Hearing Loss Association of America

The Nation's Voice for People with Hearing Loss

Submitted electronically

May 6, 2016

Department of Health and Human Services
Food and Drug Administration
Division of Risk Management Operations

Re: **Docket No. FDA–2013–D–1295**
Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Draft Guidance for Industry and Food and Drug Administration Staff

Dear FDA:

I write on behalf of the Hearing Loss Association of America in response to the FDA's reopening of the comment period for consideration of the Draft Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (PSAPs).

The Hearing Loss Association of America originally provided comments regarding the proposed revisions in the regulations on February 5, 2014. We appreciate the opportunity to augment those comments and address the request for additional guidance on specific questions raised by the FDA.

(1) The FDA is soliciting comments on the availability, accessibility, and use of hearing aids and PSAPs for consumers with hearing impairment.

The FDA received a wealth of – sometimes conflicting – comments regarding the availability, accessibility and use of hearing aids and PSAPs during the FDA workshop, "Streamlining Good Manufacturing Practices (GMPs)" held on April 21, 2016. We'd like to highlight a few of the points we made at the workshop on this topic, especially as they related to the recommendations provided in the PCAST report.

- HLAA views the President's Council of Advisors on Science and Technology (PCAST) October, 2015 report as an important document because it addresses, among other things, concerns that have been raised with us by consumers regarding the high cost of hearing aids and the barrier to access that cost incurs. Consumers call HLAA seeking financial assistance or help in finding lower cost hearing aids, telling us they cannot afford to purchase

hearing aids out of pocket. Their concerns are supported by data from the National Institute on Deafness and Other Communication Disorders at the National Institutes of Health which notes that among adults aged 70 and older with hearing loss who could benefit from hearing aids, fewer than one in three (30 percent) has ever used them. Even fewer adults aged 20 to 69 (approximately 16 percent) who could benefit from wearing hearing aids have ever used them. https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing

- HLAA agrees with the PCAST report's conclusions that the current distribution channels create barriers to access, that consumers find it difficult to shop for the best value, and that bundling of costs not only causes confusion about the true cost of the hearing aid and related hearing health care services but also often locks the consumer into the services of one provider. As emphasized in their report, more than 80 percent of hearing-care professionals used the practice of bundling in 2014. This can obscure the fact that the technology might actually account for less than half the bundled price. Thus, price and the current model of sales are two major barriers to the adoption of hearing aids.

- Finally, HLAA also agrees with the PCAST that the FDA distinction between a PSAP and a hearing aid (based on intended use rather than performance) is not clear, is confusing and can prevent some people with hearing loss from benefiting from PSAPs. The lack of clarity not only prevents the marketing of PSAPs to people with hearing loss, but also prevents manufacturers from making truthful claims about their products.

(2) The FDA also seeks comment on the degree to which current FDA regulatory requirements may be acting as a barrier to hearing aid accessibility, affordability, and use of hearing aids.

As we noted in our verbal comments presented at the FDA workshop on April 21, HLAA believes that the FDA regulatory requirements may well be acting as a barrier to hearing aid accessibility, affordability and use of hearing aids. We recommend:

- The FDA should eliminate the requirement that adults see a medical professional before purchase of hearing aids. A majority of consumers currently waive that requirement. Even when it is a covered expense under the consumer's insurance policy, seeing a medical professional involves an

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additional trip to yet another professional and a cost to the individual and to the health care system.

Further, primary care providers as gate-keepers may not always be the most appropriate professionals to turn to. Given current time pressures, these practitioners are ill equipped to adequately assess potential red flags unless the individual complains of symptoms.

On the other hand, when there is a real need to see a doctor, for example, when someone experiences overt symptoms such as sudden hearing loss, pain, drainage, balance problems or other "red flag" conditions, people typically do seek medical attention on their own. They are unlikely to treat these kinds of medical symptoms without the help of a doctor.

- The FDA should forgo the category of PSAP, and consider designating a distinct category of "basic" or "over the counter" hearing aids. HLAA agrees with PCAST that creating this separate category that would not require consultation with a credentialed dispenser would create easier access to hearing devices by consumers who need them. We support further discussions with a broad range of stakeholders about the types of regulations necessary in creating this category.

- The FDA should consider adopting consumer protection rules, for example:
    - provisions for purchase of hearing aids separately from service fees such as audiograms and aural rehabilitative services to facilitate consumer ability to shop around
    - clear complaint process for consumers
    - consumer education that allows for comparison of all hearing aids and OTC hearing aids
    - transparency in pricing and return fees
    - clear labeling at the point of sale and websites indicating the performance parameters of the device and whether the devices meet industry standards, if standards are adopted

- The FDA should also consider eliminating the category of Wireless, Class II, hearing aids, and subsuming them all into Class I devices given the range of wireless devices already available broadly.

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(3) The appropriateness of creating a ‘‘basic’’ category of hearing aids for consumers with ‘‘bilateral, gradual onset, mild-to-moderate age related hearing loss’’ with appropriate labeling for over-the-counter sale.

HLAA believes it is time to find new ways to reach people with hearing loss who have, to date, not enjoyed the benefits of hearing aids. We are seeing more studies associating untreated hearing loss with dementia, falls, diabetes, and health care utilization, as well as with social isolation and depression. It is imperative that we find a way to provide access to affordable hearing devices to individuals for whom the current system is inadequate, confusing, and expensive. We recommend that:

- The FDA forgo the category of PSAP and consider designating a distinct category of “basic” or “over the counter” hearing aids. HLAA agrees with PCAST that these OTC hearing aids would not require consultation with a credentialed dispenser but should be accompanied by appropriate labeling that allows for informed choices.
- The FDA provide strong consumer protection regulations.
- The FDA provide for clear labeling of all devices at the point of sale and websites that indicates the performance parameters of the device and whether the device meet industry standards, if standards are adopted.

(3) Whether the benefits of expanded, over-the-counter access to hearing aids in this age-related hearing loss population outweigh the risks of forgoing the condition for sale (that the consumer may waive) that requires a medical evaluation to rule out treatable, potentially progressive causes of hearing loss.

As stated previously, the medical evaluation prior to purchase of a hearing aid is rarely used by adults. People with hearing loss accompanied by overt symptoms, such as sudden hearing loss, pain, drainage, balance problems or other “red flag” conditions, typically seek medical attention on their own.

The FDA should sunset the requirement but ensure that hearing aids and/or OTC hearing aids are accompanied by written information about the “red flags” and conditions such as sudden hearing loss, acoustic neuromas, balance, ear wax or tinnitus or other symptoms that could signal a medical condition that requires the consultation of a doctor. Just as consumers have become accustomed to reading warning labels on medications, we believe that consumers could also be warned about the “red flag” conditions and respond appropriately. Further, if an OTC hearing aid is purchased from an audiologist or other hearing specialist, then it’s likely a medical referral will be made when needed, because those professionals receive training specifically designed to provide them with the expertise to identify situations that require medical attention and to refer whenever there is a question or concern.

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Thank you for this opportunity to submit these written comments.

Respectfully submitted,

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