January 7, 2022

Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration

RE: Docket No. FDA-2021-M-0555, RIN 0910-A121
Medical Devices; Ear Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

Dear Dr. Woodcock:

The Johns Hopkins Cochlear Center for Hearing and Public Health appreciates the opportunity to comment on the draft rule, Medical Devices; Ear Nose, and Throat Devices; Establishing Over-the-Counter (OTC) Hearing Aids. The Cochlear Center is based in the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health and is the only academic center in the world dedicated to studying and addressing the public health impact of hearing loss in older adults.

The Center’s faculty consist of clinicians and researchers with expertise in audiology, biostatistics, epidemiology, geriatrics, health economics, and otolaryngology. The director of the Cochlear Center (Frank Lin) previously served on the National Academy of Medicine consensus study\(^1\) from 2015-2016 and advised the White House President’s Council of Advisors on Science and Technology\(^2\) in 2015 whose reports led to the bipartisan introduction of the Over-the-Counter Hearing Aid Act by Senators Warren and Grassley in 2017. Dr. Lin subsequently testified\(^3\) before the House of Representatives on behalf of this bill in May 2017. Our Center has also previously led seminal research\(^4\) evaluating direct-to-consumer hearing devices which are the predicate to future over-the-counter (OTC) hearing aids.

This combination of the Center’s prior leadership role in the development of the Over-the-Counter Hearing Aid Act as well as the Center’s academic research on hearing loss in older adults makes the Center uniquely positioned to provide a highly informed public health perspective on this draft rule.

Our Center has previously estimated that over 40 million Americans\(^5\) have a significant hearing loss among whom less than 1 in 5 use a hearing aid\(^6\). The creation of a regulatory classification for OTC hearing aids represents a significant step forward in improving the affordability and accessibility of hearing aids in the United States. These regulations will increase competition, spur technological innovation, and ensure the safety and efficacy of OTC hearing aids, thereby benefiting millions of American adults with hearing loss.

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\(^{1}\) https://www.nationalacademies.org/our-work/accessible-and-affordable-hearing-health-care-for-adults
\(^{2}\) https://obamawhitehouse.archives.gov/blog/2015/10/26/%E2%80%8Bpcast-recommends-changes-promote-innovation-hearing-technologies
\(^{3}\) https://energycommerce.house.gov/committee-activity/hearings/hearing-on-examining-improvements-to-the-regulation-of-medical
\(^{4}\) Reed, NS, Betz, J, Kendig, N, Korczak, M, & Lin, FR. Personal sound amplification products vs a conventional hearing aid for speech understanding in noise. JAMA. 2017 Jul 4; 318(1):89-90
\(^{5}\) Goman AM, Reed NS, Lin FR. Addressing Estimated Hearing Loss in Adults in 2060. JAMA Otolaryngol Head Neck Surg. 2017 Jul 1;143(7):733-734.
Importantly, the FDA’s actions in developing this regulatory classification for OTC hearing aids also directly fulfills recommended actions issued as part of the updated National Plan to Address Alzheimer’s Disease\(^7\) that was released on December 27, 2021 by the Office of the Assistant Secretary for Planning and Evaluation in the Department of Health and Human Services. These recommendations were developed in response to prior research led by Center faculty\(^8\) that implicated hearing loss as being the single largest potentially modifiable risk factor for dementia\(^9\). The actions in the updated 2021 National Plan to Address Alzheimer’s Disease that specifically cite the imminent FDA issuance of regulations for OTC hearing aids are Action 6.B.2 and Action 6.E.3 which call for, respectively, increasing access to and reducing financial barriers to hearing aids for individuals with hearing loss.

In order to maximize the public health impact of the proposed FDA regulations for OTC hearing aids, we offer the following specific input for your consideration:

**Maximum Output**

The Cochlear Center supports the current proposed maximum output of 120 dB SPL with a volume control (or 115 dB SPL without volume control). We acknowledge that the topic of maximal permissible noise is a controversial topic as others have proposed lower overall maximum output limits with a 25 dB gain limitation. However, narrower restrictions would limit the effectiveness of OTC hearing aids, restrict the population of individuals with hearing loss who could benefit from OTC hearing aids, and substantively hinder technological innovation. A maximum permissible output of 120 dB SPL will allow OTC devices to work within a sufficient dynamic range for the signal outputs to maintain the integrity of the original amplified sound without forcing excessive compression and/or clipping of the signal which would introduce distortion and render listening more difficult. We agree with the FDA that this proposed output limit is strict enough that users have adequate time to remove the hearing aid before output levels become dangerous to the ear.

