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RE: FDA Dockets 2003P-0362; Comments in Opposition to Citizen Petition

The Hearing Industries Association (HIA) is the organization of companies that manufacture hearing aid devices and components. HIA members produce more than 90 percent of all hearing aids sold in the United States, and the Association has been long committed to providing consumers with quality devices that will improve health and enhance consumer well being. As producers of regulated devices, we work closely with the Food and Drug Administration (FDA) to ensure the safety and efficacy of our products.

The HIA is submitting these comments to express its opposition to the citizen petition submitted by Mead C. Killion, Ph.D., of Etymotic Research, Inc. (2003P-0362). The Killion Petition requests that the Commissioner of the FDA create a new over-the-counter (OTC) hearing aid classification that would allow OTC sales of hearing aids that meet safety and efficacy requirements established by rule.

Hearing Aid Distribution Channel is Not the Issue

HIA agrees wholeheartedly with Dr. Killion that hearing aids are underutilized by the population that could benefit from their use. Virtually every means of measurement confirms that only about 22 percent¹ of people who could benefit from hearing aids actually use them, and that percentage has not changed despite decades of improved design, comfort and performance. It must be noted, however, that there is no evidence that the current distribution method is a primary obstacle to hearing aid sales and use, and this method has been examined, studied and debated by those in the hearing health industry as well as by FDA for more than 30 years. It is also instructive that hearing aid use is not significantly greater in countries where the government subsidizes the cost or provides hearing aids free of charge. In Scandinavia, for example, digital hearing aids are dispensed at no cost to consumers as part of Scandinavian national health plans, yet the available information indicates that there is no significant difference in hearing aid use.

¹ MarkeTrak VI, The US Hearing Instrument Market, The VA and Direct Mail Sales Spark Growth in Hearing Aid Market, by Sergei Kochkin, Ph.D., *The Hearing Review*, December 2001, pp. 16-24, 63-65.

2003P-0362

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As indicated in the MarkeTrak surveys of the U.S. hearing aid market, major barriers to hearing aid usage include the stigma and embarrassment related to wearing hearing aids, negative attitudes towards hearing aid value, a belief that hearing loss does not seriously disrupt a consumer's daily life and costs related to hearing aid purchase.² Of critical relevance to the Killion petition, however, are the findings of HIA in surveys over the years that the *lack* of a medical referral in many situations is the single most important barrier to hearing aid use, as some consumers do not have the confidence to make such a major health related decision without a referral from their physician.

HIA believes that a diagnostic evaluation is an important step in assessing the etiology of hearing loss. Therefore, HIA believes that to eliminate the current medical referral requirement -- or the informed consumer waiver of that requirement -- by creating an OTC hearing aid classification would further erode confidence in hearing aid devices among some consumers and create confusion in others. It could also, unintentionally, create problems for individuals who would be disappointed with an improperly selected OTC hearing aid and who would likely disregard the potential benefits of professionally dispensed custom hearing aids after such an experience.

Hearing Aid Cost Concerns Can be Better Addressed in Other Ways

Hearing aids are, as the Killion petition points out, expensive, custom-manufactured medical devices. Further, at the present time, there is little assistance available to people who need hearing aids but cannot afford them. Indeed, less than 30 percent³ of hearing aid purchases include any third-party payment assistance. HIA acknowledges that OTC hearing aid sales would likely reduce the cost of hearing aid devices to some consumers. HIA does not, however, believe that this action is the best way to address hearing aid cost concerns which are listed as just one of the barriers to purchase by between 30-40 percent of potential hearing aid users.⁴

In fact, for those consumers who consider cost to be a barrier to hearing aid purchase, the opportunity already exists to purchase hearing aids through the mail or through website sales channels. These distribution networks provide a generally lower cost alternative for people with hearing losses, but many still rely on professional assistance to fit the device, although they may waive the medical exam requirement. According to MarkeTrak studies of the US Hearing Instrument Market, the percentage of hearing aids purchased through the mail was 3.5 percent in 2000.⁵ Indeed, the explosion of internet hearing aid related sites has not been shown to have increased the percentage of hearing aids purchased without direct professional involvement from the outset.

