



November 17, 2020

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

Dear Commissioner Hahn:

AARP, on behalf of our nearly 38 million members and all older Americans nationwide, urges you to publish regulations regarding over-the-counter hearing aids, as required by the Over the Counter Hearing Aid Act of 2017 (P.L. 115-52). The law required the Food and Drug Administration to propose regulations by August of this year. Continued delay in the release of these regulations further delays access to affordable treatment for millions of Americans with mild to moderate hearing loss.

As part of our mission, AARP works to ensure older Americans continue to lead active and engaging lives. A person's ability to hear greatly affects how they interact with other people, loved ones, and the environment around them. Difficulty hearing creates a barrier to social interaction, and can have a negative health impact. As you know, hearing loss is a substantial problem, affecting more than 30 million Americans. It affects more than 40 percent of Americans older than age 60, more than 60 percent of those older than age 70, and nearly 80 percent of people older than age 80. Left untreated, hearing loss can negatively affect older people's quality of life by preventing them from engaging with others, leading to social isolation and limiting ability to work. Hearing loss also has been associated with depression, dementia, cognitive decline, and poorer physical functioning. Unfortunately, hearing aid usage by those experiencing hearing loss is very low, with only about 20 percent of those affected using a hearing aid. A significant factor in the lack of utilization is the cost of hearing aids – which average over \$2,000 per ear. Aside from cost, other factors such as access and social stigma prevent people from using these life-altering technologies. OTC hearing aids would help alleviate many of these burdens.

Establishing an OTC hearing aid category, as required by P.L. 115-52, will create greater opportunities for millions of Americans to get relief. We understand the unprecedented strain the FDA is under during the current public health emergency. If these overdue proposed regulations are not able to be published at this time, we request an update on their status and a reasonable timeframe for publication. If you have any questions or need more information, please feel free to contact me or Andrew Scholnick of our Government Affairs staff at 202-434-3770 or [ascholnick@aarp.org](mailto:ascholnick@aarp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "David Certner", is written over a light blue horizontal line.

David Certner  
Legislative Counsel and Legislative Policy Director  
Government Affairs