AMERICAN ACADEMY OF
OTOLARYNGOLOGY–
HEAD AND NECK SURGERY®

January 18, 2022

Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 10852

[Submitted online at: https://www.regulations.gov]

RE: Docket No. FDA-2021-M-0555, RIN 0910-Al21; Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

Dear Acting Administrator Woodcock,

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS)[1], I am pleased to submit the following comments on the "Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids" proposed rule published in the *Federal Register* on October 20, 2021.

We wish to provide detailed comments on several specific proposals contained in the proposed rule. Our comments will address the following issues within the rule: definition of the word "perceived" regarding hearing loss, labeling requirements, equitable access to information, return policies, maximum insertion depth, sales to children, output maximums, state exemptions, and conditions for sale.

The AAO-HNS would like to thank the Food and Drug Administration (FDA) for the extensive conversations they have had with stakeholders in drafting these over the counter (OTC) draft regulations, as well as for accepting input and taking the appropriate amount of time to ensure that these regulations were well drafted. While the AAO-HNS does have some comments on specific sections of the rule overall, we are very pleased with the patient protections and package warnings that were included in the proposed regulations and recommend that these elements be finalized.

[1] The AAO-HNS is the nation's largest medical organization representing specialists who treat the ear, nose, throat, and related structure of the head and neck. The Academy represents approximately 10,000 otolaryngologist-head and neck surgeons practicing in the United States who diagnose and treat disorders of those areas.

T: 1-703-836-4444
F: 1-703-833-5100
W: www.entnet.org
A: 1650 Diagonal Road, Alexandria, VA 22314

Definition

The AAO-HNS has concerns regarding the use of the term "perceived" regarding hearing loss. We also feel that a holistic definition of what comprises a mild to moderate sensorineural hearing loss should be contained in the packaging of these devices as well as in the advertisements for these products. The AAO-HNS would be pleased to work with the FDA to help craft such a statement. We understand and agree that Congress' intent in passing the Over-the-Counter Hearing Aid Act, as enacted through the FDA Reauthorization Act of 2017, was to allow patients to purchase hearing aids without seeing a physician or hearing professional, and to therefore increase the use of hearing aids. However, the term "perceived" as currently drafted does not benefit patients or consumers. It is quite possible that patients who do not have any hearing loss will purchase hearing aids, and patients who have more severe hearing loss will purchase the wrong hearing aids. The result of this confusion is that patients will not receive the benefits that they have been accorded by law and implementing regulations.

Many hearing aid manufacturers and other sources currently offer free online hearing tests. These tests, while not as exact as in-person exams conducted in sound booths by an audiologist, provide enough basic information to allow potential candidates to identify whether they have the degree of hearing loss that may benefit from a hearing aid. They also have the potential to steer candidates to a full examination if the hearing loss is greater than recommended for the OTC devices. **In light of this, the AAO-HNS recommends that FDA provide resources for patients identifying where free, online hearing exams are available to help determine whether OTC hearing aids may be appropriate. We also feel it would be beneficial for the FDA to support this type of testing on the agency's website.**

Labeling Requirements

The FDA is seeking comment on the external labeling requirements for OTC hearing aids. The AAO-HNS thanks the FDA for the proposed labeling requirements, and strongly supports the majority of what the FDA has proposed. **The AAO-HNS recommends the labeling requirements be written in as simple and concise a manner as possible, in language that is readily understandable by potential consumers of these devices.** The purpose of the regulation is to make hearing aids more accessible to the general public. If the requirements are written in technical scientific language, it is possible that the intended audience will not understand the labelling as written. As a result, possible purchasers of OTC hearing aids might not be able to adequately understand simple operating instructions and warning signs which might indicate the need for an examination. Both of these situations will prevent the purchaser from obtaining the maximum benefit from the device, or worse not allow them to recognize signals indicating the need for professional evaluation. Poor experiences will also likely result in unwillingness to consider amplification which would improve their future hearing and lifestyle.

The AAO-HNS also recommends that additional detail be included in the labeling requirements addressing maximum device output level. Requiring the maximum output level to be clearly listed will help consumers choose the proper hearing aid if they have opted to take a hearing test. Additionally, if consumers purchase hearing aids with too high a decibel level, it could result in additional hearing loss.

