

United States Senate  
WASHINGTON, DC 20510

February 8, 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),<sup>1</sup> as set forth by the *Over-the-Counter Hearing Aid Act*. With the public comment period now closed, we write to urge the FDA to finalize the rule without delay and in a manner that is consistent with congressional intent.

More than 38 million Americans experience some degree of hearing loss.<sup>2</sup> Older Americans are particularly affected, with nearly one in three people between the ages of 65 and 75<sup>3</sup> and around half of adults 75 or older reporting difficulty hearing.<sup>4</sup> Americans with hearing loss are at a greater risk of developing Alzheimer’s Disease and Alzheimer’s Disease Related Dementias,<sup>5</sup> and they are also more likely to experience feelings of loneliness and isolation, which the COVID-19 pandemic has only exacerbated.<sup>6</sup> Despite the prevalence of hearing loss, only one in five people who could benefit from a hearing aid use one.<sup>7</sup> One of the primary reasons for this is cost. Hearing aids are not generally covered by private health insurance plans or traditional

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<sup>1</sup> 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).

<sup>2</sup> 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>.

<sup>3</sup> 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>.

<sup>4</sup> *Id.*

<sup>5</sup> 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>.

<sup>6</sup> 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/>.

<sup>7</sup> 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>.

Medicare and can cost thousands of dollars, making them prohibitively expensive for many Americans.<sup>8</sup>

President Trump signed the *Over-the-Counter Hearing Aid Act* into law in 2017. This law, based on the bill led by Senators Warren, Grassley, 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 (OTC) to Americans with mild and moderate hearing loss.<sup>9</sup> 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.

To ensure the final regulation is consistent with congressional intent, we urge the FDA to exclude any unnecessary restrictions that hinder access to OTC devices or limit their effectiveness 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 preventing the introduction of any limits on gain. These standards were appropriately based on 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. Further, these standards will ensure the maximum effectiveness and innovation of OTC devices without compromising consumer safety.
- Maintaining the federal preemption of state laws governing the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC products, which is necessary to ensure consumers can access these devices without interference. This was based on guidance from the President’s Council of Advisors on Science and Technology (PCAST) and NASEM.<sup>10</sup> Without federal preemption, a wide array of state laws would prevent consumers from easily and directly accessing OTC hearing aids, limiting the number of consumers who would otherwise be helped by this law.<sup>11</sup> 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.

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.

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<sup>8</sup> 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/>.


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


<sup>10</sup> 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](https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf); The National Academies of Sciences, Engineering, and Medicine, “Recommendations,” June 2016, [https://www.nap.edu/resource/23446/Hearing\\_Recommendations.pdf](https://www.nap.edu/resource/23446/Hearing_Recommendations.pdf).

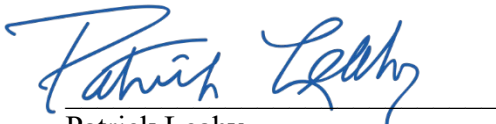
<sup>11</sup> *Id.*

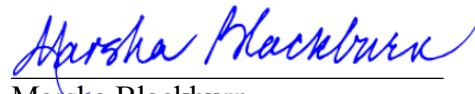
It has been over four years since the *Over-the-Counter Hearing Aid Act* was passed into law. We appreciate President Biden's commitment to promoting OTC hearing aids for Americans with hearing loss, as outlined in his Executive Order on Promoting Competition in the American Economy, and we are encouraged that FDA has taken this critical step to finally issue a proposed rule. 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.

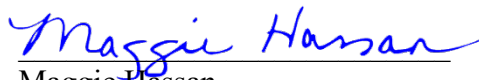
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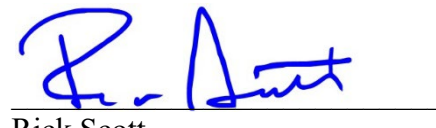
  
Elizabeth Warren  
United States Senator

  
Charles E. Grassley  
United States Senator


  
Patrick Leahy  
United States Senator


  
Marsha Blackburn  
United States Senator


  
Maggie Hassan  
United States Senator


  
Rick Scott  
United States Senator

  
Lindsey Graham  
United States Senator

  
Chris Van Hollen  
United States Senator

  
Bernard Sanders  
United States Senator

  
Kevin Cramer  
United States Senator

  
Rand Paul  
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