**Minimum Technologic Specifications for OTC Hearing Aids**

We applaud the inclusion of minimum technologic specifications (e.g., permissible internal noise levels, latency, harmonic distortion, frequency response range, and response smoothness). These criteria are aligned with ANSI/CTA–2051 “Personal Sound Amplification Performance Criteria.” Importantly, these criteria are an appropriate deviation from the current ANSI standards for hearing aids which allow permissible deviations from self-stated criteria. Such a step ensures that FDA-approved OTC hearing aids would meet the minimum technologic criteria needed for hearing aid efficacy.

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\(^7\) https://aspe.hhs.gov/reports/national-plan-2021-update#strat-6d  
Clarification of OTC hearing aids as being self-fitting and role of the 510(k) pathway

Under the proposed regulations, it appears that OTC hearing aid controls could be applied to 510(k) exempt legacy hearing aids, 510(k) exempt wireless air-conduction hearing aids, or 510(k) non-exempt self-fitting air conduction hearing aids. This would raise the possibility that certain hearing aids (i.e., legacy or wireless air-conduction hearing aids that are not considered to be self-fitting) could be marketed as OTC while still being 510(k) exempt.

We urge the FDA to clarify that OTC hearing aid controls may only be applied to self-fitting hearing aids and hence subject to 510(k) review. As presently defined, a self-fitting hearing aid (§ 874.3325 (21 CFR 874.3325)) is “a hearing aid that incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fittings and settings.” Such a definition of a self-fitting hearing aid appears substantively similar to the attribute of an OTC hearing aid per the FDA Reauthorization Act (FDARA) which states that an OTC hearing aid is a device that “through tools, tests or software allows the user to control the OTC HA and customize it to the user's hearing needs.” The present rule language in E.2.d. is also consistent with FDARA and states, “We are proposing to codify the requirement that an OTC hearing aid must include tools, tests, or software through which a lay user can control the device and customize it to the user’s hearing needs”.

Failure to clarify that OTC hearing aid controls can only be applied to self-fitting hearing aids (and hence subject to 510(k) review) raises the risk that companies may choose to market OTC hearing aids that are not explicitly self-fitting in order to avoid the review required by the 510(k) process. In a nascent OTC hearing aid market, companies may be particularly incentivized to pursue this route in order to bring their hearing aids more quickly to market. Such actions could, therefore, potentially lead to many of the early OTC hearing aids on the market being ineffective and sow consumer distrust and skepticism of this class of devices.

For the present time, we agree with the FDA that self-fitting OTC hearing aids should be subject to 510(k) review to ensure the safety and efficacy of early OTC hearing aids reaching the market. However, in order to not hinder innovation or unnecessarily delay companies from being able to bring an OTC hearing aid to market, we strongly recommend that: 1) the FDA provide clear guidance on the specific data and information needed for 510(k) review in order to streamline the process for companies trying to bring devices quickly to market; and 2) the FDA evaluate an exemption for OTC self-fitting hearing aids from the 510(k) pathway no later than two years after enactment of these regulations and when sufficient experience will have accrued to evaluate this potential exemption.

Conclusion

Over-the-counter hearing aids are a highly anticipated step towards an improved hearing care ecosystem in the United States. The Cochlear Center for Hearing and Public Health thanks the FDA for their efforts in drafting the proposed rule which will benefit millions of American adults with hearing loss. We strongly believe that the combined maximum output limitations and technologic minimum specifications
are appropriate to meet the hearing needs of the vast majority of adults with hearing loss and will allow for broad technological innovation while ensuring safety and efficacy. We urge the FDA to clarify that OTC hearing aid controls may only be applied to self-fitting hearing aids which are currently subject to the 510(k) process.

Sincerely,

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