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American Academy of Audiology Regulatory Recommendations for Over-the-Counter Hearing Aid Devices and Personal Sound Amplification Products

The American Academy of Audiology (the "Academy") is the world's largest professional organization of, by, and for audiologists, representing over 12,000 members. The Academy promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research. In anticipation of formal rulemaking related to the development of a category of over-the-counter (OTC) hearing aids and the finalization of draft guidance related to personal sound amplification products (PSAPs), the Academy respectfully submits the following recommendations for consideration by the U.S. Food and Drug Administration (FDA). These recommendations are being offered to ensure that the audiologist's expertise in managing a patient's hearing health outcomes are taken into consideration as FDA looks to create a new category of OTC hearing aids. The Academy looks forward to working with the FDA as regulations are finalized through the rulemaking process.

- ***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.***

  The Academy endorses the rights of individuals to self-direct their hearing care provided that care is safe and effective. The Academy supports the concept that consumers may be able to "self-identify" the presence of a communication problem or a functional limitation or participation restriction. However, no studies suggest that consumers can differentiate degree, type or etiology of hearing loss, or to discriminate those hearing losses that require audiologic or medical intervention. Therefore, the Academy does not support the concept of "self-diagnosis" with respect to self-directed hearing care, and instead recommends that the term "self-identification" be used to identify the consumer's ability to determine the need for hearing care. Ideally, individuals who believe they have a communication problem or functional limitation hearing loss are best served by having a comprehensive audiological evaluation prior to their accessing any treatment option. The Academy advocates for inclusion of labeling language that advises the consumer 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.***

  The Academy firmly believes that OTC devices should be labeled as intended for use by adults over the age of 18. Every effort should be made to ensure these devices are not acquired or

used by individuals under the age of 18 years except when dispensed or prescribed by a licensed audiologist. In addition to regulatory language and labeling requirements that reinforce this principle codified in Section 709 (a)(q)(1)(A)(ii) of the FDA Reauthorization Act, the Academy requests that labeling requirements for OTC hearing devices include the following statement: "Use of OTC devices by individuals less than 18 years of age should only occur under the direction of a licensed audiologist."

Infants and children identified with hearing loss are generally managed by audiologists from the point of identification forward, which may include the use of amplification devices as a part of the treatment process. Throughout the course of this treatment process, there may be infants and children who have short-term or temporary hearing losses for whom traditional hearing aids may not be necessary. In such cases, the audiologist may determine that an OTC type device or PSAP may be the most suitable treatment option for children due to the nature of the loss and other factors. For example, children who have a mild conductive hearing loss who, for medical reasons, must wait for surgical correction and therefore might benefit from a lower cost alternative to a traditional hearing aid. Similarly, OTC or PSAP devices may be beneficial for specific situational needs for children, such as if a child has minimal hearing loss, or an auditory processing disorder without hearing loss. In these situations, a simple amplifier could provide the needed acoustic boost when the child is in the educational environment. Within this context, there may be instances where an OTC device, or a PSAP, may be a suitable alternative for children.

The Academy does not advocate that the intended age limit be changed to allow open access to OTC devices by parents. Due to the role of the audiologist as the primary care giver for children with hearing loss, we suggest the labeling requirements include the qualifier of allowing children to access the device only under the direction of their audiologist.

- ***Recommendation 3: Labeling of OTC devices should advise consumers to seek an evaluation by an audiologist if they are not receiving satisfactory results with an OTC device.***

  Many view the emergence of OTC devices as a catalyst for improving accessibility and affordability of hearing care. They believe the availability of OTC devices expands the market to include individuals with perceived mild to moderate hearing loss who may not have previously sought treatment for hearing loss through more traditional channels. Utilization of OTC devices may prove to be another entry point into the hearing health care system and lead to consumers seeking hearing health care from an audiologist as hearing needs increase or change over time. Conversely, there are concerns that a consumer may purchase an OTC device which does not meet their hearing or communication needs, especially as OTC devices are not intended for use by all individuals with hearing loss. The potentially detrimental effects of undertreated hearing loss are well-documented and could negatively impact long-term hearing ability just as much as over-amplification. Furthermore, if a consumer does not receive satisfactory results from the OTC device, they may be discouraged from seeking further treatment. The Academy encourages

the FDA to include labeling information directing consumers to seek an evaluation by an audiologist if they do not receive the results they hope for when purchasing an OTC device.

