Over the Counter Hearing Aids

(Approved by the Board of Directors of the Educational Audiology Association February 2018)

Over the Counter Hearing Aids: Statement from the Educational Audiology Association

The Food and Drug Administration Reauthorization Act of 2017 was passed by Congress and signed into law by President Trump on August 3, 2017. This legislation includes the Over-the-Counter Hearing Aid Act of 2017 that mandated the Food and Drug Administration (FDA) to develop regulations for the purchase of over the counter (OTC) hearing aids by adults with perceived mild to moderate hearing loss. The intent of this bill was to increase affordable access to hearing health care by individuals over 18 years of age. However, in doing so, consumers can bypass diagnostic hearing evaluations and consultation with an audiologist. Regulations may take up to three years to be developed and finalized, and educational audiologists should increase their awareness and advocacy efforts during and following the regulation process. Educational audiologists should be aware of the following considerations to help protect students from potential harm that could result from improper and unsupervised use of OTC hearing aids.

The Educational Audiology Association (EAA) recommends the following guidelines and labeling for OTC devices:

- A strong statement that OTC devices are intended for adults only, 18 years of age and older, with mild communicative and hearing deficits. These devices should never be utilized with individuals under the age of 18, unless under the direct care and supervision of a licensed audiologist.
- Labeling that identifies specific acoustic standards including output limits that are being met. This practice is necessary to limit gain levels and to ensure OTC devices will not cause additional harm to hearing.
- Specific language that explains OTC devices are not intended for greater than a mild hearing loss or for auditory deficits other than those related to sensory deficiencies. This provision would include treatment for symptoms such as those related to tinnitus and/or dizziness.
- A warning label identifying symptoms requiring otologic and/or audiologic consultation.
- Consumer information with recommended best practices including a statement that greater success with OTC devices may be obtained with a comprehensive audiological evaluation and individualized treatment program.

In a statement to the FDA (http://www.asha.org/News/2016/ASHA-and-Other-Stakeholders-Advise-FDA-on-Hearing-Aid-Regulations/), the American Speech Language Hearing Association (ASHA) asserted that children treated with OTC hearing devices are at risk for severe complications due to untreated ear disease; inadequate amplification leading to severe, permanent, and disabling language impairment; as well as noise-induced hearing loss due to inappropriate levels of amplification. The American Academy of Audiology (AAA) has also made recommendations for regulations that pertain to children (see text box). Although legislation requires that OTC devices have warning labels regarding use by children, there is concern about the lack of meaningful safeguards to ensure these devices are not purchased or used by those younger than 18 years of age. It is not possible for children to self-diagnose or for parents to diagnose type, degree, and severity of hearing loss. Furthermore, children with hearing loss need management by an audiologist who can recommend additional therapy and habilitation, as needed, including speech-language-listening therapy, and educational monitoring.

The Educational Audiology Association agrees with ASHA's statement and AAA's recommendations. Furthermore, the complex

AAA OTC Recommendations

Recommendation 1: Labeling for OTC devices should include language that advises the user that better outcomes are achieved when a comprehensive audiological examination is conducted prior to the acquisition of an OTC device.

Recommendation 2: Labeling should address utilization of OTC devices, including both hearing aids and/or PSAPs, by individuals under the age of 18. Specific language should be included noting that use of OTC devices by individuals less than 18 years of age should only occur under the direction of a licensed audiologist.

Recommendation 4: Labeling of OTC devices should specify that the output may exceed levels that could cause either additional hearing loss or initial hearing loss in those with normal hearing. Standards for the acoustical characteristics of these devices should be set to limit these risks.

Recommendation 6: The Academy recommends that the FDA regulations related to the sale and purchase of OTC devices specify that OTC devices are medical devices and not consumer electronics.

nature of pediatric hearing loss makes professional diagnosis even more imperative. Approximately 50% of childhood hearing loss is genetic, with a third of those cases being associated with a medical syndrome. In addition to early and accurate diagnosis, pediatric hearing loss requires monitoring due to the progressive and/or fluctuating nature of some losses. We are also concerned that foregoing accurate diagnosis by a pediatric or educational audiologist could prevent infants and toddlers from entering the early intervention system and even prevent school-age children from receiving appropriate support services.

While the language of the bill states that these devices are intended for adults only, it has not yet been determined how this provision will be regulated by the FDA. Regardless of the regulations, it may be difficult to prevent adults from purchasing the OTC hearing devices for a child. Therefore, it will be imperative to invest in a strong consumer and retail education campaign. Parents and caregivers must be educated on the importance of early, accurate diagnosis and treatment of children with hearing disorders by a licensed audiologist in conjunction with the child's physician. Another approach to broaden access to appropriate treatment and discourage parents and caregivers from opting for less expensive OTC devices would be to advocate strongly for state mandated insurance coverage of hearing aids for children.

Next steps in the regulatory process:

1. The FDA has 3 years to develop rules on how OTC hearing aids will be regulated.

2. Regulations will be developed through a 2-step rule making process.

    a. FDA will publish proposed rule in the Federal Register and ask for public comments on the proposal.

    b. After considering comments and potentially making changes, the FDA will publish the final rule in the Federal Register and indicate an effective date for the rule.

3. Hearing aid manufacturers will need to produce OTC hearing aids that meet the requirements established by the FDA; identify retail outlets to sell their products; develop marketing plans to reach consumers; and adhere to FDA regulations.

4. The US Department of Health and Human Services is required to collect data on user safety and satisfaction with the devices and report back to Congress on any adverse effects 2 years after the regulations are in place.

EAA will continue to collaborate with our fellow professional organizations as the regulatory process moves forward and apprise membership when specific advocacy efforts are needed.