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## United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

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December 5, 2019

ADM Brett Giroir, M.D.  
Assistant Secretary for Health  
Acting FDA Commissioner  
United States Department of Health and Human Services  
Food and Drug Administration  
200 Independence Ave, SW  
Washington, DC 20201

Dear Dr. Giroir,

Hearing loss is one of the most common conditions affecting older Americans. According to the National Institute on Aging, approximately one in three people between the ages of 65 and 74 has hearing loss, and nearly half of older adults over the age of 75 have difficulty hearing. Hearing difficulties can lead to other problems in adults, including depression and a decline in cognitive abilities. Furthermore, studies have shown that older adults with hearing loss have a greater risk of developing dementia. Hearing aids can greatly assist those with hearing loss to lead normal lives. Sadly, although hearing aids are considered prescription products, they are not generally covered by health insurance or Medicare and can cost thousands of dollars. For seniors or those on limited budgets, at these prices, hearing aids may not be obtainable. Of the 48 million Americans who experience age-related hearing loss only around 14 percent are able to afford hearing aids.

In 2017, President Trump signed into law the Over-the-Counter (OTC) Hearing Aid Act, which we introduced with Senators Hassan and Isakson. This law removes outdated regulations blocking consumer access to affordable hearing aids by amending the Food, Drug, and Cosmetic Act, and allowing the Food and Drug Administration (FDA) to categorize certain hearing aids as over-the-counter and issue regulations regarding those hearing aids to ensure this new category of OTC hearing aids meets the same high standards for safety, consumer labeling and manufacturing protections as all medical devices.

In October of 2018, the FDA announced these rules would be a priority on their Fall 2018 Unified Agenda and would be able to deliver the proposed rules well in advance of the August 2020 statutory deadline. It is now December of 2019 and we have yet to see these regulations come to fruition. Given the ever increasing need for these devices, we request answers to the following questions by no later than December 19, 2019:

1) What is the status of the OTC hearing aid rules and regulations?

2) When do you expect to finalize the OTC hearing aid rules?

Thank you in advance for your prompt attention to these matters. Should you have any questions please contact Karen Summar or Kirsten Wing of Finance Committee Staff at 202-224-4515 or Susannah Savage of Senator Warren's staff at 202-224-4543.

Sincerely,



Chuck E. Grassley  
United States Senator  
Iowa



Elizabeth Warren  
United States Senator  
Massachusetts