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2996 '04 FEB -6 P12:16

VIA HAND DELIVERY

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

2990 '04 FEB -5 P5:1

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

Dear Sir or Madame:

The International Hearing Society (IHS) submits the following comments under 21 C.F.R. §10.30(d) in strong opposition to the Citizen Petitions submitted in August 2003 by two individual audiologists, Mead Killion, Ph.D., of Etymotic Research, Inc. (2003P-0362) and Gail Gudmundsen, Au.D., of GudHear, Inc. (2003P-0363). IHS represents the majority of licensed and certified hearing instrument specialists, and other dispensers of hearing aids, in the United States and Canada.

These petitions request that FDA withdraw, or substantially revise, its restricted device regulations for hearing aids (21 CFR §§801.420 and 801.421). Proposed changes could have the effect of allowing the sale of these Class I medical devices over-the-counter (OTC) without the need for supervision by physicians or other state licensed hearing health professionals. The primary rationale for this request is an expressed belief that the cost of these instruments would be reduced and access increased. The petitioners argue further that such changes in FDA regulations would expand utilization of hearing aids by the estimated 28 million Americans who are hearing impaired. IHS believes the proposed changes would not expand the utilization of hearing aids. We strongly **oppose** the petitions. We request FDA-CDRH to deny these petitions for the reasons explained in greater detail below.

IHS unequivocally supports the goal of encouraging more Americans to successfully use hearing devices to treat various forms of hearing loss. That is the driving mission of our association. At the same time, IHS and its members have worked together with FDA for over 30 years to insure that patients with hearing loss are properly screened, tested, and if needed, fitted with the appropriate device from which they could derive the maximum benefit. It is appealing to simplify the regulatory system. IHS has previously offered numerous proposals to FDA to do so.

The petitioners propose to place these devices on the shelves of local pharmacies and grocery stores next to the supply of reading glasses and aspirin. However, such a proposal is deceptive, simplistic and would jeopardize the public health for the reasons stated below. As discussed below, our first-hand experience in testing and fitting hearing aids indicates the following: (1) each device is dramatically different, especially now with digital v. analog technology; (2) users have very different needs; (3) a variety of cheaper listening devices is already available direct-to-consumer (DTC); (4) these DTC and mail-order devices are returned in greater percentages than custom-fit devices; (5) users require training, counseling and patience

2003P-0363 C4

to adapt properly to amplified sound; (6) market data has shown that once a cheaper listening type device is selected and discarded by a consumer, they generally do not upgrade to more advanced technology; (7) the supervision of a trained and licensed hearing health professional is important for safe use to screen for treatable medical conditions, test for extent and cause of hearing loss, and to select, fit, adjust and train the user with the appropriate device in order to achieve the best possible clinical result.

The petitioners and other commenters supporting the petition raised a number of issues upon which we comment directly below.

Position of Supporters of OTC Use	**Response of International Hearing Society**
Protections built into §801.421 can be preserved through OTC sale (e.g., advice to see a doctor, medical exams within 6 months prior to purchase, opportunity to review user information brochure (UIB) prior to sale).	Petitioner Gudmundsen concedes that these protections remain necessary. Since the petitioner concedes that a patient should still consult a physician concerning hearing loss and the use of a hearing instrument, then the device is not appropriate for non-prescription OTC sale by definition. FDA defines a prescription device as "[a] device which, because of... the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device..." (21 CFR §801.109) Before a hearing device is used, a patient requires audiometric testing to determine if an instrument is required and the level of amplification required. Likewise, all "licensed practitioners" (otolaryngologists, otologists, audiologists, hearing instrument specialists, etc.) are trained to screen a patient for "red flag" symptoms of treatable medical conditions and refer them to a medical specialist if any condition is present. Many of these professionals also prescribe, fit, adjust and train the patient in the use of the device. Without these services, the device cannot be effective and is not safe (e.g., a serious medical condition could be undiagnosed; an improperly fit device can damage hearing further, slip too deeply into the ear canal, render distracting and painful feedback, be falsely relied upon, etc.) In addition, Petitioner advocates OTC sale of devices that could amplify sound to 115dB Sound Pressure Level. This level is 25 dB above the "safe level" for individual's noise exposure. Indeed, Petitioner Killion himself

