

Congress of the United States

Washington, DC 20515

May 28, 2024

Hon. Robert M. Califf, M.D., MACC
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We write today to urge the U.S. Food and Drug Administration (FDA) to strengthen protections for individuals with hearing loss by informing consumers that a hearing aid employs proprietary software. Such software forces consumers to return to the original manufacturer or network-affiliated clinics and providers for repairs, replacements, and adjustments. Hearing aids are essential medical devices for millions of Americans, but, for many consumers, proprietary software introduces barriers to maintaining the devices while increasing costs.

Americans buy over 4 million hearing aids annually.¹ These devices are critical in preventing social isolation, depression, and cognitive decline in elderly people with hearing loss.² A recent study also found that adults with hearing loss who used hearing aids regularly had a 24% lower mortality risk than those who do not use them.³ Further, untreated hearing loss has been associated with an increased risk of dementia, walking problems, and accidental injuries⁴ as well as a 46% increase in health care costs over a 10-year period.⁵

1 “About Hearing Industries Association.” *Hearing Industries Association*, <https://betterhearing.org/about/about-hearing-industries-association/>.

2 Bowl, Michael R., and Dawson, Sally J. “Age-Related Hearing Loss.” U.S. National Library of Medicine, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6671929/> Aug. 2019.

3 “Hearing Aids May Help People Live Longer.” *Newsroom*, Keck School of Medicine of USC, 9 Jan. 2024. <https://keck.usc.edu/news/hearing-aids-may-help-people-live-longer/>.

4 “The Hidden Risks of Hearing Loss.” Johns Hopkins Medicine, 1 Nov. 2022, <https://www.hopkinsmedicine.org/health/wellness-and-prevention/the-hidden-risks-of-hearing-loss>.

5 “Patients with Untreated Hearing Loss Incur Higher Health Care Costs over Time.” *Johns Hopkins Bloomberg School of Public Health*, 8 Nov. 2018, <https://publichealth.jhu.edu/2018/patients-with-untreated-hearing-loss-incur-higher-health-care-costs-over-time>.

In recent years, the hearing aid industry has made significant technological advancements, including Bluetooth, telecoil, and noise reduction technologies that improve the lives of those who wear hearing aids. Today's advanced technologies allow hearing aids to be programmed to the consumer's exact hearing needs, making them more effective, convenient, and comfortable to wear. However, many hearing aid manufacturers also use proprietary software that prevents specialists and other manufacturers from repairing or replacing their devices. These hearing aids are more commonly known as "locked" hearing aids.

While some may ultimately choose a locked hearing aid, such devices can also be more challenging to use or more costly for consumers. For example, when a consumer buys a locked hearing aid from a company that goes out of business, they are left unable to repair it should it break or even need routine repairs. Additionally, when a consumer moves or is traveling far from where they originally purchased the hearing aid, they may effectively become unable to have the device serviced at all.

Furthermore, requiring consumers to return to a specific manufacturer prevents them from finding cheaper options for necessary services. With an average price of approximately \$2,500,⁶ a hearing aid is already a major investment for most consumers who need them. For more severe hearing loss, one hearing aid can cost upwards of \$6,000.⁷ Hearing aid manufacturers' restrictions on repairs allow manufacturers to depress competition and further drive up prices for services, which can leave hearing aids out of reach for low- and middle-income individuals. Therefore, it is crucial that consumers be empowered to make informed decisions when buying a hearing aid, including having the knowledge from the outset of whether they are buying a locked hearing aid.

We commend the FDA's dedication to ensuring that consumers have the information required to make informed decisions as they invest in a hearing aid by already including robust labeling regulations with respect to other important attributes of the devices. **That is why we respectfully ask the FDA to inform consumers that a hearing aid contains proprietary software that would require the consumer to return it to the original manufacturer or network-affiliated clinics or providers for repairs, replacements, or adjustments by, at a minimum, proposing and finalizing a rule updating existing regulations to require a disclaimer on the label of the hearing aid.** This disclaimer could save consumers money and ensure that they can always access the services they need for their device.

⁶ Jilla, Anna Marie, et al. "Hearing Aid Affordability in the United States." U.S. National Library of Medicine, 18 Apr. 2023, <https://pubmed.ncbi.nlm.nih.gov/33112178/>.

⁷ Everett, Cara. "10 Best Hearing Aids of February 2024: Expert Reviewed." Edited by Brad Ingrao and Kathleen Cameron, *10 Best Hearing Aids of February 2024: Expert Reviewed*, National Council of Aging, 1 Feb. 2024, <https://www.ncoa.org/adviser/hearing-aids/best-hearing-aids/>.

The FDA has the ability to improve labeling requirements for medical devices, including hearing aids. We urge the agency to rely on its existing authority under, *inter alia*, 21 U.S.C. §§ 331, 334, 351, 352, 360i, 360j and Section 709 of the *FDA Reauthorization Act of 2017*. We encourage the FDA to employ these authorities to strengthen labeling requirements by requiring this disclaimer on the label of hearing aids. In addition, we urge the FDA to consider other actions the agency can take to support competition in the hearing aid industry and lower prices for consumers.

Thank you for your commitment to protecting consumers with hearing loss. By notifying consumers that a hearing aid contains proprietary software, we can empower them to save money and help individuals make informed decisions critical to their health and wellbeing. We look forward to your prompt response.

Sincerely,



Kevin Mullin
Member of Congress



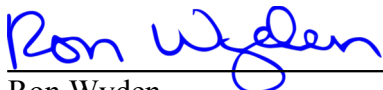
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United States Senator



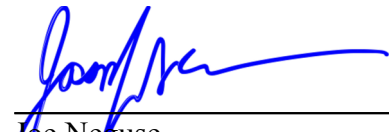
Marsha Blackburn
United States Senator



Chris Van Hollen
United States Senator



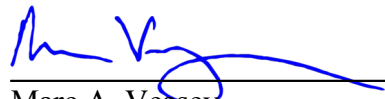
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United States Senator



Joe Neguse
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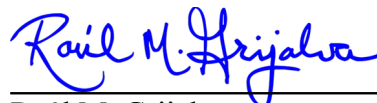
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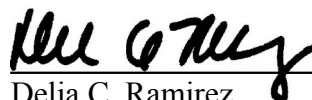
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