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Food and Drug Administration
Dockets Management Branch
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Re: FDA Dockets 2003P-0362 and 2003P-0363; Comments in Support of Citizen Petitions

Dear Sir or Madam:

The undersigned submits the following comments under 21 C.F.R. § 10.30(d) in support of the citizen petitions submitted by Mead C. Killion, Ph.D., of Etymotic Research, Inc. (2003P-0362) ("Killion Petition") and Gail Gudmundsen, Au.D., of GudHear, Inc. (2003P-0363) ("Gudmundsen Petition").

I. INTRODUCTION

The Killion Petition requests that the Commissioner of the Food and Drug Administration ("FDA" or the "Agency") create a new over-the-counter ("OTC") hearing aid classification that would allow OTC sale of hearing aids that meet safety and efficacy requirements established by rule.

The Gudmundsen Petition requests that the Commissioner of FDA revise the hearing aid regulations by revoking 21 C.F.R. § 801.421 in its entirety, revoking references to 21 C.F.R. § 801.421 in 21 C.F.R. § 801.420, and replacing 21 C.F.R. § 801.420(c)(3) with new language proposed in the petition. The effect of these changes would be to remove the current requirement of a medical evaluation within six months prior to sale, or, for adults, a knowing waiver of such an examination, as a condition for sale of hearing aids.

We support the Killion and Gudmundsen Petitions because the actions requested would confirm that the direct sale of hearing aids is permissible under

2003P-0363

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FDA regulations. It should also be noted, however, that we believe that direct-to-consumer sale of hearing aids is consistent with the existing regulations, provided that the conditions of sale set forth in 21 C.F.R. §§ 801.420-421 are met. The three principal conditions are: (1) medical examination within six months prior to the sale or, for adults, a knowing waiver of such an examination; (2) provision by the manufacturer of a User Information Brochure ("UIB") that contains specified warnings and notices for both dispensers and users; and (3) an opportunity for the consumer to review the UIB prior to sale. While each of these requirements can be satisfied by direct sale, to remove any ambiguities and as discussed further below, granting the two petitions at issue would benefit patients by making sophisticated, low-cost hearing aids more readily available, without adding any significant health risk.

II. PUBLIC HEALTH CONSIDERATIONS FAVOR DIRECT-TO-CONSUMER HEARING AID SALES AND GRANTING THE KILLION AND GUDMUNDSEN PETITIONS WILL CONFIRM THE APPROPRIATENESS OF SUCH SALES

There are strong public health reasons that favor the direct sale of hearing aids. Ample data demonstrate, as summarized below, that the majority of U.S. residents with hearing impairment do not use hearing aids. Moreover, there also are ample data to demonstrate that hearing impairment substantially diminishes work and social functioning. Thus, greater availability of hearing aids presents the potential for significant public health benefits.

The underutilization of hearing aids has been recognized by medical associations, FDA, and by Congress. For example, in testimony before the U.S. Senate Special Committee on Aging in 1993, the President of the American Speech-Language-Hearing Association ("ASHA") asserted that "[h]earing aids can help millions of people who do not currently use them." ^{1/} Recent data show that 28 million Americans are hard of hearing. This number increased by 1.4 million

^{1/} The Hearing Aid Marketplace: Is the Consumer Adequately Protected? Hearing Before the Special Committee on Aging of the Senate, 103d Cong., 1st Sess. 94 (1993) (statement of Thomas J. O'Toole, Ed.D., President, American Speech-Language-Hearing Association).

between 1997 and 2000. 2/ Of those with hearing loss, older persons are disproportionately affected. 3/ Although those aged 65 and over make up only 12.8 percent of the U.S. population, they account for roughly 37 percent of all hearing impaired individuals. 4/ Moreover, as the U.S. population grows older, these numbers will most likely continue to grow. Reports already indicate a significant increase in hearing loss in those aged between 45 and 65. 5/ "In fact, in absolute numbers, there are more "baby boomers" with a hearing loss – 10 million – than there are people over the age of 65 with a hearing loss – 9 million...." 6/ As this age group enters senior citizen status, the demand for affordable hearing aids likely will increase dramatically.

Of the 28 million people affected by hearing loss 22.3 million do not own or otherwise have a hearing aid. 7/ Specifically, according to data collected by ASHA, 3 out of 5 older Americans with hearing loss and 6 out of 7 middle-aged Americans with hearing loss do not use hearing aids. 8/ The effects of hearing

2/ See, Only one in five owns a hearing aid, at <http://www.hear-it.org> (last visited June 17, 2003).