² MarkeTrak IV, The US Hearing instrument Market, Correlates of Hearing Aid Purchase Intent, by Sergei Kochkin, Ph.D. *Hearing Journal*, Vol. 51(1), January 1998, pp. 30-41, and MarkeTrak III, Why 20 Million in US Don't Use Hearing Aids for Their Hearing Loss, *Hearing Journal*, 46(1)20-27; 46(2):26-31; 46(4):36-37, 1993.

³ MarkeTrak VI, The US Hearing Instrument Market, The VA and Direct Mail Sales Spark Growth in Hearing Aid Market, by Sergei Kochkin, Ph.D., *The Hearing Review*, December 2001, pp. 16-24, 63-65.

⁴ MarkeTrak IV, The US Hearing instrument Market, Correlates of Hearing Aid Purchase Intent, by Sergei Kochkin, Ph.D. *Hearing Journal*, Vol. 51(1), January 1998, pp. 30-41, and MarkeTrak III, Why 20 Million in US Don't Use Hearing Aids for Their Hearing Loss, *Hearing Journal*, 46(1)20-27; 46(2):26-31; 46(4):36-37, 1993.

⁵ MarkeTrak VI, The US Hearing Instrument Market, by Sergei Kochkin, Ph.D., The VA and Direct Mail Sales Spark Growth in Hearing Aid Market, *The Hearing Review*, December 2001, pp. 16-24, 63-65.

HIA and many of the major hearing health associations are addressing cost issues through the support of H.R. 3103, the Hearing Aid Assistance Tax Credit Act sponsored by Rep. Jim Ryun (KS-2) and currently co-sponsored by 35 other Representatives, and a companion bill in the Senate, S. 2055, sponsored by Senator Norm Coleman (MN). The bills provide for a \$500 tax credit towards the purchase of a hearing aid for those who are 55 and older or 18 and younger. The credit would be for \$1,000 if two hearing aids were purchased. HIA believes that cost issues can be better addressed by focusing on such tax credits or insurance issues than by permitting OTC sales as proposed in the Killion petition.

Do No Harm

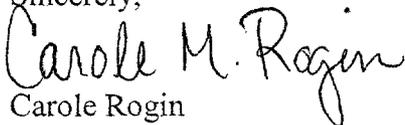
HIA also notes that comparisons have been made between the sale of glasses and the sale of hearing aids. We do not believe that this comparison is valid, however, given that the etiology of a hearing loss is often more complex than that of a vision loss. The analogy between hearing loss and presbyopia (far-sightedness requiring reading glasses) is misleading. People with sensorineural hearing loss have damage to their sensory end-organ – the cochlear – whereas people requiring reading glasses have a damaged mechanical system (the lens). The perceptual problems that may be associated with hearing loss cannot be addressed with mere amplification; mechanical vision problems can.

Hearing aids and reading glasses are also different in their practical use by consumers. Hearing aids are inserted into the ear canal, while glasses are simply applied to the body. Indeed, contact lenses which are inserted into the body appropriately require evaluation and fitting by a professional as do hearing aids. As the benefit of reading glasses is immediate, the consumer can decide at the time of purchase if a particular pair may be beneficial. As a result, reading glasses can be sold over the counter at a substantially lower price than glasses dispensed at an optician's or an optometrist's office. FDA regulation and professional practice recognize that this is not so with hearing aids.

In summary, HIA urges FDA to reject the Killion petition. The Association, its members and their clients with hearing loss have worked within the current regulatory scheme for almost 30 years. The hearing aids, dispensing practices and the consumer benefits have all flourished in this environment, and HIA urges the Agency not to change it without compelling evidence.

Thank you for this opportunity to comment on the petition. Please feel free to call me if you seek clarification of anything in this document, 703-684-5744.

Sincerely,



Carole Rogin
Executive Director
Hearing Industries Association