OTC Hearing Aid Consensus Statement Published by AAA, ADA, IHS, and ASHA

By Karl Strom, editor

A new class of over-the-counter (OTC) hearing devices is coming, but how should the US Food and Drug Administration (FDA) define and regulate these devices? A consensus paper published August 14 by four national hearing care professional organizations recommends the devices be called “Self-fit OTC Hearing Devices” and be intended for mild-to-moderate hearing losses of 26-55 dB HL (26 max HFA-FOG/110 dB max output), offer input compression and volume controls, contain clear and easy-to-understand labeling both on the inside and outside of the packaging, and require at last one FDA 510(k) filing to ensure the basic safety and efficacy of the device. The 35-page consensus statement, “Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness,” was developed by a Working Group of the American Academy of Audiology (AAA), Academy of Doctors of Audiology (ADA), American Speech-Language-Hearing Association (ASHA), and International Hearing Society (IHS). The organizations state that “As representatives of the major hearing healthcare professional associations in the United States, we believe that we can contribute, based on our combined expertise, to the current rule making process by submitting proposals that would provide for the reasonable assurance of safety and effectiveness, while adhering to the congressional mandate.”

The recommendations have also been endorsed by the Hearing Industries Association, and have been submitted for consideration by other consumer organizations, including the Hearing Loss Association of American (HLAA).

The consensus paper is divided into five key recommendations:

1) **Establish product requirements appropriate for OTC hearing devices targeting mild-to-moderate adult hearing impairment.** Easily one of the most contentious issues in the OTC hearing aid debate is the amount of hearing loss and corresponding safe output limits for which the devices should be intended. The consensus paper uses the ASHA definition of mild-to-moderate hearing loss from 26-55 dB HL (a 30 dB range) which would easily cover the majority of people with hearing loss. It also recommends a high-frequency average full-on gain limit (HFA-FOG) of 25 dB (2cc coupler), with an input level of 50 dB SPL. Additionally, it recommends OTC devices use a signal processing scheme that reduces gain as input level increases, and as a minimal standard, employs input compression and a volume control. In order to prevent long-term over-exposure to sound, the peak (or maximum) 2cc-coupler OSPL90 should not exceed 110 dB SPL, states the working group. It's worthwhile to note that this exceeds the upper limits of some of the standards currently being employed in the EU.

For obvious safety reasons, the consensus paper recommends OTC products be limited only to instant-fit eartips (ie, custom earmold fabrication should be limited to licensed hearing care professionals). Due to the majority of Americans—including seniors—now using cell phones, the devices should use the ANSI Standard RF immunity rating system and meet the M2/T2 standard (if a T-coil is available), which is the current minimal standard for today's hearing aids.

2) Out-of-the-box labeling with "Red Flag" warnings and a strong recommendation to consult with a licensed hearing care professional. Two other major contentious issues surrounding an OTC hearing device center on those consumers with life-threatening medical issues (eg, an acoustic neuroma) or the possibility that consumers might be dissuaded from seeking professional assistance if their device does not work for them or give up if their unique hearing loss is not satisfactorily resolved. Additionally, several hearing care professionals and organizations are concerned that an OTC device will be used for a child instead of providing them with the necessary care associated with pediatric hearing loss. With that in mind, the consensus statement recommends out-of-the-box labeling that states:

"This device is intended for use only by adults (minimum age 18) with mild-to-moderate hearing loss, who have difficulties hearing conversational speech. This device is not intended for use by children. Benefits from this device may vary from individual to individual. If you have any questions, concerns or need further assistance with regards to your ability to hear it is recommended that you consult with a hearing healthcare professional before purchasing this device."