3/ For example, 4.6% of individuals between the ages of 18 and 44 have hearing loss; 14% of individuals between the ages of 45 and 65 have hearing loss; and 54% of the population over age 65 has hearing loss. See *Id.*

4/ Mayur Desai, et. al., U.S. Centers for Disease Control and Prevention, National Center for Health Statistics, Trends in Vision and Hearing Among Older Americans, Aging Trends No. 2 (2001).

5/ See, Francesca Lyman, Many boomers facing 'premature' hearing loss, available at <http://msnbc.com/news/622315.asp?cp1=1> (last visited June 17, 2003).

6/ *Id.*

7/ See, Only one in five owns a hearing aid, at <http://www.hear-it.org> (last visited June 17, 2003). Of the 5 million Americans that do own hearing aids, nearly one million don't wear them. (we've changed our website) See, American Speech-Language-Hearing Association, The prevalence and Incidence of Hearing Loss in Adults at http://www.asha.org/public/hearing/disorders/prevalence_adults.htm (*citing* Better Hearing Institute (1999). Facts about hearing disorders).

8/ See, American Speech-Language-Hearing Association, The prevalence and Incidence of Hearing Loss in Adults at

impairment on patients' functioning have been widely reported in the literature. 9/10/ Moreover, the benefits afforded by hearing aid use have been documented to be dramatic. 11/.

One of the main reasons cited for the underutilization of hearing aids is that the cost of hearing aids is too high. 12/ Currently, hearing aids cost between \$750 and \$3,500 per device, depending on the type and number of features. However, these costs are exacerbated by numerous factors such as maintenance costs. Moreover, the cost of cleaning, repairs, and other hearing aid adjustments can reach over \$150.00 per service, and hearing aid batteries must be replaced approximately weekly, adding further costs. Medicare presently covers none of these costs. Thus, in the 10 years since Congress last held hearings on these issues, not only has the U.S. population grown, so too has the number of hearing impaired Americans and the need for affordable hearing aids – and all data indicate that these trends will continue.

In addition to the cost of the equipment itself, the hearing aid evaluation process entails significant costs for the potential purchaser. Debate about the optimal evaluation for a potential hearing aid user has been ongoing since FDA's hearing aid regulations were promulgated in 1977, although the requirement for a physician's evaluation or waiver remains unchanged. Two principal reasons have been presented for continuing to require the involvement of physicians (or other healthcare professionals) in the hearing aid sale: (1) to prevent elderly

http://www.asha.org/hearing/disorders/prevalence_adults.cfm (*citing* Kochin, S. & Rogin, C., Quantifying the obvious: The impact of hearing instruments on the quality of life, *The Hearing Review*, 7(1), 6-35 (2000)).

9/ National Council on the Aging: The consequences of untreated hearing loss in older persons: Summary. Washington, DC: NCOA, May (1999).

10/ Kramer SE, Kapteyn TS, Kuik DJ, Deeg DJ (2002). The association of hearing impairment and chronic diseases with psychosocial health status in older age. *J Aging Health*, 14(1): 122-37.

11/ National Council on the Aging: The consequences of untreated hearing loss in older persons: Summary. Washington, DC: NCOA, May (1999).

12/ *Id.* (*citing* Weinstein, B.E., Treatment efficacy: Hearing aids in the management of hearing loss in adults, *Journal of Speech and Hearing Research*, 39, S37-S45 (1996)).

consumers from being pressured into buying costly hearing aids they do not truly need; and (2) to prevent a potentially treatable cause of hearing loss from being missed. Neither of these concerns justifies preventing a proportion of the 20 million Americans in need of hearing aids from obtaining the technologically advanced, low-cost hearing instruments manufacturers now seek to make available through direct-to-consumer channels.

Regarding cost, much testimony in the 1993 Senate Special Committee hearings focused on the high cost of hearing aids. As noted above, costs for hearing aids can range up to several thousand dollars per device.^{13/} It is, thus, quite understandable that legislators placed a high priority on protecting elderly, fixed-income consumers from unnecessary expenditures of this magnitude. The risk/benefit ratio of investing in hearing aids, however, no longer favors the same level of caution based solely on price. As manufacturers now may offer reasonably priced hearing aids for direct sale the potential benefit a hard-of-hearing person may gain from the purchase of hearing instruments substantially outweighs the financial risk.

