United States Senate
WASHINGTON, DC 20510

January 18, 2022

Janet Woodcock
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock:

We are pleased the U.S. Food and Drug Administration (FDA) issued the proposed rule for "Establishing Over-the-Counter Hearing Aids" (Docket No. FDA-2021-N-0555),[1] as set forth by the *Over-the-Counter Hearing Aid Act*. We write to urge the FDA to finalize the rule without delay. To ensure the final regulation is consistent with congressional intent, it must not contain any unnecessary restrictions that hinder access to over-the-counter (OTC) devices or their utility for Americans with mild or moderate hearing loss. For these reasons, we strongly support maintaining the maximum sound pressure level identified in the proposed rule and oppose the introduction of any limits on gain. In addition, we believe that federal preemption of state laws governing the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC products is necessary to ensure consumers can access these devices without interference, as the *Over-the-Counter Hearing Aid Act* established. Maintaining these provisions will ensure that the final regulation successfully increases competition, spurs innovation, and brings down prices for consumers, while meeting the high standards of safety, manufacturing protections, and consumer labeling required of all medical devices.

More than 38 million Americans experience some degree of hearing loss.[2] Older Americans are particularly affected, with nearly one in three people between the ages of 65 and 75[3] and around half of adults 75 or older reporting difficulty hearing.[4] Americans with hearing loss are at a greater risk of developing Alzheimer's Disease and Alzheimer's Disease Related Dementias,[5] and they are also more likely to experience feelings of loneliness and isolation, which the COVID-19 pandemic has only exacerbated.[6] Despite the prevalence of hearing loss, only one in

[1] Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, 21 Fed. Reg. 58150-58191 (to be codified at C.F.R. Parts 800, 801, 808, and 874).
[2] The New York Times, "Hearing Aids for the Masses," Shira Ovide, April 12, 2021, https://www.nytimes.com/2021/04/12/technology/hearing-aids.html.
[3] National Institute on Aging, "Hearing Loss: A Common Problem for Older Adults," November 20, 2018, https://www.nia.nih.gov/health/hearing-loss-common-problem-older-adults.
[4] *Id*.
[5] U.S. Department of Health and Human Services, "National Plan to Address Alzheimer's Disease: 2021 Update," December 27, 2021, https://aspe.hhs.gov/reports/national-plan-2021-update.
[6] NPR, "Untreated Hearing Loss Linked To Loneliness And Isolation For Seniors," Rochelle Sharpe, September 12, 2019, https://www.npr.org/sections/health-shots/2019/09/12/760231279/untreated-hearing-loss-linked-to-loneliness-and-isolation-for-seniors. ; The Seattle Times, "For older adults, isolation can lead to overwhelming loneliness,"

five people who could benefit from a hearing aid use one.[7] One of the primary reasons for this is cost. Hearing aids are not generally covered by private health insurance plans or traditional Medicare and can cost thousands of dollars, making them prohibitively expensive for many Americans.[8]

President Trump signed the *Over-the-Counter Hearing Aid Act* into law in 2017. This law, based on our bill with Senators Hassan and Isakson, removes outdated regulations blocking consumer access to affordable hearing aids and allows certain types of hearing aids to be made available over-the-counter to Americans with mild to moderate hearing loss.[9] By introducing more competition into the hearing aid market, the law, once properly implemented, will provide consumers with more options at a price they can afford.

We write to convey our support for key provisions of the FDA's proposed rule and to ensure that the final regulation is aligned with congressional intent.[10] Specifically, we agree with the FDA's proposed maximum 120 decibel (dB) sound pressure level (SPL) for an OTC hearing aid that implements input-controlled compression and a user-adjustable device volume control. The proposed 120 dB SPL ensures maximum consumer access to OTC hearing aids, while providing assurances of safety and effectiveness. As the FDA's proposed rule suggests, such a device should only reach the maximum permissible limit of 120 dB SPL for a brief period to allow for maximum effectiveness in certain circumstances (e.g., listening to a symphony) without distorting the original sound or compromising consumer safety.[11] We agree that the standard set forth is appropriate based on the guidance from the American National Standards Institute (ANSI), National Institute for Occupational Safety and Health (NIOSH), National Academies of Sciences, Engineering, and Medicine (NASEM), and other stakeholder-driven input sessions described in the proposed rule.

