# United States Senate

WASHINGTON, DC 20510

June 29, 2022

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

Dear Commissioner Califf:

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 bring to your attention to a new investigation by our staff regarding the nature of dominant hearing aid manufacturers' efforts to undermine the rule and diminish the effectiveness of over-the-counter (OTC) hearing aids. We hope that you review our findings, which provide important context on the public comment process, and that you finalize a rule that ensures OTC hearing aids are safe, effective, accessible, and affordable for all Americans.

The findings of the investigation, provided in detail in the attached report, include:

- **Americans Believe OTC Hearing Aids Will Have Significant Benefits.** In the public comments, Americans shared their personal stories and explained what accessible, affordable, safe, and effective OTC hearing aids would mean to them and their loved ones.
- **Key Health Care Professional Groups Support FDA's Proposed Rule.** Many comments submitted by health care professionals, including the Academy of Doctors of Audiology (ADA), indicated support for the proposed rule and affirmed that it would allow for safe and effective OTC hearing aids. In ADA's comment letter, the organization wrote that it "enthusiastically supports the Proposed Rule."[2] Other health care experts expressed their support for FDA's preemption provisions and described claims that federal preemption would undermine state consumer protection laws as "unfounded."[3]
- **Dominant Hearing Aid Manufacturers Are Seeking to Weaken FDA's Proposed Rule.** Dominant hearing aid manufacturers have opposed key provisions of the FDA's proposed rule – most notably the 120 decibels (dB) sound pressure level (SPL) output limit, the absence of a gain limit, and federal preemption requirements. For example, comments from Starkey, the largest U.S.-based hearing aid manufacturer, and the Hearing Industries Association, a trade group that represents giant manufacturers and

[1] U.S. Food and Drug Administration, Federal Register Notice, "Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids," October 20, 2021, https://www.federalregister.gov/documents/2021/10/20/2021-22473/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids.
[2] Regulations.gov, "Comment from Academy of Doctors of Audiology," https://www.regulations.gov/comment/FDA-2021-N-0555-0981.
[3] Regulations.gov, "Comment from Frank Lin," https://www.regulations.gov/comment/FDA-2021-N-0555-1069.

distributors, revealed serious attempts to undermine the effectiveness of OTC hearing aids.[4]

- **Dominant Hearing Aid Manufacturers and Aligned Groups Backed Astroturf Campaigns to Weaken FDA's Proposed Rule and Distort Public Perception.** In total, our staff identified what appear to be 19 industry-driven form letters, and language from these letters appeared in over 400 comments, accounting for nearly 40 percent of all publicly available comments that FDA received on the proposed rule. Although written by individuals, many of these letters used identical or nearly-identical language that either raised concerns with or recommended changes to the maximum output level, gain limit, and federal preemption requirements or any combination of the three – suggesting that they were sent as part of extensive industry-backed "astroturf" campaigns designed to give the impression of an independent grassroots response.

We support key provisions of FDA's proposed rule, which we believe will expand access to hearing aids, reduce consumer costs, and ensure that the new OTC hearing aid market is robust. The attached report reveals a powerful entrenched industry using astroturf lobbying tactics to influence FDA's rulemaking process and weaken the agency's OTC hearing aid rule.

We urge FDA to finalize a rule that is consistent with congressional intent and ensures OTC hearing aids are safe, effective, accessible, and affordable for all Americans. 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.

Sincerely,

Elizabeth Warren
United States Senator

Charles E. Grassley
United States Senator

[4] Regulations.gov, "Comment from Starkey," https://www.regulations.gov/comment/FDA-2021-N-0555-0968; Regulations.gov, "Comment from Hearing Industries Association," https://www.regulations.gov/comment/FDA-2021-N-0555-0970.