Congress of the United States
Washington, DC 20515

April 6, 2022

Dr. Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, Docket No. FDA-2021-N-0555

Dear Commissioner Califf:

We write to you today to revisit the importance of amending certain provisions of the Food and Drug Administration's (FDA) Proposed Rule (86 FR 58150) to establish a regulatory category for over-the-counter (OTC) hearing aids in accordance with the *Over-the-Counter Hearing Aid Act*. Now that the public comment period is closed, there is an overwhelming consensus that the designated output and gain limits for OTC hearing devices must be amended.

As you know, OTC hearing devices are intended only for those over the age of eighteen with "perceived mild-to-moderate hearing loss." However, the proposed rule allows OTC devices to be amplified up to 120 decibels (dB) without imposing any hearing gain limit. This threshold allows those with hearing loss greater than the intended mild-to-moderate level to access OTC hearing devices. This hurts consumers and patients in two ways. First, it means individuals suffering from greater levels of hearing loss could put off a needed visit with a licensed hearing professional. Doing so could lead to worsening their existing symptoms, delaying an accurate diagnosis and treatment, and even creating irreparable damage to their hearing. Secondly, it means those with perceived mild-to-moderate hearing loss would be exposed to harmful levels of noise that could result in further damage to their long-term hearing. In order to avoid these concerns, FDA should impose a gain limit of 25 dB and an overall output limit of 110 dB.

Ninety-one stakeholders ranging from patient advocacy organizations to trusted hearing providers submitted formal comments to the FDA expressing concern that the proposed 120 dB maximum output limit and omission of a gain requirement will put patient safety at risk. These stakeholders include the American Academy of Otolaryngology - Head and Neck Surgery, American Society on Aging, the American Speech-Language-Hearing Association, the American Academy of Audiology, and more.

Proper safeguards must be in place to protect Americans suffering from hearing loss. As you finalize the Proposed Rule, we urge you to remember the staggering number of individuals and organizations who have spoken out in the name of patient and consumer safety.

Thank you for your thoughtful consideration. Should you have any further questions, please reach out to Patrick Maillet (patrick.maillet@mail.house.gov) in Rep. McCollum's office.

Sincerely,

Betty McCollum
Member of Congress

Rosa DeLauro
Member of Congress