January 18, 2022

The Honorable Janet Woodcock
Acting Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids: FDA-2021-N-0555-0001

Dear Acting Commissioner Woodcock,

The undersigned organizations are writing in regards to a Food and Drug Administration (FDA) proposed rule establishing the regulatory framework for a new category of over-the-counter (OTC) hearing aids that adults with mild-to-moderate hearing impairment could acquire without the involvement of licensed hearing care professionals. We greatly appreciate the FDA's work to advance the affordability and accessibility of hearing aids for those with mild-to-moderate hearing impairment. However, we have concerns about certain provisions in the proposed rule that could exacerbate hearing loss, and we urge the FDA to make essential changes outlined below.

Background

The importance of making hearing aids more accessible to older adults cannot be overstated. According to a 2018 study by the Commonwealth Fund, 75 percent of Medicare beneficiaries who need hearing aids do not have them.[1] Furthermore, there are disparities between racial groups in hearing aid ownership, as Black and Hispanic beneficiaries report higher treatment gaps in hearing aid access rates than White enrollees.[2,3] The Build Back Better Act, currently the focus of congressional deliberations, would ease this problem by providing Medicare coverage of hearing aids for the first time. However, even if this legislation is adopted into law, Congress proposes limiting Medicare coverage of hearing aids to beneficiaries with moderately severe or greater hearing loss. Medicare would not cover hearing aids for beneficiaries with mild-to-moderate hearing loss. Moreover, one of every two Medicare beneficiaries has an annual per capita income of less than $26,200 and often cannot afford to get the help they need, placing them at higher risk for depression, social isolation, and other physical and behavioral health challenges that can accompany hearing loss.[4]

Recommendations on Output Limit, Gain, and Right-to-Return

[1] Willink, Amber, et al. "How Medicare Could Provide Dental, Vision, and Hearing Care for Beneficiaries." How Medicare Could Provide Dental, Vision, Hearing Care, The Commonwealth Fund, 18 Jan. 2018, https://www.commonwealthfund.org/publications/issue-briefs/2018/jan/how-medicare-could-provide-dental-vision-and-hearing-care.

[2] Reed, Nicholas S., et al. "Trends in Hearing Aid Ownership among Older Adults in the United States from 2011 to 2018." JAMA Internal Medicine, vol. 181, no. 3, 2021, p. 383., https://doi.org/10.1001/jamainternmed.2020.5682.

[3] Arnold, Michelle L., et al. "Hearing Aid Prevalence and Factors Related to Use among Older Adults from the Hispanic Community Health Study/Study of Latinos." JAMA Otolaryngology–Head & Neck Surgery, vol. 145, no. 6, 2019, p. 501., https://doi.org/10.1001/jamaoto.2019.0433.

[4] Jacobson, Gretchen, et al. "Income and Assets of Medicare Beneficiaries, 2016-2035." KFF, Kaiser Family Foundation, 21 Apr. 2017, https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/.

First, it is critical that the FDA amend its rule to fix provisions related to gain (the amplification of sound as it enters the hearing aid) and output limit (the amplified sound delivered to the ear) to align with professional society consensus recommendations. After Congress passed the Over-the-Counter Hearing Aid Act in 2017, the four leading professional hearing care associations—American Academy of Audiology (AAA), Academy of Doctors of Audiology (ADA), American Speech-Language and Hearing Association (ASHA), and International Hearing Society (IHS)—developed consensus recommendations on how to ensure that OTC hearing aids targeting mild-to-moderate hearing impairment would be safe and effective. The 2018 consensus recommendations[5] include specific limits on gain (i.e., for an input level of 50 dB SPL is 25 dB or lower) and output (i.e., the peak or maximum no greater than 110 dB SPL, in combination with input compression and volume control) to protect users against possible further hearing damage and loss

Unfortunately, the FDA draft regulations include a higher ceiling on output than the professional associations recommended and *no limit on gain, ignoring both the 2018 consensus recommendations and* real-world evidence.[6] The FDA's proposed rules establish an output limit between 115 and 120 dB for OTC hearing aids. According to the professional societies, this ceiling is considered 5-10 dB too high for sustained use. In 2021, the World Health Organization issued its "World Report on Hearing" that included a recommended level of leisure sound exposure below 80 dB for a maximum of 40 hours per week.[7] Further, the Centers for Disease Control and Prevention (CDC) has indicated that individuals can suffer exacerbated hearing loss if subjected to sound at 120 dB levels for as little as one minute.[8]

The FDA suggests in the proposed rules that this problem can be mitigated if OTC hearing aid users reduce the volume or remove the devices within 28 seconds to avoid further hearing damage. This is an unrealistic expectation to apply to older adults with hearing loss who may also face physical or cognitive health challenges. While making hearing aids more accessible and affordable will benefit many older adults, there is concern that many purchasers of OTC hearing aids will not undergo consultation with a hearing care specialist prior to the purchase of this medical technology and will not be provided adequate instruction on the use of potentially dangerous or ineffective volume level.

We, therefore, urge to FDA to consider three changes to its rule on OTC hearing aids.

1. **We recommend that the FDA adopt the lower output limit to 110 dB, as recommended by the four leading hearing care associations.**

2. The proposed rules do not set a limit on gain. This also poses grave safety concerns and could result in device efficacy issues. **We support the recommendation of hearing care associations and otolaryngologists who recommend the FDA establish a gain limit for an input level of 50 dB SPL at 25 dB or lower.**

---

[5] "Regulatory Recommendations For OTC Hearing Aids: Safety & Effectiveness: Consensus Paper From Hearing Care Associations ." American Speech-Language-Hearing Association (ASHA), Aug. 2018, https://www.asha.org/siteassets/uploadedFiles/Consensus-Paper-From-Hearing-Care-Associations.pdf.

[6] https://hearingreview.com/inside-hearing/research/real-world-evidence-on-gain-and-output-settings-for-individuals-with-mild-to-moderate-hearing-loss.

[7] "World Report on Hearing." WHO, World Health Organization, 3 Mar. 2021, https://www.who.int/publications-detail-redirect/world-report-on-hearing.

[8] "Too Loud! for Too Long!" CDC, Centers for Disease Control and Prevention, 28 July 2017, https://www.cdc.gov/vitalsigns/hearingloss/infographic.html.

3. **Finally, the FDA should require OTC hearing aid manufacturers to allow consumers the right to return these devices in coordination with the Federal Trade Commission (FTC).** Without this ability, many older adults may be left without recourse if they purchase a hearing aid, which proves ineffective, fits poorly, or does not meet the beneficiary's hearing needs.

Thank you for your consideration of our requests. We would be pleased to engage in further discussion on this matter as the final rules are being developed. Please contact Ryne Carney, Director of Policy and Advocacy Research at the Alliance for Aging Research at rcarney@agingresearch.org, with any questions or schedule a time for discussion.

Sincerely,

Alliance for Aging Research
HealthyWomen
National Caucus and Center on Black Aging
National Consumers League
National Minority Quality Forum