Many patients already have decided that the benefits of mail order hearing aids outweigh the risks, and internet-savvy consumers are reaching the same conclusion. ^{14/} In response to FDA's proposed rulemaking contemplating banning mail order sales, many consumers wrote to the agency to describe their satisfaction with mail order products, and urging that the right to purchase hearing aids through the mail not be revoked. ^{15/} One consumer commented that she could not afford to purchase hearing aids through traditional channels: "As a retiree and living on a very limited income, I can only afford the mail order aids which are priced in the hundreds. And even that is a tight squeeze." ^{16/} But, she insisted that her lower priced instruments allowed her to function in society. Therefore, to

^{13/} Hearings, *supra* note 1 at 11 (statement of Doris H. Lomax).

^{14/} Numerous companies' websites advertise hearing aids for sale via the internet, providing evidence that internet sale of hearing aids has become widespread. *See, e.g.,* www.naturear.com; www.mildlosshearingdevice.com; www.1stdigitalhearingdevice.com.

^{15/} *See, e.g.,* Letter of Margalo Schneider to Jane Henney, M.D., March 5, 2000.

^{16/} *Id.*

this individual, the ability to buy mail order hearing aids meant “the difference . . . between living a normal life and isolation.” 17/

In addition to being more affordable, customers who purchase hearing aids through the mail can thereby avoid the pressure tactics sometimes exerted in face-to-face contacts between dealers and vulnerable individuals. 18/ Senator William Cohen described the typical scenario as involving door-to-door salespeople pressuring elderly consumers who could not walk away from the dealer. 19/ Senator Cohen reported cases of unsolicited home visits where dealers would either downplay the importance of the medical waiver or ignore the requirement altogether. 20/ By contrast, when potential customers consider purchasing hearing aids directly, either in a retail store or via the internet, the required information must be conveyed to each consumer, every time and this can be verified easily by consulting the point-of-sale. Customers would always be advised that a medical evaluation is in their best interest, and they would be offered the opportunity to sign a waiver before proceeding with the transaction. Consumers purchasing hearing aids directly would always be able to walk away from the transaction with the click of a mouse, or by walking to the next aisle of a store. The FTC has agreed that consumers can more easily avoid unwanted solicitations made through the mail, where they can simply not read or respond to the mailed sales literature, and it may be more difficult for consumers to extricate themselves from door-to-door sales. 21/

Another reason sometimes raised for barring direct sales is that consumers may not obtain a proper hearing aid fit without the involvement of a dispenser. These concerns, however, are alleviated by technological advances in the materials used in the outer casing of the hearing aid. While in the past it was necessary to take an earmold impression in order to provide a properly fitting hearing aid, current hearing aid technology employs a soft material tip that automatically conforms to the shape of the ear canal. Thus, the use of this material

17/ *Id.*

18/ Hearings, *supra* note 1 at 8 (statement of Senator William Cohen).

19/ *Id.*

20/ *Id.*

21/ 60 Fed. Reg. 54184 (1995).

obviates the need for a third party to take an impression of the customer's auditory canal in order to obtain a proper fit. The Killion Petition acknowledges this advance by advocating a new classification for OTC sale of "one-size-fits-most" hearing aids.

As discussed above, we believe that direct-to-consumer sales of hearing aids are permissible under current FDA regulations, and that granting the two citizen petitions at issue would serve to confirm this. We also recognize that the Killion and Gudmundsen Petitions would alter FDA policy by removing the requirement for medical evaluation or waiver. However, we believe that neither creating an OTC classification as requested by Killion, nor revising the hearing aid regulations as requested by Gudmundsen, presents any incremental health risk.

One potential argument against the instant petitions, particularly against removing the requirement for medical examination or waiver, is the same argument that has been used by opponents of direct sale of hearing aids under the current regulations: that patients thereby may be encouraged to forego a physician examination. We do not believe this is a likely result, for the following reasons. First, the substitute wording provided by Gudmundsen properly reinforces the need for such an examination under certain conditions. Second, the population of patients who may elect direct purchase of a hearing aid also may well have waived the examination if required to do so under 21 C.F.R. § 821.421. In addition, it is possible that consumers may be more amenable to medical evaluation *after* experiencing the benefit of wearing hearing aids made possible by direct-to-consumer sale. For example, some patients with longstanding loss of hearing may simply feel that nothing can be done. Patients may be encouraged to seek appropriate medical evaluation once they understand that assistance is available, and that most hearing losses can be alleviated to at least some degree. Moreover, although past criticisms of direct sale have included the potential for deferred or missed diagnosis of conditions that could be treated if medical evaluation is waived, little or no data has been cited to substantiate this concern. FDA has acknowledged that "the number of persons who will in fact require a medical or surgical treatment is relatively small in comparison to the number of individuals who may benefit from amplification." ^{22/} Authorities (including FDA) agree that only 5-10% of individuals with hearing problems have conditions that are medically or surgically treatable. ^{23/}, ^{24/}, ^{25/}. FDA recently stated that because of this low yield,

^{22/} 42 Fed. Reg. 9288 (1977).