We also support the FDA's conclusion not to include a gain limit for OTC hearing aids, consistent within NASEM's recommendation in its 2016 report.[12] The maximum output limit of 120 dB SPL already provides a standard for safety and effectiveness to protect the consumer. We agree that establishing a gain limit will only restrict the ability for innovation and design of an effective device for people with mild to moderate hearing loss.

Paige Cornwell, Sept 19, 2021, https://www.seattletimes.com/seattle-news/mental-health/for-older-adults-isolation-can-lead-to-overwhelming-loneliness/.

[7] U.S. Food and Drug Administration, "FDA Issues Landmark Proposal to Improve Access to Hearing Aid Technology for Millions of Americans," Press Release, October 19, 2021, https://www.fda.gov/news-events/press-announcements/fda-issues-landmark-proposal-improve-access-hearing-aid-technology-millions-americans.

[8] Hearing Health Foundation, "Why So Many Can't Afford to Hear Better," June 14, 2018, https://hearinghealthfoundation.org/blogs/why-so-many-cant-afford-to-hear-better. ; AARP, "Does Medicare Cover Hearing Aids?," Accessed January 18, 2022, https://www.aarp.org/health/medicare-qa-tool/does-medicare-cover-hearing-aids/.

[9] Over the Counter Hearing Aid Act, S.670, https://www.congress.gov/bill/115th-congress/senate-bill/670.

[10] Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, 21 Fed. Reg. 58150-58191 (to be codified at C.F.R. Parts 800, 801, 808, and 874).

[11] *Id.*, 58162-58163.

[12] NASEM, "Hearing Health Care for Adults: Priorities for Improving Access and Affordability," Board on Health Sciences Policy, Committee on Accessible and Affordable Hearing Health Care for Adults, Blazer, D.G., S. Domnitz, and C.T. Liverman, Eds., 2016, https:// www.nap.edu/catalog/23446/hearinghealth-care-for-adults-priorities-forimproving-access-and.

Finally, we agree with FDA's proposed federal preemption provisions on state and local government laws, regulations, orders, or other requirements pertaining to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids.[13] *The Over-the-Counter Hearing Aid Act* established clear lines on federal preemption, and the FDA accurately reflects congressional intent in this proposed rule. The President's Council of Advisors on Science and Technology's (PCAST) 2015 letter report on hearing loss identified that "complex state regulations restrict the distribution channels for hearing aids" and recommended that FDA "preempt State requirements that the OTC devices be sold by credentialed dispensers." They conclude that "the net benefit [of this approach] to the public would be large and positive."[14] NASEM also advised the federal government to "preempt any future state laws and regulations seeking to limit over-the-counter access."[15] We note that this provision is in alignment with congressional intent as it does not preempt a state or local government's ability to establish or continue in effect professional licensing requirements.

It has been over four years since the *Over-the-Counter Hearing Aid Act* was passed into law. We appreciate President Biden's commitment to promoting over-the-counter hearing aids for Americans with hearing loss, as outlined in his Executive Order on Promoting Competition in the American Economy, and we are encouraged that FDA has taken this critical step to finally issue a proposed rule. As we have written FDA leadership before, we hope to see a final rule that promotes competition and reflects the best interests of consumers and the public. We ask you finalize this rule without delay and in a manner that is consistent with congressional intent.

Sincerely,

Elizabeth Warren
United States Senator

Charles E. Grassley
United States Senator

[13] Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, 21 Fed. Reg. 58166-58168 (to be codified at C.F.R. Parts 800, 801, 808, and 874).
[14] Letter to President Obama from the President's Council of Advisors on Science and Technology, October 2015, https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf.
[15] The National Academies of Sciences, Engineering, and Medicine, "Recommendations," June 2016, https://www.nap.edu/resource/23446/Hearing_Recommendations.pdf.