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January 26, 2004

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Dockets 2003-P-0362, 2003-P-0363

To Whom It May Concern:

The Academy of Dispensing Audiologists (ADA) requests that the following two Citizens Petitions be denied:

1. **FDA docket # 2003-P-0362**, "Petition to Create a New OTC Hearing Aid Classification that Grants OTC Sales, Distribution and Use Status to One-Size-Fits-Most Hearing Aid Devices", proposed by Mead Killion, President, Etymotic Research, Inc.

2. **FDA docket number 2003-P-0363**, "Professional and Patient Labeling for Hearing Aid Devices" proposed by Gail Gudmundsen, GudHear Inc.

ADA is an organization of approximately 1200 audiologists whose current qualification for membership is limited to audiologists who have earned the Doctor of Audiology (Au.D.) degree. ADA Fellows provide diagnostic hearing examinations, hearing rehabilitation services, counseling services for hearing impaired patients and their families, hearing aid evaluations, hearing aid fittings and follow-up services as a part of their professional practices. Dispensing Audiology has evolved to its current professional level because of the value the hearing impaired consumer places on the professional component in this important rehabilitative process. To eliminate this process would be to undermine the reasoning and evidence which originally brought about the FDA Hearing Aid Regulations.

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2003P-0362 C13

Section I. Re: Gudmundsen Petition 2003-P-0363

The Academy of Dispensing Audiologists believes the Gudmundsen petition as written, DOES NOT provide sufficient protection to the consumer for the following reasons:

1. The proposed wording would remove all effective forms of consumer protection by eliminating any and all currently mandated requirements for professional (medical and/or audiological) evaluation of an individual's hearing loss.

2. There is, in fact, significant potential consumer harm from eliminating the professional component (U.S. Food & Drug Administration, 1977; Gleitman et al., 1992; Kasper et al., 1999; Chartrand, 2003; Kirkwood, December 2003).

3. The February 15, 1977 Federal Register lists seven conditions for which a medical evaluation is recommended prior to purchase of a hearing aid. The final regulation requires that the hearing aid dispenser advise the prospective user to consult promptly with a licensed physician (preferably a physician who specializes in diseases of the ear) if the dispenser observes any of the listed conditions in the prospective user" (U.S. Food & Drug Administration, 1977). One of these conditions, which is omitted from Dr. Gudmundsen's suggested language change is condition (vi) "Audiometric air-bone-gap equal to or greater than 15 decibels at 500 Hz, 1000 Hz and 2000 Hz". This finding can be determined only through a hearing evaluation. The Federal Register further states that this symptom, as well as the seven conditions that Dr. Gudmundsen lists, "would indicate a medical problem that should be diagnosed and treated." While some of the symptoms in Gudmundsen's proposed language change may be recognized by the consumer, in the absence of a hearing evaluation the consumer has no way of knowing whether the above condition exists and consequently lacks the necessary information to self-refer to a physician.

4. Gudmundsen claims that "some...advocate placing additional 'barriers' in the path toward obtaining a hearing aid" by requiring "a comprehensive audiological evaluation performed by an audiologist in addition to a medical examination". Contrary to this statement, audiologists and consumers are actively promoting HR2821 and S1647 (currently before the legislature) which have significant bipartisan sponsorship and will allow Medicare recipients direct access to the services of an audiologist without the need for a physician referral, which is already allowable in the Veterans Administration, the Office of Personnel Management and many private health insurance plans.

5. Children under the age of 18 should still be **required** to obtain both medical and audiological intervention (as under the current regulation) due to the very different nature of childhood hearing loss and its impact on speech and language development and academic progress (in addition to underlying medical conditions which are more prevalent in this age group). Merely "suggesting" that this group should follow that path is not sufficient to protect the interests of minors who cannot act on their own behalf.

Section II. Re: Killion Petition 2003-P-0362

The Academy of Dispensing Audiologists believes that the Killion Petition, as written DOES NOT provide sufficient consumer protection for the following reasons:

SAFETY

1. There is no objective research and/or data to address efficacy and safety issues with "one size fits most" or OTC hearing aids, particularly as OTC is a category of devices that has been heretofore prohibited from sale. What little historical data we do have documented concerns numerous violations and consumer risk surrounding the mail order "Crystal Ear" device. The FDA is aware of the widely criticized claims of Crystal Ear, (*HJ Report*, 1999; *HJ Report*, 2002), and has written several warning letters about the company's marketing practices. The jury acquitted Crystal Ear on August 7, 2002 on criminal charges of fraud and false representation. However, post-trial comments by the prosecutor predicted what might happen on a much wider and potentially more devastating scale, should more direct purchase OTC hearing aids flood the market. These comments include: "If people purchase a Crystal Ear, they might not go to a hearing professional and, as a result, not get the help they need"; and "In some cases, the failure to see a professional could result in a consumer whose hearing loss has an underlying medical cause not having the condition diagnosed and treated" (*HJ Report,* 2002). In addition, ABC News aired a special segment on Crystal Ear, March 30, 1998, in which the company and product were portrayed negatively by unhappy users and hearing professionals (*HJ Report,* 1998).

