

United States Senate
WASHINGTON, DC 20510

October 12, 2021

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

Dear Acting Commissioner Woodcock:

We write to urge the U.S. Food and Drug Administration (FDA) to issue the proposed rule regarding over-the-counter hearing aids without delay and no later than November 6, 2021, in accordance with President Biden’s Executive Order on Promoting Competition in the American Economy.¹ We are pleased to see that the Office of Information and Regulatory Affairs has recently completed its review of the proposed rule, more than four years since our *Over-the-Counter Hearing Aid Act* was signed into law. As such, we request that you release the rule as soon as possible.

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 75³ and around half of adults 75 or older reporting difficulty hearing.⁴ Americans with hearing loss are also more likely to experience feelings of loneliness and isolation, which the COVID-19 pandemic has only exacerbated.⁵ Despite the prevalence of hearing loss, only 14% of people use hearing aids. One of the primary reasons for this is cost. Hearing aids are not generally covered by health insurance or traditional Medicare and can cost thousands of dollars, making them prohibitively expensive for many Americans.⁶

¹ The White House, “FACT SHEET: Executive Order on Promoting Competition in the American Economy,” July 9, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/>.

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

⁶ 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>.

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.⁷ By introducing more competition into the hearing aid market, the law will provide consumers with more options at a price they can afford. Yet, it has been four years since the *Over-the-Counter Hearing Aid Act* was passed into law and we are still awaiting the proposed rule.⁸

On July 9, 2021 President Biden directed the Department of Health and Human Services to “publish for notice and comment a proposed rule on over-the-counter hearing aids” within 120 days of the order.⁹ We appreciate the President’s commitment to promoting over-the-counter hearing aids for Americans with hearing loss and are encouraged that the Office of Information and Regulatory Affairs has completed its review of the proposed rule.¹⁰ We urge your office to finalize the rule without delay to, at a minimum, meet the deadline set forth in the President’s executive order.

In doing so, it is our expectation that FDA will issue hearing aid regulations that are consistent with the law and reflect the intent of the *Over-the-Counter Hearing Aid Act* to expand consumer access to affordable hearing aids. Specifically, we hope that the rule does not contain any unnecessary restrictions that hinder access to these devices or their utility. The regulations must succeed in increasing competition, spurring innovation, and bringing down prices for consumers, while meeting the high standards of safety, manufacturing protections, and consumer labeling required of all medical devices. We hope to see a final promulgated rule that promotes competition and reflects the best interests of consumers and the public.

We thank you for your time and consideration and look forward to the upcoming release of a proposed rule.

Sincerely,


Elizabeth Warren
United States Senator


Charles E. Grassley
United States Senator

⁷ Over the Counter Hearing Aid Act, S.670, <https://www.congress.gov/bill/115th-congress/senate-bill/670>.

⁸ FDA Reauthorization Act of 2017, Public Law 115-52.

⁹ The White House, “Executive Order on Promoting Competition in the American Economy,” press release, July 9, 2021, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>.

¹⁰ Office of Information and Regulatory Affairs (OIRA), “Executive Order Submissions with Review Completed in Last 30 Days,” Accessed October 5, 2021, <https://www.reginfo.gov/public/do/eoReviewSearch>.