Concerning "red flag" conditions, the Working Group also recommends the following outside-the-box labeling:

*"**Important notice for the prospective users**: Hearing loss is a medical condition best addressed in consultation with a licensed hearing healthcare professional. If you experience any of the following conditions, do not purchase this product and consult a hearing care*

professional before proceeding:

- *Visible deformities of the ear since birth or from injury*
- *Fluid, pus, or blood coming out of the ear within the previous three months*
- *Sudden, quickly worsening, or fluctuating hearing loss within the previous three months*
- *Dizziness or periodic vertigo associated with hearing loss*
- *Hearing loss in only one ear or a large difference in hearing between ears*
- *Ear wax build up or feeling that something is in the ear canal*
- *Pain or discomfort in the ear*
- *Tinnitus or ringing in one or both of your ears."*

3) Inside-of-the-box labeling. In addition to the *User Instructional Brochure*, the consensus paper urges emphasizing that the device is not intended for children, that it should not be worn for more than 12 hours a day if the sound level causes discomfort, and provides numerous examples when to stop using the device and/or seek professional care from a licensed practitioner. Details regarding the technical data about the device (eg, Max OSPL90, HFA-FOG, Battery type, etc) should also be included inside the packaging.

4) Define new OTC category as "Self-fit OTC Hearing Devices" and use risk class requirements for safety and effectiveness. Confusion by consumers about the difference between a hearing aid and personal sound amplification product (PSAP) have been an ongoing concern, and the creation of an OTC device category threatens to exacerbate the problem. The consensus paper recommends defining the new category as "Self-Fit Over-the-Counter Hearing Devices" to clearly distinguish them from hearing aids and PSAPs. According to the Working Group, all device classification should be based on intended use, conditions for sale, and risk classification. Therefore, it follows that the new OTC devices be classified with traditional hearing aids as Class I and Class II devices and be required to undergo a first-time FDA premarket authorization (ie, 510(k) clearance). Those devices receiving 510(k) would then be applicable for premarket clearance exemptions.

5) Adequate provisions for consumer protection and oversight by FTC. The reputation of hearing healthcare has suffered in the past due to unscrupulous companies, and the FDA and Federal Trade Commission (FTC) have provided strong federal guidance, along with the states, in protecting consumers. Currently, 32 states have return and refund policies for hearing aids, but the OTC Hearing Aid Act may pre-empt these protections. The Working Group's recommendation is that FDA, in coordination with the FTC, establish strong consumer protection regulations, and strongly recommends that return and refund policies be defined for this new category. It also recommends that specific attention be called to marketing claims for this new category, and that FDA and FTC create a process to ensure that all product claims are substantiated by data, scientific evidence, and/or clinical studies.

The *OTC Hearing Aid Act* was passed by Congress and signed into law by President Trump in August 2017 as part of the *FDA Reauthorization Act of 2017* (FDARA). It is designed to provide better affordability and accessibility for adults with perceived mild-to-moderate hearing loss, and give them access to OTC hearing aids without being seen by a hearing care

professional. Under the law, FDA must create and regulate a category of OTC hearing aids for adults with “perceived” mild-to-moderate hearing loss that ensures the same high standards for safety, consumer labeling, and manufacturing protection as other medical devices. FDA must establish an OTC hearing aid category within 3 years of passage of the legislation (which was passed in August 2017), and finalize a rule within 180 days after the close of the comment period.

However, what level of safety, labeling, and consumer protections will be included have been hotly debated between stakeholders (see HR’s Special Report on the recent NASEM Committee workshop). The Consumer Technology Association (CTA) has been pushing for a logo that would signify a *voluntary* compliance to a performance standard originally intended for personal sound amplification products (PSAPs). At the other end, the Hearing Industries Association (HIA) advocated for higher levels of safety and consumer protection, as well as manufacturing and performance standards.

Although when the FDA will propose the new regulations is unknown, it is anticipated that the Agency will host several hearings, as well as the required comment period. Comments from the FDA’s Srinivas “Nandu” Nandkumar, PhD, at last year’s ADA Convention suggested that the Agency is engaging in discussion with various stakeholders and will probably use most, if not all, of the allotted time leading up to its deadline of August 2020, which will be followed by a mandatory commentary period—making it possible that the final regulation will not be finalized until early 2021. Other factors work against a faster timeline. Traditionally, hearing devices have received a lower priority in comparison to other life-saving medical devices, and the FDA continues to have a backlog of issues requiring attention. Additionally, under a new law, the Agency now has to find two regulations to delete for every one it adds.

Karl Strom is editor in chief of The Hearing Review *and has been reporting on hearing healthcare issues for 25 years.*