2. *Any hearing aid inserted into the ear canal can potentially cause harm to the user.* This is especially of concern in diabetes which affects a significant number of Americans. Diabetics are at increased risk from complications of injury to the ear canal (Chartrand, 2003; Leonetti, 2004). This would also be true for patients who are taking blood-thinners such as aspirin and warfarin, which are common medical management regimes for patients over 60 years old. There is real risk of infection from abrasion (Leonetti, 2004), bleeding and wax impaction. As there are currently no requirements for reporting medical complications from the use of hearing aids, there is much anecdotal evidence, but little documented research to detail the prevalence of these conditions. Both professionals dispensing hearing aids and medical professionals who treat the complications of hearing aid use cite numerous examples of medical complications from hearing aid use (see examples in **Appendices A and B**, authors' contact information available upon request).

3. Some manufacturers, such as Songbird Hearing, Inc., are currently providing *de facto* OTC devices after attempting to sell them through professional outlets and largely failing to create a safe and effective product. This product, when it was introduced, was marketed by a very large number of audiologic practices. Nearly every professional practice has discontinued their use, not because of the low price, but because of their failure to fit comfortably in a large number of ears, ensuing medical complications and/or

failure of the consumer/patient to reorder devices. Anecdotally, the seduction of a low cost device caused consumers to be less cautious. Some patients wanted the cheap alternative hearing device to work so badly that they would attempt to wear it when their ears were abraded and bleeding. Fortunately, these consumers were under professional care which discouraged them from engaging in such risky behavior. Such would not be the case in a deregulated situation. Despite the low price of this disposable device to the consumer, the benefits simply did not outweigh the discomfort and the cost per unit. Please see **Appendix B** for a representative letter from a practitioner documenting this phenomenon.

4. The petitioner is comparing "glasses", a non-invasive externally worn device, with "hearing aids", which are inserted into the ear canal. Because of this critical distinction, these two devices have inherently different degrees of potential harm and health risk (U.S. Food & Drug Administration, 1977; Gleitman et al., 1992; Kasper et al., 1999; Chartrand, 2003; Kirkwood, December 2003). A more suitable analogy would be to compare OTC hearing aids to contact lenses which have a similar degree of invasiveness. Of note is that *current state and federal regulations limit availability of contact lenses to patients who have received prior eye examination and prescription from an eye care professional*. They are not available OTC for reasons of health and safety.

5. To disrupt the current delivery system which does protect the health and safety of the consumer, and to allow for a delivery system which has no such protection cannot be justified in the absence of formal research.

COST

1. ADA agrees that the cost of hearing aids may be a deterrent to some hearing-impaired consumers; however, a survey of 2753 non-users of hearing aids revealed that "*although one half of the respondents indicated that hearing aids are too expensive–holding this attitude did **not** appear to be related to purchase intent*" [emphasis added] (Kochkin, 1998). A recent article by Chartrand and Chartrand (2004) states that the "primary barriers to seeking help are manifold psychosocial blocks that build higher and higher over time" and that "*denial, as a psychosocial artifact of hearing loss is the primary reason why, at any price (even $0), the cost (of hearing aids) is perceived as too high for some*" [emphasis added]. Even in countries where hearing aids are provided at no cost to the consumer, hearing aid usage figures vary little from our own; and those who could benefit from hearing aids are not obtaining them (Clutterbuck, 2003).

2. There is other empirical evidence (Kirkwood, August 2003) to suggest that many non-users of hearing aids have concerns **not related to price,** and we submit that these reasons account for a significant number of hearing impaired who do not purchase hearing aids. Nonetheless, advocacy steps are being taken to increase affordability. The proposed Hearing Aid Assistance Tax Credit Act (HR3103) which is garnering bipartisan support in Congress, calls for a tax credit of up to $500 to anyone 55 years of

age or older who purchases a hearing aid.

3. Killion's statement that "professional fees often put hearing aids out of the reach of the indigent" is largely untrue. Many states' Medicaid programs pay for hearing evaluations and hearing aids for their medically indigent population. For Medicare recipients, who are by far the largest group of hearing aid candidates and wearers, there is currently coverage for medical evaluation of hearing, including the cost of an initial audiological evaluation for the purpose of establishing the diagnosis of a hearing loss. It is incumbent upon hearing aid manufacturers and our profession to continue to search for more affordable solutions -- but not by compromising the valuable professional component in our current hearing aid delivery model.

4. As a profession, audiologists are addressing additional issues of cost and accessibility in order to better insure patient satisfaction. The Medicare Audiologic Rehabilitation Act of 2003 introduced by Rep. Jay Inslee, and promoted by the American Speech, Language and Hearing Association, is proposing coverage of audiologic rehabilitation and treatment services under Medicare "so that more seniors can afford needed follow-up care for their hearing devices".