- ***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.***

  The category of OTC devices has been established to include targeting listeners with up to moderate hearing loss. Consequently, appropriate gain and output levels (as defined by current prescriptive gain methods), will provide output levels that exceed NIOSH and OSHA recommendations in higher gain and output devices, with consistent exposure to moderately high (or greater) sound levels throughout the day. Therefore, utilizing labeling to acknowledge such a risk is important. In addition, gain and output levels should be limited to the lowest possible levels that remain appropriate for these degrees of hearing loss as specified by currently accepted and validated prescriptive gain methods. Since many devices will include amplitude compression, gain limits should be considered as a function of input level.

  Though the FDA Reauthorization Act passed by Congress on August 3 directs the FDA to create a category of OTC hearing aids for adults with perceived mild to moderate hearing loss, the Academy maintains its position that OTC devices be labeled as intended for use by adults with mild hearing loss and with mild communicative impairments. As stated, the Academy believes the FDA should take steps to caution consumers about the effects of potential over-amplification, but also recognizes the need for setting acoustical characteristic standards for these devices in order to limit such risk. Conversely, for those consumers experiencing moderate hearing loss with moderate communicative impairments may find that the devices provide less than optimal amplification. The Academy believes that professional intervention, either through device adjustment or through prescriptive recommendations for devices with specific gain configurations, may be necessary for OTC devices to provide appropriate amplification for those with moderate hearing loss.

- ***Recommendation 5: Labeling of OTC devices should advise consumers to seek an evaluation by an audiologist when they notice any change in their hearing, including temporary changes, as sustained long-term exposure to moderate to high output levels may have a negative effect on hearing.***

  Depending on the agreed upon gain and output limitations, OTC devices have the potential to lead to hearing loss in some individuals due to long term exposure to sound levels exceeding OSHA and NIOSH recommendations. Listeners with normal hearing may be particularly at risk. As noted previously, there is no data supporting the concept that individuals can differentiate degree, type or etiology of hearing loss. Indeed, some data have suggested listeners with normal hearing may mistakenly self-identify as having poor hearing thresholds and therefore may purchase and use an OTC device. The Academy recommends that consumers be advised to seek

immediate attention from an audiologist should they notice any change in their hearing or communicative function resulting from the use of an OTC product.

- ***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.***

  The Academy recommends that the FDA create regulations related to the sale and purchase of OTC devices to ensure consumers understand that these are to be used to improve communicative impairment and, as such, are medical devices and not consumer electronic products. Certain types of hearing loss may require audiologic or medical intervention. Red flag warning signs should be included with all labeling for products intended to manage hearing loss or communication deficits, and that indications for referral for an audiologic or otologic evaluation should be clearly noted. Retailers and distributors should be required to implement measures to provide consumers with access to clear, easy to understand safety information for OTC devices. One such measure could include having the consumer sign an acknowledgment that they have read and understood the safety and labeling information related to the OTC device prior to purchase. The Academy also encourages the FDA to develop regulations establishing a formalized trial period to allow consumers, who have purchased an OTC device, to have the option to return that device.

- ***Recommendation 7: The FDA should take steps to mitigate consumer confusion regarding the difference between PSAPs and OTC hearing aid devices.***

  Hearing aids, including OTC hearing aids, and PSAPs are not interchangeable from the standpoint of intended use, but may overlap greatly in terms of the amplification and processing strategies applied. Given the two distinct intended uses of each classification of product, and the related level of regulatory oversight, marketing for these devices should appropriately and clearly convey to consumers the intended use of the product. The Academy is concerned about the ability of the consumer to differentiate between OTC hearing aids and PSAPs. We applaud efforts to protect consumers who use OTC devices with appropriate labeling and device gain and output limitation. These same protections are, however, currently not applied to PSAP devices. Therefore, as supported by published data, users of current PSAP devices may actually be exposed to higher sound levels than users of appropriately regulated OTC devices. The Academy urges the FDA to define and regulate these devices in such a way as to minimize consumer confusion and maximize consumer satisfaction and protection. We encourage the use of appropriate labeling to allow the consumer to differentiate between OTC hearing aids and PSAPs and would also advocate that gain and output limitations be applied to both OTC hearing aids and PSAPs to ensure proper safeguards exist for consumers purchasing such devices.