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	concedes (on p. 3) that "repeated exposures above safe time-intensity 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.
Ms. Gudmundsen additionally suggests that the buyer should be required to request the UIB which can be sent in the mail or put on a web site	Such labeling or "adequate directions for use" after the fact, if obtained at all, would not be sufficient to fulfill the requirements of 502(f)(1). The UIB must be available with the device upon purchase. It is not realistic to suggest that users would receive important use information if they were required to request it for later delivery and it did not accompany the device upon purchase.
Only 5 million of the 28 million hearing impaired individuals use hearing aids. Greater availability means greater use.	It is the goal of all hearing health professionals to encourage greater use of hearing aids by those who could benefit from amplification. We question, however, whether OTC devices would increase use significantly or improve consumer health. Generally, parties advocating a switch from Rx to OTC have the burden of producing evidence to support both their rationale for the switch and that the safe use of the device without the supervision of a licensed professional can be achieved. Cheaper hearing aids like "super hearing devices" or "listening devices" are available OTC today. There is no evidence that a significant number of consumers are using these readily available devices today. Better devices require custom fit earpieces or in-the-ear systems to work properly. Professional counseling is also essential. Without the intervention of licensed hearing health professionals, availability does not translate to safe use.
Only 5-10% of individuals with hearing loss have treatable medical conditions. Therefore, requiring a medical exam prior to purchase, or an adult waiver, is not essential.	5-10% of the 28 million Americans with hearing loss equals 1.4- 2.8 million cases that may be missed or remain undiagnosed unless these individuals are brought into the hearing health system.

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	Interest in hearing amplification devices is a major incentive for patient interaction with hearing health professionals. The system is currently structured to minimize entry barriers by allowing access and initial medical screens to be conducted by trained physicians, audiologists or hearing aid specialists. Without these screens, and subsequent referral if "red flag" symptoms are present, millions of cases of serious and/or treatable hearing loss may be missed. These patients will, instead, visit their local pharmacies and purchase a hearing aid off the shelf to treat the symptom and not the disease. Further, in some cases, hearing loss can be restored if medical intervention occurs promptly. Such ameliorative intervention would be greatly impeded if the petitions were granted.
One of the main reasons for under utilization of hearing aids is their high cost. OTC devices would increase utilization by lowering cost.	Prices for hearing aids can range from $350-$3,500, a very wide range, depending on the unit size, whether it is behind the ear, or in the ear, analogue v. digital technology, product features, testing services requested, etc. Health plans may pay some of these costs depending on a particular patient's terms of coverage. Given the potential benefit derived, these costs are no higher than any other segment in the health care market. Also, many lower cost hearing aid like devices are available now through mail order sales, electronics stores, price clubs, discount chains, and specialty shops. They are aggressively advertised and marketed. If cost was a major consideration, many more Americans would own these instruments. Market research has demonstrated much more sophisticated causes for non-use including: stigma, stubbornness, negative association with aging, unnoticed incremental loss, use of an ineffective or cheap device, poor training or adjustment, and unrealistic expectations or impatience.
Manufacturers may now offer reasonably priced aids for direct sale through mail order or otherwise.	IHS and the medical community have consistently opposed mail order sales. FDA itself acknowledged concern about mail-order sales in its ANPR and Part 15 hearings. The September 15, 1993 report of the AARP also documented improper mail-order sales and

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	opposed mail-order purchases by first-time users (Comments to FDA, Jan. 10, 1994). The basis of that opposition includes the issues discussed above; inadequate opportunity to: (1) medically screen; (2) test for need; (3) fit properly; and (4) train and counsel the user. Despite this, mail-order sales are legal in virtually all states, without any need to visit a hearing health professional. Internet, TV and consumer periodicals are filled with alluring offers to buy hearing aids directly. Prices vary from $5.95 for listening devices or super hearing devices to several thousand dollars for the latest in-the-ear canal digital adjustable models. Utilization still remains consistently low. Elderly consumers are often unable to distinguish between effective and ineffective models. Often the device shipped does not fit properly or is otherwise not appropriate for use. Customers have no product support network to counsel them on function, operation, adjustment or use.
OTC sale would avoid pressure tactics such as door-to-door solicitation.	Granting the petitions would not preclude door-to-door sales. That being said, we are unaware of any manufacturers advocating such tactics. Further, IHS operates a well-publicized consumer hotline for complaints. No complaints have been received indicating the existence of a door-to-door salesforce. The anecdotal evidence cited in one comment letter was from an unsubstantiated statement made during a 1993 hearing, more than 10 years ago. Moreover, FDA and FTC can prevent any such sales abuses, if they exist, directly under existing authority. OTC sales would have many other policy implications that render this rationale insignificant.
Technological advances obviate the need for proper fitting. Soft tips automatically conform to the shape of the ear. "One size fits most."	This argument is untrue. If anything, the wide range of instruments available today make proper fitting more important. Behind the ear models and in-the-ear-canal models are tailor made requiring accurate specifications to stay in place, and for comfort and efficient use. Some cheap "super hearing devices" come with a supply of soft rubber tips of different sizes to allow the consumer to select the tip