Equitable Access to Information

The AAO-HNS applauds the FDA for researching how available literature and information on OTC hearing aids can be made available and accessible to all. This will help patients choose the best possible hearing aid option for themselves in order to allow for a greater quality of life. **The AAO-HNS recommends adding links to websites where one can obtain non-promotional information about hearing loss that includes possible treatments, both medical and through amplification. Links to websites where potential consumers can perform a self-hearing test should be added to any informational websites. We would also suggest the preparation of video instruction on operation and warning signs which warrant further evaluation would be beneficial to be included among the information in the links provided.** As previously stated, these tests are not as exact as exams performed by hearing professionals, but they do provide a reasonably accurate range and can help consumers purchase the hearing aid that is best suited for them.

Return Policies

The FDA did not propose to require sellers to accept returns of OTC hearing aids but is seeking comment on how state and local laws would interact with OTC hearing aid requirements. **The AAO-HNS disagrees with the FDA on this point and recommends a requirement that consumers be permitted to return OTC hearing aids.** Requiring returns is in the best interest of the consumer and could encourage more patients to purchase OTC hearing aids if they know that hearing aids which are not improving their hearing can be returned. It might also give the consumer confidence to proceed with a professional evaluation and examination to determine the best solution for their hearing loss.

OTC hearing aids should be able to be returned if there is an improper fit that causes pain or limits the benefits of amplification, improperly functioning devices, or simply if the device is not improving one's hearing. Requiring returns may improve the quality of hearing aids and the accuracy of promotional materials. This in turn will maximize the chance that these devices will be beneficial to consumers and encourage them to seek professional care if the initial OTC hearing aid is not satisfactory.

The financial resources of consumers purchasing OTC hearing aids will be quite variable and many people may only be able to afford one pair of hearing aids in their lifetime. If the first purchase does not improve the patient's hearing, they may not be able to purchase additional hearing aids and

would not seek further needed care. Even if the hearing aids do work properly, causes of dissatisfaction that could prevent consumers from achieving maximal effectiveness include inadequate output and/or gain or an improper fit inside the consumer's ear canal which does not allow proper transmission of the sound waves or causes such pain that the consumer will not wear them. These reasons, and general consumer protection laws demonstrate why returns should be required. **The AAO-HNS both strongly supports state laws requiring returns and strongly encourages the FDA to require returns in states that do not require such returns.**

Maximum Insertion Depth

The FDA is seeking comment on the establishment of a maximum insertion depth for OTC hearing aids. When one sees a physician, or other hearing professional, hearing aids are fit precisely to a patient's ear canal. For a number of reasons, this is not feasible with OTC hearing aids. The AAO-HNS asserts that the maximum depth should be based on established average length for male and female patients, also considering ethnic diversity, to prevent insertion that will reach the bony external auditory canal and potentially cause harmful outcomes such as significant pain, damage, and infection.

Safety should be the first consideration in determining these lengths. A maximum length should be established that will not create damage in the adult ear, but at the same time is long enough that the device will not fall out of the ear. **The AAO-HNS recommends a maximum depth of insertion for males of 9 mm and 7.5 mm for females, based on a variety of anatomical studies recognizing the inherent variation[2], recognizing that this maximum may not be ideal in all circumstances.**

Sales to Children

OTC hearing aids are not designed for children and the proposed regulations clearly state that any hearing aids sold over the counter are solely for adults age eighteen and over. The FDA is seeking comment on potential enforcement mechanisms and how to ensure that only adults are using OTC hearing aids. The proposed rules are designed to ease the sale of hearing aids. As such, many of the AAO-HNS' recommendations, such as the appropriate maximum insertion depth, are not designed for children. If the proposed regulations allowed sales to children, then the maximum insertion depth would need to be adjusted to allow for children's smaller ears.

