

Congress of the United States
Washington, DC 20515

October 27, 2020

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

Dear Commissioner Hahn,

We are writing regarding our legislation, the Over the Counter (OTC) Hearing Aid Act of 2017, P.L. 115-52, which became law over three years ago. This act aimed to increase access to hearing aids for individuals suffering from mild to moderate hearing loss. The law required the Food and Drug Administration (FDA) to propose regulations by August of this year. We request an update on the status of the required regulation and ensure they reflect the policy goals.

The regulations that govern access to hearing aids has been largely untouched since the 1970's and only 20 percent of Americans who could benefit from hearing aids actually receive one.¹ This low rate of utilization has been attributed to the high cost of hearings aids (over \$4,000 per pair), stigma, and the difficulty of accessing them. Unfortunately, these factors still persist today. The President's Council of Advisors on Science and Technology and the National Academies of Science Engineering and Medicine both recommended that Congress establish a new OTC category for hearing aids designed to treat mild to moderate hearing loss to increase consumer access and reduce costs associated with them.² Based on these recommendations, our legislation aimed to improve the innovation needed to increase access to hearing aids for those who needed them.

Our legislation provided a path forward for those suffering from mild-to-moderate hearing loss, but who could not or would not access traditional hearing aids by giving them another option. The availability of OTC hearing aids will provide solutions to the key reasons identified by experts for low utilization. An OTC hearing aid, regulated as safe and effective by the FDA, would cost hundreds of dollars, not thousands. By unleashing the consumer electronics industry's power to innovate, under FDA's oversight, we can overcome the stigma associated with hearing aids. New products could allow consumers to have their hearing aids on the same mobile platform used in their daily lives. Allowing those with mild and moderate hearing loss to directly access and self-fit hearing aids will drastically expand the availability and accessibility of the needed device. Delay in providing regulations impedes this needed progress.

We request an update on the status of the regulation as required by the OTC Hearing Aid Act of 2017. If barriers to completing the Agency's work have arisen, we request a response on the specifics of any barriers so that we can work with you to address them. Finally, we request that you provide us an updated timeline for issuing the regulation.

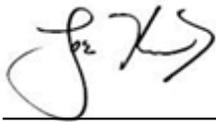
¹ <https://www.asha.org/articles/untreated-hearing-loss-in-adults/>

² https://www.hearingloss.org/wp-content/uploads/Cassel_Christine-PCAST.pdf;
<https://www.asha.org/uploadedFiles/Consensus-Paper-From-Hearing-Care-Associations.pdf>

We are cognizant of the tremendous strain put on the agency as it has endeavored to respond to the coronavirus pandemic. It is our view that, now more than ever, it is important for consumers to be able to access an OTC hearing aid to alleviate the many negative consequences of hearing loss that can lead to and exacerbate isolation. An OTC hearing aid can be acquired without the need for an office appointment with a health professional. We should be doing everything we can to encourage the ability of consumers to address health issues without needless exposure to the coronavirus.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "JP Kennedy", written above a horizontal line.

Joseph P. Kennedy, III
Member of Congress

A handwritten signature in blue ink, appearing to read "Earl L. 'Buddy' Carter", written above a horizontal line.

Earl L. "Buddy" Carter
Member of Congress