

# AMERICAN ACADEMY OF AUDIOLOGY

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January 21, 2004

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

Re: Dockets 03P-0362 and 03P-0363

Dear Sir or Madam:

I am writing on behalf of the American Academy of Audiology (hereafter, the Academy) in response to Citizen Petitions 03P-0362 submitted by Etymotic Research, Inc. (Etymotic Research) and 03P-0363 submitted by GudHear, Inc. (Gudhear). The Academy is the professional organization representing over 9,000 audiologists in the United States who diagnose and provide audiologic treatment for hearing loss including the selection, fitting, and management of hearing aids and other amplification devices. The Academy is dedicated to the advancement of techniques and methods of evaluating the need for amplification, as well as the appropriate selection, fitting, and management methods for hearing instruments as part of a well-developed continuum of rehabilitative care for those individuals with hearing loss.

The GudHear Petition urges the Food and Drug Administration (FDA) to revoke the current requirement that individuals undergo a medical evaluation prior to purchasing a hearing aid. The Etymotic Research Petition requests that the FDA permit hearing aids to be sold over-the-counter (OTC). Thus, if granted, both Citizen Petitions would have the effect of allowing consumers to purchase hearing aids without first undergoing an evaluation by a qualified and licensed

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2003P-0363

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hearing care professional. Although the Academy can find some merit in certain arguments of both petitions, taken together, the synergistic effect of granting both could lead to widespread confusion and abuse that prompted the initial FDA regulations in the 1970s. As discussed below, the Academy does not believe that this would be in the best interest of public health, and, as such, we respectfully request that FDA deny both Citizen Petitions.

**I. The GudHear Petition Should be denied, and the Requirement For a Medical Evaluation Should be Amended to Include a Comprehensive Audiological Assessment Performed by an Audiologist Prior To Obtaining a Hearing Aid.**

Pursuant to current FDA regulations, an individual may not purchase a hearing aid without present[ing] to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid.<sup>1</sup>

In over 80-95 percent of cases, hearing loss is not treatable by medical or surgical intervention.<sup>2</sup> This brings into question the necessity for a pre-purchase medical evaluation, as also argued in the GudHear Petition. Although the GudHear Petition may have merit in this regard, the Academy is not in favor of the elimination of prepurchase hearing health care. Instead, the Academy strongly believes that every person seeking treatment of a hearing disorder through the use of a hearing aid should be evaluated by a licensed audiologist prior to obtaining a hearing aid. The accurate assessment of hearing provides the basis and starting point from which most decisions regarding medical, surgical, or audiological treatment begin. Thus, the Academy continues to support comments<sup>3</sup> submitted to FDA in 1994, in response to the agency's Advanced Notice of Proposed Rulemaking addressing federal hearing aid requirements<sup>4</sup>, stating that the

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<sup>1</sup> 21 C.F.R. § 801.421(a) (emphasis added). Under certain circumstances, the medical evaluation requirement may be waived. *Id.*

<sup>2</sup> Bratt G, Freeman B, Hall JW, Windmill I. 1996. The audiologist as an entry point to healthcare: Models and perspectives. *Seminars in Hearing*, 17:227-234.

Yaremchuk K, Schmidt J, Dickson L. 1990. Entry of the hearing impaired into the health care system. *Henry Ford Hospital Medical Journal*, 38:13-15.

<sup>3</sup> The comments were submitted by a coalition of professional organizations representing the profession of audiology, including the Academy of Dispensing Audiologists, the Academy of Rehabilitative Audiology, the American Academy of Audiology, the American Speech-Language-Hearing Association, and the Educational Audiology Association.

<sup>4</sup> See 58 Fed. Reg. 59,695 (Nov. 10, 1993).

patient is best served by undergoing a comprehensive prepurchase audiological assessment performed and interpreted by a qualified and licensed audiologist.<sup>5</sup> If the prepurchase medical evaluation is eliminated without substitution of appropriate procedures, the best interest of the public will likely be compromised.