EFFICACY

ADA believes that OTC hearing devices will not provide sufficient efficacy in correcting hearing loss to counterbalance the risks of use cited above, for the following reasons:

1. Killion's proposal is centered on the common myth that "the hearing aid" will resolve the issues surrounding hearing impairment, rather than acknowledging that, unlike reading glasses, "the hearing aid" is one part of a *multi-dimensional* rehabilitation package which includes professional services critical for the acceptance, benefit and satisfaction of the consumer. For example, there has been shown to be a direct and strong correlation between the satisfaction rate of hearing aid users and the amount of professional counseling provided (Kochkin, 2002). Chartrand and Chartrand (2004) point out that "no hearing-impaired person can obtain the value-added (rehabilitation) services outside the legitimate hearing aid delivery system. Attempting a do-it-yourself approach is a formula for certain failure".

2. Killion cites the 2000 Kochkin article which claims that 20% of hearing aids end up unused in dresser drawers. But an updated 2001 report by the same author states that there are (increasingly) "fewer in-the-drawer aids (11.7% in 2000 vs. 16.2% in 1997)" (Kochkin, 2001). We believe this is a result of improved quality and better patient care as consumers move away from the more traditional retail hearing aid store model (28.8%) to the care of an audiologist (65%) who can provide the necessary and more comprehensive rehabilitative services.

3. It is also impossible to conceive of the idea that the consumer could use any hearing aid

without requiring any follow-up service whatsoever. The gamut of potential pitfalls includes dealing with raw, sore, or bleeding ears from poor fit, wax impactions from jamming a hearing aid into the cerumen of the ear canal, wax and debris plugging up the hearing aid rendering it unusable and unserviceable by consumer-friendly measures, squealing hearing aids from poor fit or earwax in the ear canal. These and a myriad of other problems are dealt with in hearing professionals' offices on a daily basis. These problems can neither be addressed nor resolved through an over-the-counter sales model. But, there is evidence it will serve to further perpetuate the notion that "Hearing aids don't work", and ultimately dissuade the consumer from pursuing any further assistance. (Appendix C)

4. The petitioner's comparison of a hearing aid to "reading glasses" is simplistic and faulty. First, reading glasses are an effective entry-level corrective device designed to accommodate presbyopia, which is considered a fairly straightforward and easily treated condition, and they can often entirely alleviate this type of visual deficiency. More challenging visual refractive conditions, e.g., astigmatism, myopia, need for bifocals or trifocals, require the consumer to see a vision specialist for an evaluation, recommendation and treatment. This is also the case for the provision of ALL contact lenses. It is clear that consumers and eye professionals alike recognize that a professional component is necessary at some point.

   Second, the majority of visual problems are the results of ocular-muscular or refractory defects which are truly "correctable", (with contacts or lenses). With the exception of the 5% hearing loss which is conductive in nature and may be treated medically or surgically, there is no such thing as resolving/completely correcting, or "normalizing" a hearing loss with a hearing aid either in the early stages of hearing loss, or in more advanced cases. The vast majority of adult hearing losses involve defective sensory and/or neural systems with infinitely more complexities and limitations. Consequently, the consumer's expectations, and the psychological impact of post hearing aid fitting results that will not achieve "20/20", can only be addressed by a professional competent in these issues through counseling and auditory rehabilitation training and experience (Abrams, 1992; Kaplan et al., 1997; Chartrand & Chartrand, 2004).

   Clearly, providing significant help for a hearing problem demands much more than simply "sticking a hearing aid in the ear". This is in stark contrast to "putting on reading glasses". The critical nature of follow-up rehabilitative services is widely recognized by consumers and professionals as an important component in hearing aid benefit and continued use (Abrams, 1992; Kaplan et al., 1997; Chartrand & Chartrand, 2004).

   Finally, Killion proposes that OTC hearing aids be permitted with a range up to 115 dB SPL. This upper limit encompasses the prescriptive requirements of almost all hearing-impaired patients, including those with very severe hearing losses. It is far beyond the SPL limit needed for the "starter" devices described by Killion. To continue with the optical analogy, OTC reading glasses are only currently available for a very *limited* range of ophthalmic disorders. With hearing loss, as the impairment worsens, the need for

professional intervention and assistance increases dramatically. With more severely impaired patients the challenge in providing effective correction becomes much greater, as do the psychosocial complications from the associated hearing loss.

As an organization of actively practicing doctors of audiology, ADA has given careful consideration to the petitions as put forth by Killion and Gudmundsen in the context of costs to the hearing impaired consumer, and in terms of safety and the efficacy of the proposed OTC distribution model.

In view of available evidence, we respectfully request that both of these petitions be denied in their current forms as they expose the consumer to significant health and safety risks. There are no objective studies which currently justify the passage of either proposal; and it is our belief that the consumer's health and safety are best served by preserving the requirement for a professional component to hearing aid fittings which includes medical or (preferably) audiological evaluation prior to purchase of a hearing aid.

Respectfully submitted on behalf of the Academy of Dispensing Audiologists,

Cynthia Ellison, Au.D.
President
Academy of Dispensing Audiologists