a speech recognition test in the presence of noise. Any such effect, if it exists, is at best a weak second-order effect. The first-order effect introduced by the double-blind requirement in hearing aid research is that the experimenter will be unable to interact properly with the subject to adjust the hearing aid to the level of maximum performance.

DO WE COME OUT AHEAD?

There is no question that FDA has been successful in halting misleading advertising. The side effects of the present FDA proscriptions are severe, however. I propose that FDA modify its approach to regulating the hearing aid industry, in the following manner:

1. FDA should not restrict the distribution of scientific reprints. Substituting the judgment of FDA staff members for that of the

scientific review process makes little sense. Prohibiting the distribution of material already published by independent, ethical, peer-reviewed journals is unwarranted interference in the free exchange of ideas.

2. FDA should not restrict the distribution of computer software for fitting hearing aids or for audiometric equipment. The audiology professional is capable of deciding whether audiometric testing or fitting software is suitable to his or her needs. FDA involvement needlessly ties the hands of the professional and slows new-test development.

3. FDA should leave the design of research protocols up to those doing the research. To my knowledge, no study in the history of hearing research has been performed with a protocol similar to the one proposed by FDA.

4. FDA should consult with prominent hearing scientists and then issue corrected consumer information, to partially undo the damage done by its own inaccurate statements. Consumers trust FDA. This trust carries a heavy responsibility for accuracy.

5. FDA should not require prior approval for advertising. FDA—along with the Federal Trade Commission—should instead maintain normal surveillance over accuracy in advertising. Requiring prior approval for advertising delays the dissemination of timely, accurate information. Companies should keep solid evidence in company files to support any advertising claims. FDA should not delay manufacturers' capacity to provide new-design information to the public.

6. FDA should not censor statements of scientific conclusions used in advertising, such as the following: "The research of Smith and Jones (1991) indicates that, for individuals with moderate-to-severe hearing loss, the ——hearing aid typically provides a significant improvement in understanding speech in the presence of high-level noise." It is either true or false that Smith and Jones published this conclusion.

7. When there is disagreement between a company and FDA on a scientific issue, a high-level scientific review board should be available to arbitrate. (I recommend the use of present or former university deans or directors of hearing-research programs.)

8. FDA should study ways to ease the present pressures that discourage design innovation.

9. FDA should stop regulating no-risk consumer devices such as hearing aids. In my view, such a step would greatly benefit the hearing-impaired consumer.

10. If FDA wishes to take a useful, active role, it should prohibit home-visit hearing aid sales without express request (for example, from an invalid who is unable to travel). Anecdotal evidence indicates that many of the hearing aids left unused in dresser drawers were purchased as a result of such sales calls.

In sum, the proposed FDA regulations are repressive and too high a price to pay to stop a few unethical hearing aid advertisements, especially when such advertisements can easily be stopped directly. ■