## **II. The Etymotic Research Petition Should be Denied Because the Petitioners Have Not Demonstrated That the Public Health Can be Adequately Protected Without Requiring a Comprehensive Audiological Assessment Prior to the Purchase of a Hearing Aid.**

In the Academy's view, the Etymotic Research Petition does not demonstrate that the public health can be adequately protected without requiring a comprehensive audiological assessment prior to the purchase of a hearing aid.<sup>6</sup> As described above, the prepurchase audiological assessment provides a mechanism for identifying conditions that require medical referral and for determining if hearing aids or other amplification devices are an appropriate treatment option. Thus, in the absence of a prepurchase audiological assessment, serious medical problems may go undiagnosed. In addition, individuals for whom hearing aids are not an effective course of treatment will lack this knowledge, and, as a result, may purchase a hearing aid with the false hope that they will experience improved hearing. In such cases, the potential for psychological and financial harm is present.

The Academy is particularly concerned about the potentially negative effects on children of allowing OTC sale of hearing aids without appropriate assessment. If a parent purchases a hearing aid for his or her child without first having the child undergo a comprehensive audiological assessment to determine the underlying cause of the problem and develop an appropriate course of treatment, the developmental, educational, and social consequences for the child potentially could be serious.

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<sup>5</sup> The 1994 comments also stated that mail order hearing aids only should be permitted with proof that a prepurchase audiological assessment has been completed, and an assurance that the fitting, verification, and orientation to the hearing aid can be provided by an audiologist. The Academy continues to adhere to this position.

<sup>6</sup> It is important to note that an insistence on a prepurchase comprehensive audiological assessment places no judgment on the model for delivery of amplification devices. Should one-size-fits-all or over-the-counter hearing instruments prove one day to be safe and efficacious, nothing in the prepurchase assessment would preclude an audiologist from prescribing such technology and describing its potential advantages and disadvantages.

In the Academy's view, the Etymotic Research Petition relies on several unsupported assumptions. For example, the Petitioner assumes that hearing aids and hearing loss are equivalent to reading glasses and presbyopia, that 80% of the potential hearing aid population is underserved because of the delivery model and cost, and that the safety and efficacy of OTC hearing aids are known and acceptable. However, there is little empirical evidence to support these assumptions.

The analogy of hearing aids to reading glasses presumes that sensorineural hearing loss should be treated in a manner similar to presbyopia. That simple error of refraction is more analogous to conductive hearing loss than sensorineural hearing loss, a much more complicated sensory endorgan disorder with concomitant impact on the central auditory system. There is little evidence to suggest that simple approaches to this complex disorder will be efficacious in a manner similar to reading glasses. Further, it is unlikely that a person with sensorineural hearing loss will be able to determine benefit from OTC hearing aids prior to purchase in a manner similar to reading glasses.

In addition, one of the most important arguments of the Etymotic Research Petition is that the current model of hearing aid distribution reduces access to hearing instruments for 80 percent of those with hearing loss. The assumption is that 80 percent of those with hearing loss do not pursue amplification because of barriers relating to the dispensing model and cost. This assumption is theoretical, at best. Data suggest that most individuals with hearing loss who do not have hearing aids choose not to pursue use of amplifications for any number of reasons not relating to cost or access.<sup>7</sup> Evidence from socialized medical systems, where hearing aids are provided at no cost, shows a similar share of those who do not pursue hearing aid use.<sup>8</sup> There is little evidence to suggest that accessibility is the primary limiting influence to hearing aid acceptance.

Finally, it should be noted that virtually every state has licensure laws and business laws that govern the fitting and sale of amplification devices. These laws exist because states have independently determined that the safety and efficacy of amplification devices for consumers with hearing impairment require state protective legislation. Changing FDA regulations in the manner proposed by the Petitioners would conflict with these state regulations.

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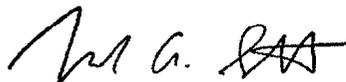
<sup>7</sup> Kotchkin S. 1998. MarkeTrak IV: Correlates of hearing aid purchase intent. *The Hearing Journal*, 51(1):30-38.

<sup>8</sup> Clutterbuck N. 2003. Public funding and hearing aid dispensing. A report from Australia. *Audiology Today*, 15(1):25-26.

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In closing, for the reasons set forth above, the Academy respectfully requests that FDA deny the aforementioned Citizen Petitions. Should the agency have any questions regarding the information presented in these comments, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "M. A. Stach". The signature is fluid and cursive, with a large initial "M" and "A".

Brad A. Stach, Ph.D.  
President