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	that fits best. Those tips can end up disconnected from the device and lodged in a user's ear requiring medical removal.
The hearing impaired will be more amenable to medical evaluation after an OTC device purchase.	This conclusion, which is offered by one legal commenter, is baffling. One would have to assume that a user who buys the device off-the-shelf is more likely than those who visit audiologists or hearing aid specialists to avoid seeing an otolaryngologist. In any event, the petitioner who requests the Rx-OTC switch has the burden to demonstrate that the device can be used safely without the supervision of a licensed professional. This line of argument includes no survey or other data. It also seems to imply that medical evaluation is advisable, as provided under current regulations.
A hearing aid is easier to readjust than other electronic devices; e.g., TVs, cell phones, VCRs (Aaron Thornton, Dec. 12, 2003)	That is very reassuring when we evaluate how many elderly Americans, and younger ones, are unable to successfully program numbers and voice messages on their cell phones, or time shift program recording on their VCRs. A large percentage of the time of hearing instrument specialists is spent instructing users to properly fit, adjust and use their hearing instruments.

FDA spent much of the last 10 years examining methods to standardize and improve testing protocols to determine candidacy for hearing amplification devices. FDA also advocated eliminating the medical waiver requirement contained in §801.421 because of a concern that it was being used too often. FDA has consistently stated that hearing aids should only be sold and used following a comprehensive hearing examination by a physician, preferably one specializing in diseases of the ear. IHS has worked tirelessly with the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). The two organizations have developed a screening questionnaire and checklist used by hearing health professionals to evaluate potential treatable medical conditions and make the proper medical referrals.

It would be totally inconsistent, and somewhat hypocritical, for the FDA to reverse course 180 degrees, and consider over-the-counter sales. Such action would be analogous to legalizing drugs because you can't control their use. There is no practical method in the current OTC marketplace to insure that trained professionals evaluate the use by purchasers of these products. Likewise, if the Agency still believes, as we do, that each member of the hearing health team performs an important public health function, OTC-status for hearing aids is inappropriate.

In addition, the petitioner, or commenters, must furnish detailed and specific clinical evidence to demonstrate that professional supervision is not needed to use these devices properly

and safely. We do not believe this evidence exists. Further, we believe that the minimal evidence cited by the petitioners, or commenters favoring the petitions, actually supports rejection of the petitions by substantiating the efficient functioning of the current regulations (e.g., May 1999, National Council on Aging report, p. 2, which concluded that those who use hearing aids have improved mental health, better relationships. greater independence and security, etc.).

Further, a significant body of state licensing laws would be rendered moot should the FDA take the actions advocated in the petitions. Indeed, virtually every state has laws governing both the licensing of hearing health professionals and the conditions for sale of hearing devices. Adopting the proposals in the Citizen Petitions would unnecessarily confuse the hearing impaired public and wreak havoc on state hearing health care delivery systems.

In summary, the community of hearing instrument specialists supports the current system. Hearing impaired consumers have a full range of choices, but are encouraged to see a physician before the purchase, and to seek out medical evaluation if red flag symptoms appear. It is an old, and overused, adage in Washington, D.C. that "if it ain't broke, don't fix it." Here, any proposal that would move in the direction of switching hearing aids from Rx to OTC could have a significant "ripple effect." That action could discourage medical care and reduce or eliminate essential services rendered by licensed hearing health professionals. These services are necessary in order to protect consumers, to successfully evaluate need, and to select and use the appropriate device.

Accordingly, IHS strongly urges that the aforementioned Citizen Petitions be rejected. IHS further urges that, in order to protect the hearing impaired public, FDA take regulatory action against false and misleading claims and mail order and internet sales. Proper testing and fitting by experienced professionals is required to protect all consumers, regardless of where they purchase their device. In the interest of consumer protection and consistency, FDA should enjoin these misleading promotional practices or seize the products. Despite the best efforts of numerous State Attorneys Generals who entered into two separate Assurances of Voluntary Compliance with purveyors of certain mail order amplification devices, such misleading promotional practices persist, to the detriment of the hearing impaired public.

Please contact me or our Washington Counsel, Marc Scheineson at 202/414-9243 and Karen Sealander at 202/756-8024, with any questions, or if we may be of further consideration in this matter.

Sincerely,

W.F. Samuel Hopmeier, BC-HIS
President

cc: Mr. Joseph M. Sheehan (jms@cdrh.fda.gov)

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