

Congress of the United States
Washington, DC 20515

September 16, 2021

President Joseph R. Biden
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear President Biden:

We write to you today regarding the confusion that has been created by the federal government regarding the sale of over-the-counter (OTC) hearing aids, and to express our support for robust access to quality hearing health technologies for all Americans. This issue is particularly important to all of us because some of us depend on a hearing device ourselves, many of us have a loved one who requires specialized hearing assistance, and all of us represent constituents who either already depend on a hearing device or should be using one. To achieve our mutual goal of increased access to hearing aids, we appreciate your recent Executive Order asking the Department of Health and Human Services (HHS) to swiftly finalize the OTC proposed rule, which the FDA was required by law to promulgate by August 2020. However, while your Administration continues to finalize this rule, we remain concerned that the growing confusion has led to a patchwork of conflicting regulations leaving consumers at risk.

Failure to issue these regulations has caused chaos in the marketplace as many companies have started selling hearing devices as OTC before they are legally permitted to do so, leaving it up to the states to protect consumers. To be clear, devices that are currently marketed as OTC hearing aids are nothing more than cheap amplification devices that can further damage the user's hearing.

In response, a bipartisan group of 15 state attorneys general in Arizona, Louisiana, South Carolina, Georgia, Oregon, North Carolina, Arizona, Ohio, Texas, Connecticut, Michigan, Nevada, Kentucky, Vermont, Iowa and Kansas have issued warnings citing the risk that these personal amplification devices could cause further hearing damage.¹ To bring certainty back to the marketplace and, most importantly, protect consumers, we hope you will seriously consider the recommendations put forth in a 2018 consensus paper developed by several hearing care associations, including:

- product requirements appropriate for OTC hearing devices targeting mild-to-moderate hearing impairment;

¹ <https://www.iowaattorneygeneral.gov/for-consumers/ag-miller-cautions-consumers-considering-over-the-counter-hearing-device-purchases>

- concise, outside-of-the-box labeling appropriate for OTC with strong recommendations to consult with a hearing healthcare professional;
- comprehensive, inside-the-box labeling appropriate for over-the-counter medical devices;
- a new OTC category definition that it is easily comprehensible by consumers and in line with risk class requirements for safety and effectiveness; and
- adequate provisions for consumer protection in coordination with the Federal Trade Commission (FTC).²

When Congress passed legislation to allow OTC hearing devices, it did so to achieve the bipartisan goal of better serving the American public with affordable, accessible hearing technologies. While we remain committed to that goal, we fear that unclear regulations will lead to widespread misuse of amplifiers that do not address actual hearing loss and can exacerbate the underlying problems due to poor self-diagnosis.

As Congress looks to the future, post OTC regulations, we recognize that more remains to be done to ensure patient access to a wide range of hearing health technologies, including Medicare coverage of hearing aids fit by audiologists or hearing instrument specialists. However, this goal can only be accomplished when we all work together and ensure all the facts are accurate and complete. We look forward to building on the successes we have already achieved for patients and families, and thank you for your consideration of these recommendations. Should you have any further questions, please reach out to Patrick Maillet (patrick.maillet@mail.house.gov) in Rep. Betty McCollum's office.

Sincerely,



Betty McCollum
Member of Congress



Rosa DeLauro
Member of Congress



Jan Schakowsky
Member of Congress



Lucile Roybal-Allard
Member of Congress

/s/

André Carson
Member of Congress

² <https://www.asha.org/siteassets/uploadedfiles/consensus-paper-from-hearing-care-associations.pdf>