



HLAA Weighs in on the FDA's Over-the-Counter Proposal

BY BRIAN MEYER

In 2017 the Over-the-Counter (OTC) Hearing Aid Act was enacted. This new law allows adults 18 and older with mild to moderate hearing loss to purchase hearing devices without the intervention of a hearing health care professional. The Food and Drug Administration (FDA) proposed a rule in October 2021 to implement the OTC Hearing Aid Act.

HLAA filed comments on the FDA's proposed rule with recommendations about labeling, return policy, usability and clarifying that all OTC hearing aids are self-fitting. Ten consumer organizations and the Rehabilitation Engineering Research Center on Technology for the Deaf and Hard of Hearing (DHH-RERC) signed on to our comments. For more information, visit hearingloss.org.

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Our Comments Labeling

Adjunctive Technology (Smartphone or App Required)

In our comments, HLAA and the organizations signing on recommended the FDA require labeling to inform consumers about the product before purchase. This includes informing consumers whether technology such as a smartphone or app is required to be able to use or set up the OTC hearing aid. Without such critical labeling, consumers might be unable to use the device as intended or may not even be able to use it at all.

Compatibility

In our comments, we also recommended the FDA require that information about the device's compatibility with cellphones should be included in the labeling. We noted that cellphones must already be labeled as hearing-aid-compatible (HAC) and, we said that the mobile device is only "half the equation." The other half requires hearing aids be able to interface with cellphones. We recommended the FDA require labeling about a hearing aid's compatibility and provide its microphone (M) and if present, telecoil (T) coupling rating.

Connectivity

HLAA and the other organizations also recommended the agency require labeling providing information about all modes of wireless connectivity to other devices; for example, indicating that the OTC device has a telecoil, Bluetooth or any other coupling method to devices such as a cellphone, computer or listening system.

Free Trial Period

We also recommended the FDA require a free trial period of at least 45 days with the ability to return an OTC hearing aid without penalty. We noted that consumers need sufficient time to adjust to and listen using an OTC hearing aid.

Other Issues

Classify All Self-Fitting as OTC

HLAA and the organizations recommended that the FDA remove “self-fitting” from the hearing aid classification and explicitly define the OTC classification as self-fitting OTC. The agency is proposing that “self-fitting” should be a classification under prescription air conduction hearing aids while also being eligible as an OTC hearing aid. We indicated that these distinctions are subtle and would likely be confusing.

Document Usability

As a condition of approval, HLAA and the organizations recommended the FDA require that manufacturers submit documentation which demonstrate safety and effectiveness especially focusing on usability without professional intervention. Specifically, we pointed out the usability of an OTC hearing aid is critical since it impacts both the user experience and the effectiveness of the device.

Other Perspectives

More than 1,000 comments were filed with the FDA regarding OTC hearing aids, providing input from different perspectives.

Numerous comments came from the hearing health community recommending technical specifications such as a maximum output level of 110dB and a full-on gain limit of 25dB. Many noted the importance of proper fitting and adjustment of hearing aids.

National Association of Attorneys General (NAAG)

NAAG submitted comments signed by 43 state attorneys generals (AGs) addressing consumer protection laws and preemption of state laws by federal law and FDA regulations. The AGs also asked the FDA to explicitly state the type of state requirements that the final rule would not preempt.

Federal Trade Commission

The Federal Trade Commission (FTC) submitted comments supporting the proposed rule. It noted the proposal would reduce regulatory costs for a significant

range of hearing devices. Since these proposed rules remove barriers to distribution channels, the FTC said, “...that should lead to lower average prices for hearing aids.” FTC staff also discussed the preemption of state laws in the proposed rule. It agreed that most of the current state exemptions to federal law granted previously by the FDA should be rescinded since, “many [exemptions] expressly permit state restrictions that would impede or even bar the sale of OTC hearing aids.”

Sens. Warren and Grassley

Senators Elizabeth Warren (D-MA) and Charles Grassley (R-IA), sponsors of the OTC legislation, supported key provisions in the proposed rule. They noted that the maximum output limit of 120db SPL (sound pressure level) is appropriate based on guidance from the American National Standards Institute (ANSI), National Institute for Occupational Safety and Health (NIOSH) and the National Academies of Sciences, Engineering, and Medicine (NASEM). The Senators also supported the FDA’s conclusion not to include a gain limit for OTC hearing aids, consistent within NASEM’s 2016 report, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*.

The Senators also noted that the proposed rule is in alignment with congressional intent concerning federal preemption of certain state and local laws as it does not preempt a state or local government’s ability to establish or continue in effect professional licensing requirements.

Conclusion

The FDA’s proposed rule represents a major milestone in making OTC hearing aids a reality for adults with mild to moderate hearing loss. Over the next several months the agency will review more than 1,000 comments on file. It may be months before the final rule is published and OTC hearing devices are available.

In the meantime, if you think you have hearing loss, don’t wait, get tested now. Once the FDA final rule is in place, even if you have mild or moderate hearing loss, you might still want to see a professional for assistance selecting the best device. Others will be empowered by the new rules to take their hearing health care in their own hands. The choice will be yours. **HL**

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