The AAO-HNS strongly supports prohibiting sales to children under age eighteen and recommends that the FDA require sellers institute a verification process to ensure that OTC hearing aids are only purchased for adults age eighteen and up. This process should include a signed affirmation stating that the users are adults, as well as warnings in multiple languages to

[2] Singh, P., Mittal, M.K., Mathur, N.N. *et al.* Morphometric Analysis of the External Auditory Canal by Computed Tomography in Indian Population. *Indian J Otolaryngol Head Neck Surg* **71,** 1115–1122 (2019). https://doi.org/10.1007/s12070-017-1200-8

ensure that the buyer is aware of the requirements that OTC hearing aids are not to be used by children. The AAO-HNS does not believe that sellers should face any penalty if they establish a process to verify that the hearing aids will be used by adults and not by children. The AAO-HNS also understands that purchasers might not have adequate fluency of the English language and therefore recommends that age verifications and warnings be included multiple languages. Rather than establishing a national standard, the languages, other than English, included in the verification process should be based on languages that are most prevalent within the geographic area of the seller.

Output and Gain Maximums

The FDA proposes to allow a maximum OSPL90 output level of 115 dB sound pressure level (SPL). However, the regulations also propose that a limit of 120 dB SPL for an OTC hearing aid would be permissible if it implements input-controlled compression and a user-adjustable device volume control. **The AAO-HNS feels that this maximum is too high, and instead recommends that the output maximum should be no greater than 110 dB (dB) in sound pressure level (SPL). For patients with a mild to moderate sensorineural hearing loss (SNHL) this level should be more than adequate to provide benefit. Limiting the output will limit the potential of noise-induced SNHL. If a maximum of 110 dB (DB) is not adequate for individual improvement, this should steer patients toward a complete examination and audiogram.** Our concern is that there will be a percentage of patients who purchase these devices to improve hearing to a better than normal level, but who instead will be risking damage similar to that which is caused by those who listen to earbuds at excessive volumes.

The AAO-HNS believes that these devices should have a maximum twenty-five dB gain limitation. Similar to the caveats identified in the preceding paragraph, excessive gain can result in noise-induced hearing loss. Consumers purchasing these products without professional advice and fitting will be unaware of this. There will also be the group of customers with minimal, if any, hearing loss who want to hear better for social reasons that could end up unintentionally damaging their hearing.

State Exemptions

The FDA is seeking comments on state exemptions to the proposed OTC regulations. **The AAO-HNS strongly encourages the FDA to defer to the states if there is a conflict between existing state law and the finalized OTC regulations.** State boards are already deeply involved in regulatory frameworks, and a one-size-fits-all regulation does not work in many cases. Providing deference to state law and regulations allows the experts on the ground to make rules that best accommodate regional needs. Additionally, the state boards are already heavily entrenched in these areas and would have greater expertise in potential local situations that may arise from this new category of devices entering the market. The AAO-HNS is seeking clarification from the FDA as to whether physicians

can sell OTC hearing aids in states where they are currently prohibited to sell them on a prescription basis, such as Massachusetts and New York.

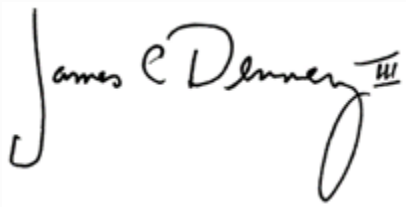
Conditions for Sale

The FDA proposes that the conditions for sale of hearing aids will continue to require a hearing evaluation unless it is waived by the user. As OTC hearing aids are only intended for adults, only adults can waive the evaluation requirements. **The AAO-HNS supports the requirement for an evaluation unless it is waived by an adult.** As previously stated in these comments, the AAO-HNS supports a certification requirement that the hearing aid being sold will not be used by a child. **The AAO-HNS recommends that the certification requirement be one of the conditions for sale of an OTC hearing aid.**

Conclusion

The AAO-HNS appreciates the opportunity to provide comments and recommendations regarding these important policies on behalf of our members. We look forward to continuing to work with the FDA as it advances its efforts to improve patient access to safe and effective quality care. If you have any questions or require further information, please contact healthpolicy@entnet.org.

Respectfully submitted,



James C. Denneny, III, MD
Executive Vice President/CEO