^{23/} *Id.* at 107 (written testimony of International Hearing Society).

“[t]oday . . . there may be less of a need for medical evaluation.” ^{26/} In more than 350 pages of testimony and supporting reports for the 1993 Senate hearings, no figures were cited to document the percent of patients who waived medical examination and suffered adverse medical consequences because treatable conditions were missed, nor were any anecdotal reports of such occurrences provided. Although there was a brief reference to serious conditions that may cause hearing loss, including multiple sclerosis and AIDS,^{27/} hearing loss generally would not be the sole or the first presenting symptom for these conditions,^{28/} and having access to affordable hearing aid solutions while facing these serious conditions would serve to improve quality of life.^{29/} Acoustic nerve tumors, in which hearing loss is often a primary underlying symptom, is characterized as unilateral in nature, with poor speech discrimination, tinnitus, vertigo, headaches, and facial numbness.^{30/} A hearing aid would not be expected to “mask” these underlying symptoms, and proper labeling can direct the sufferer to these warning signs. In more common medical conditions of which hearing loss is a hallmark symptom, such as otosclerosis, hearing aids are a preferred treatment option, particularly in cases where the hearing loss is mild; surgery is recommended with more severe hearing

^{24/} *Id.* at 268 (written testimony of Lucille B. Beck, Ph.D., Associate Chief, Audiology and Speech Pathology Service, Veterans Affairs Medical Center, Washington, D.C.).

^{25/} 64 Fed. Reg. 63932 (1999).

^{26/} *Id.*

^{27/} Hearings, *supra* note 1 at 85 (statement of Jerome Goldstein, M.D., Executive Vice President, American Academy of Otolaryngology).

^{28/} See National Multiple Sclerosis Society: Hearing Loss, at <http://www.nationalmssociety.org/Sourcebook-Hearing.asp> (Last visited December 1, 2003). Center for Disease Control: “How can I tell if I’m infected with HIV? What are the symptoms?”, at <http://www.cdc.gov/hiv/pubs/faq/faq5.htm> (Last visited December 1, 2003).

^{29/} National Council on the Aging: The consequences of untreated hearing loss in older persons: Summary. Washington, DC: NCOA, May (1999).

^{30/} See Roland P: Acoustic Neuroma (Vestibular Schwannoma) at <http://www.emedicine.com/ent/topic239.htm> (Last visited December 1, 2003).

HOGAN & HARTSON L.L.P.

Food and Drug Administration

December 9, 2003

Page 9

losses.^{31/} Thus, OTC hearing aids, which are designed for individuals with mild hearing loss, would serve as an appropriate treatment option to benefit these mild otosclerosis patients, who might otherwise not seek treatment. Thus, while we agree with Gudmundsen's proposal to maintain a recommendation in 21 C.F.R. 801.420 that patients seek a medical evaluation should certain signs indicative of potential reversible pathology be present, allowing patients to purchase directly low cost hearing aids without the requirement of a medical evaluation is in the interest of the public health because the risks are low in relation to the potential benefit to the 20 million hearing impaired individuals who presently do not use hearing aids.

III. CONCLUSION

In sum, it is the position of the undersigned that many patients who would not in any case have undergone medical evaluation may experience significant improvement in social and occupational functioning if they are allowed to purchase hearing aids directly. For all the reasons discussed above, we conclude that public health considerations support allowing direct-to-consumer hearing aid sales. We support the Killion and Gudmundsen petitions because the actions requested would confirm that direct-to-consumer hearing aid sales are permissible under FDA regulations, and, therefore, would make sophisticated, low-cost hearing aids more readily available to patients who need them.

Sincerely,



Howard M. Holstein

^{31/} See National Institute on Deafness and Other Communication Disorders: Otosclerosis, at <http://www.nidcd.nih.gov/health/hearing/otosclerosis.asp#6> (Last visited December 1, 2003).