America's Hearing Healthcare Team
Dedicated to providing care for all with hearing and balance disorders.

One Prince Street
Alexandria, VA 22314-3357
Phone: 1-703-684-4292
Fax: 1-703-519-1587
Web: www.hearingteam.org
Email: mfinley@entnet.org

Sponsored by:
AMERICAN ACADEMY OF OTOLARYNGOLOGY—HEAD AND NECK SURGERY

INTERNATIONAL HEARING SOCIETY

February 11, 2004

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

Re: FDA Dockets 2003P-0362 and 2003P-0363; Comments in Opposition to Citizens Petitions

Dear Sir or Madam:

On behalf of America's Hearing Healthcare Team, we write to express strong opposition to the Citizen Petitions submitted by Mead Killion, Ph.D., of Etymotic Research, Inc. (2003P-0362) and Gail Gudmundsen, AuD., of GudHear, Inc. (2003P-0363). The Killion Petition advocates over-the-counter (OTC) sale of hearing aids. The Gudmundsen Petition calls for removal of the current requirement for a medical evaluation prior to purchase of a hearing aid. America's Hearing Healthcare Team strongly opposes both petitions because of significant patient health and safety concerns. Accordingly, we urge that the FDA deny both petitions.

Founded by the American Academy of Otolaryngology-Head and Neck Surgery and the International Hearing Society, America's Hearing Healthcare Team is a public education and awareness effort designed to raise awareness of hearing loss, its causes, its prevention and treatment/rehabilitation options. This initiative recognizes that the hearing impaired public is best served by a team approach of licensed and qualified professionals.

Hearing aids are beneficial yet dramatically underutilized devices. We agree with Petitioners that access to these efficacious devices should be maximized. However, we do not believe that the changes advocated by Petitioners would result in an increased number of Americans benefiting from amplification. Indeed, the changes proposed by Petitioners could well result in missed medical diagnoses, lost opportunities to restore residual hearing and may even result in damage to the residual hearing of the user by the use of an OTC device.

For example, Petitioner Killion advocates OTC sale of devices that could amplify sound to 115dB Sound Pressure Level. This level is 25 dB above the "safe level" for an individual's noise exposure. Indeed, Petitioner Killion himself concedes "repeated exposures above safe time-intensify limits can cause permanent hearing loss." In effect, Petitioner proposes to "assist" the hearing impaired by asking the FDA to allow OTC sales of devices that could actually damage the residual hearing of the user.

2003P-0363

C7

In order to promote access to quality hearing health care for hearing impaired Americans, all three groups of qualified and licensed dispensers of hearing aids (physicians, hearing aid specialists, and audiologists) must remain entry points into the hearing healthcare delivery system.

Importantly, Petitioners concede that some hearing loss would benefit from medical or surgical treatment. Despite this, Petitioners maintain that, because most hearing loss does not require or would not benefit from medical or surgical intervention, that no prospective adult hearing aid purchaser should be required to be professionally evaluated by a licensed hearing health professional prior to being fitted with a hearing aid. This would contravene more than thirty years of FDA regulations and conflict with state licensing laws across the country.

Counseling and rehabilitation by a licensed hearing health professional is absolutely vital in order for the user to fully benefit from the aid. Hearing aids are not analogous to eyeglasses, as Petitioners would have regulators believe. Hearing aids are complex medical devices, particularly with the advent of sophisticated digital technology. Each potential hearing aid user has not only a unique hearing loss but also a unique home and work environment in which to utilize the hearing aid. Individualized testing, fitting and counseling by a licensing hearing health professional is absolutely essential for a hearing impaired individual to obtain the maximum benefit from amplification.

Petitioners maintain that one of the main reasons for underutilization of hearing aids is their high cost and that OTC devices would increase utilization by lowering cost. Yet, even now -- in the current regulatory structure -- many lower cost hearing aid like devices are available through the internet and through mail order sales and other outlets. We have all seen the aggressive promotional campaigns that tout these products. If cost were as significant a consideration as Petitioners maintain, then many more Americans would be currently purchasing these instruments.

In reality, the fact that only 20 percent of those who could benefit from amplification actually use a device is much more complicated than Petitioners would have their readership believe. Indeed, market research has revealed far more complex reasons for this underutilization than price, including the gradual nature of hearing loss, the denial of potential users, a negative association with aging, prior use of an ineffective device, as well as unrealistic expectations.

The current regulations governing the conditions for sale of hearing aids appropriately require that all prospective hearing aid users be screened by a licensed hearing health professional (physicians, audiologists or hearing aid specialists) for treatable medical conditions, and referred to a physician (preferably one specializing in diseases of the ear), if certain "red flag" conditions (such as sudden unilateral hearing loss) are present. This important public health protection must be preserved, and is impossible to achieve in the regulatory scheme proposed by Petitioners.

America's Hearing Healthcare Team also wishes to comment on the changes advocated by one of the commenters. In their letter dated January 21, 2004, the American Academy of Audiology (AAA) advocates that all prospective hearing aid users must be seen by an audiologist and only an audiologist in order to enter the hearing health care delivery system. AAA is advancing a patently self-serving and unsubstantiated position.

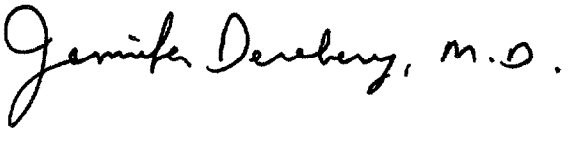
Indeed, the system advocated by AAA would impede access to hearing health care and would result in a decline in the quality of hearing health care, as well as the real probability of missed medical diagnoses. The AAA position overlooks the fact that hearing aid specialists -- who are licensed by virtually every state -- routinely administer the tests necessary to identify the red flags necessitating medical referral, conduct tests that measure hearing loss, and assist in fitting the proper hearing aid if one is required. AAA further fails to acknowledge that physicians specializing

in diseases of the ear are uniquely qualified to perform these services and that physicians rightly belong at the helm of the hearing healthcare delivery team.

America's Hearing Healthcare Team strongly believes that the changes advocated by the Petitioners would be detrimental to public health and safety, and we urge that the Citizen Petitions be dismissed. We urge the FDA to instead direct its resources to putting a stop to the persistent stream of false and misleading promotional claims made by certain mail order and Internet purveyors of hearing instruments. Despite the best efforts of Attorneys General across the country, false, misleading and deceptive claims about hearing instruments persist, which not only harm the public, but add to the negative association of the use of hearing aids.

Thank you for your consideration. Please contact Neil Ward, MD at the American Academy of Otolaryngology-Head and Neck Surgery at 703.519.1557 or Karen Sealander at McDermott, Will & Emery representing the International Hearing Society at 202.756.8024 with any questions or for further information.

Sincerely,



M. Jennifer Derebery, MD
President
American Academy of Otolaryngology—
Head and Neck Surgery

W.F. Samuel Hopmeier, BC-HIS
President
International Hearing Society

cc: Mr. Joseph Sheehan, FDA

America's Hearing Healthcare Team

One Prince Street, Alexandria, VA 22314-3357 • Phone: 1-703-684-4292 • Fax: 1-703-519-1587 • Web: www.hearingteam.org • Email: mfinley@entnet.org