September 16, 2022

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Via Email: fdadockets@oc.fda.gov

Re: OTC Hearing Aid Rule, 21 C.F.R. part 800 (2022), Docket No. FDA-2021-N-0555

Hon. Commissioner Dr. Robert M. Califf, MD,

We, the undersigned State Attorneys General, submit this letter in an effort to best protect individuals with hearing impairments in need of "Prescription hearing aids" as outlined in 21 C.F.R. part 800 as amended on August 22, 2022 ("the Rule"). Currently, all fifty states have individual hearing aid laws designed to protect consumers by addressing traditional consumer protection issues – such as warranties and return policies – and to clearly define who, in each respective state, is permitted to legally fit for and dispense hearing aids. After the enactment of the Rule, due to what we believe to be unintended verbiage, questions exist as whether Prescription hearing aids require a prescription. Therefore, the states respectfully request the Food and Drug Administration ("FDA") to clarify the Rule's definition of "Prescription hearing aids" does *not*, in fact, require a prescription. Guidance on the definition will allow states to more easily bring their individual laws into congruence with FDA definitions and will ensure a smooth transition to offering both OTC and Prescription hearing aids.

First and foremost, the goal of this letter is not to ask the FDA to reverse or reconsider any part of the Rule. We recognize and respect the long process the FDA undertook – including an extensive comment period – to allow for OTC hearing aids, and we applaud the FDA in offering consumers additional and more economical choices when it comes to addressing hearing loss.

The new FDA rule essentially creates two tiers of hearing aids: "OTC" for mild to moderate hearing loss and "Prescription" hearing aids for more severe hearing loss. Prior to the Rule, state laws only addressed what are now known as Prescription hearing aids. However, since no actual prescription was necessary, hearing aids in our states were not and are not labeled as such, nor

were all individuals required to have prescribing abilities to lawfully fit for or dispense hearing aids.

Although we do not believe it to be the objective, the use of the term "Prescription hearing aid" poses unintended consequences to maintaining the status quo of those who may fit for and dispense hearing aids throughout a number of states. By labeling non-OTC hearing aids as "prescription" hearing aids and placing non-OTC hearing aids within the scope of 21 C.F.R. § 801.109, there is now uncertainty regarding whether non-OTC hearing aids may only be obtained upon an order or prescription from a practitioner with authority under state laws to order or prescribe medical devices. Arguably, the Rule now raises concerns whether currently licensed hearing aid providers will be permitted to continue to fit and provide patients with Prescription hearing aids, depending on how the individual state statute is written. In turn, this affects consumers in receiving Prescription hearing aids if they are limited as to those in their states who can fit and dispense.

Take for example, Ohio's law regarding the fitting, sale, and return of hearing aids. Ohio R.C. 1345.30 *et seq.* This law states, in pertinent part, there are three classes who may fit for and dispense hearing aids: (1) licensed hearing aid fitters and dealers; (2) physicians; and (3) audiologists. In Ohio, only the second group listed – physicians – are authorized to prescribe in the state, meaning that, arguably, licensed hearing aid fitters and dealers and audiologists could no longer assist those with more-than-moderate hearing loss to obtain proper Prescription hearing aids. Approximately twenty[1] other states have laws drafted in a similar manner that will need to be appropriately amended.

Further, uncertainty regarding implementation of the Rule may frustrate rather than advance the original purpose of the FDA's rulemaking to increase access to hearing aids. If a prescription is necessary to obtain Prescription hearing aids, many consumers who experience severe hearing loss may require two appointments—one with a physician or other licensed professional with prescriptive authority and another with a hearing aid specialist to dispense the hearing aids. Requiring multiple appointments creates additional barriers to care that did not previously exist. This concern is heightened due to the fact such barriers would impact those suffering from severe hearing loss.

To ensure continued access to hearing aids, clarification is required. This clarification is being requested not in an effort to delay consumer access to OTC hearing aids, nor is it being requested to, in any way, protest or oppose the Rule; rather, it is being made to ensure that those in need of Prescription hearing aids have the same access to such devices as they did prior to the enactment of the Rule.

Providing clarification would advance both the goals of the Rule and the undersigned Attorneys General in increasing access to hearing aids for people with diverse needs. If prescription

[1] Alabama, Colorado, Hawaii, Iowa, Kentucky, Maine, Missouri, Nebraska, New Jersey, New York, North Dakota, Ohio, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia, West Virginia, Wisconsin, Wyoming.

authority is not required for non-OTC hearing aids, the FDA should clarify as soon as practicable to avoid undue interruptions in necessary care for adults with severe hearing loss.

Finally, states' attorneys general, states' agencies, and states' legislatures need additional time to enact these changes. Although many states have begun analyzing how they can best change their laws to accommodate for the duality of OTC and Prescription hearing aids, realistically, the two-month implementation period simply is neither practical nor feasible. By issuing guidance now, it will allow for less changes at the state level and will allow for states to have a better understanding of the Rule's requirements that must be considered when amending current state legislation. Many state legislatures have been in recess during this entire two-month time and do not even convene until 2023.

Therefore, we respectfully request the FDA issue guidance on whether "Prescription hearing aids" require a prescription. The states' Attorneys General remain hopeful that given this additional direction, our laws can be changed to best protect those seeking OTC and Prescription hearing aids by preserving adequate access to both. Thank you for your consideration.

Respectfully,

DAVID YOST
Attorney General of Ohio

TOM MILLER
Attorney General of Iowa