

United States Senate
WASHINGTON, DC 20510

November 13, 2020

The Honorable Stephen M. Hahn, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hahn,

We write to urge the U.S. Food and Drug Administration (FDA) to issue the proposed rule related to over-the-counter hearing aids, as required by Section 709 of the *FDA Reauthorization Act of 2017* (P.L. 115-52), without delay.

Hearing loss is one of the most common conditions affecting older Americans. According to the National Institute on Aging, nearly one in three Americans between the ages of 65 and 74, and almost half of people over the age of 75, have difficulty hearing.¹ Hearing difficulties are associated with depression and dementia and increase the risks of falls in older adults.² Hearing aids can help people with hearing loss live normal lives. Unfortunately, although hearing aids are considered prescription products, they are not generally covered by health insurance or original Medicare and can cost thousands of dollars.³ Only around 14 percent of Americans with hearing loss use hearing aids.⁴

In 2017, President Trump signed into law the *Over-the-Counter (OTC) Hearing Aid Act*, which we introduced with Senators Hassan and Isakson. The law removes outdated regulations blocking consumer access to affordable hearing aids by amending the Food, Drug, and Cosmetic Act and allowing the FDA to categorize certain hearing aids as over-the-counter. It also requires the FDA to issue regulations regarding OTC hearing aids to ensure these devices meet the same high standards for safety, consumer labeling, and manufacturing protections as all medical

¹ 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#:~:text=Approximately%20one%20in%20three%20people,admit%20they%20have%20trouble%20hearing.>

² Journal of the American Geriatrics Society, “Can Hearing Aids Delay Time to Diagnosis Dementia, Depression, or Falls in Older Adults?” Elham Mahmoudi, PhD, et al, September 4, 2019, [https://onlinelibrary.wiley.com/doi/10.1111/jgs.16109.](https://onlinelibrary.wiley.com/doi/10.1111/jgs.16109)

³ 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.>

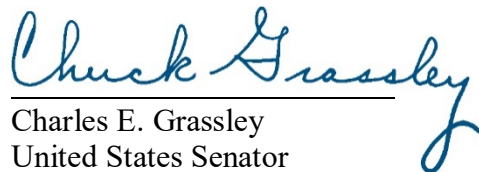
⁴ *Id.*

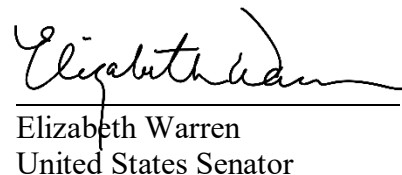
devices. The law (Section 709 of P.L. 115-52) required the FDA to issue these proposed regulations no later than August 18, 2020.⁵

Since 2017, the FDA has assured us that it would issue these regulations in compliance with its statutory deadline. In October 2018, the FDA announced that these rules would be a priority on their Fall 2018 Unified Agenda and that the agency would be able to deliver the proposed rule in advance of the deadline.⁶ And in February of this year, the agency informed us that it was “developing a proposed rule to issue by August 18, 2020.”⁷ However, the FDA has yet to issue its OTC hearing aid proposed rule.

The impact of the novel coronavirus on the agency’s priorities and workload cannot be overstated, and we appreciate the FDA’s continued efforts to respond to this global crisis that has profoundly affected so many Americans. However, despite the pandemic, hearing loss continues to be a problem for millions of Americans, and we believe that the FDA must also make issuing the OTC hearing aid regulations a priority, consistent with the law. We respectfully request that the agency release the proposed rule without delay.

Sincerely,


Charles E. Grassley
United States Senator


Elizabeth Warren
United States Senator

⁵ P.L. 115-52.

⁶ U.S. Food and Drug Administration, “Fall 2018 Unified Agenda: FDA’s New Regulatory Work to Advance Health and Safety,” October 17, 2018, <https://www.fda.gov/news-events/fda-voices/fall-2018-unified-agenda-fdas-new-regulatory-work-advance-health-and-safety>.

⁷ Letter from Karen Gross, Associate Commissioner for Legislative Affairs, to U.S. Senators Chuck Grassley and Elizabeth Warren, February 12, 2020.