February 27, 2023

Honorable Melony Griffith, Chair
Honorable Katherine Klausmeier, Vice Chair
Senate Finance Committee
3 East
Miller Senate Office Building
Annapolis, Maryland 21401

RE: Support of SB449 (as amended in the House reprint for HB401)

Dear Members of the Senate Finance Committee:

I am Chief Audiology Officer for Miracle-Ear, Inc. – a leading hearing aid provider with 18 offices in Maryland. Miracle-Ear believes that patient safety, satisfaction, and access are of paramount importance in helping individuals address their hearing needs.

I write in support of SB449, as amended and issued as a reprint on February 22, 2023, for HB 401, which authorizes licensed audiologists and hearing aid dispensers to order the use of prescription hearing aids, consistent with intent of the U.S. Food and Drug Administration (FDA) and the Maryland Department of Health.[1] We ask that you adopt the language approved by the house for HB 401 for SB 449.

As you know, in August 2022, FDA promulgated regulatory changes to increase access to hearing aids, including establishing OTC hearing aids as a new category of medical devices.[2]

In the same regulation, FDA reclassified all Class I and II non-OTC hearing aids (i.e., traditional hearing aids that have been dispensed by state-licensed audiologists and hearing aid dispensers for the last 50 years) from "restricted medical devices" to "prescription medical devices" governed by 21 C.F.R. 801.109. Pursuant to 21 C.F.R. §801.109, non-OTC hearing aids may only be dispensed upon "the prescription or other order" of a practitioner licensed by law to direct the use of such device. In other words, for the first time in the United States, consumers and patients may only obtain non-OTC hearing aids upon a prescription or other order from a practitioner licensed under state law to direct the use of a "prescription hearing aid."

FDA leaves it to states the authority to define which providers are qualified to prescribe or order non-OTC hearing aids (i.e., now effectively "prescription hearing aids"). FDA delegated this authority to states because the Agency does not have jurisdiction over practitioner licensure—this is left to states. However, shortly before the regulatory changes became effective, FDA issued supplemental guidance to states in a "Dear State Official" letter, making it clear that the agency's intent was not to disrupt access to

[1] U.S Food and Drug Administration, Dear State Official Letter (October 13, 2022), *available* at https://www.fda.gov/media/163084/download; Maryland Department of Health, Over-the-Counter Hearing Aid, OTC Memo.pdf (maryland.gov)

[2] U.S Food and Drug Administration, Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, (August 17, 2022), *available* at https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids

prescription hearings dispensed by state-licensed audiologists and hearing instrument specialists (referred to as hearing aid dispensers in Maryland). Specifically, in its guidance, FDA clarified that the regulatory changes related to the classification of non-OTC hearing aids as prescription medical devices:

> "Does not change the necessary qualifications of who may provide hearing healthcare with prescription hearing aids, including the recommendation, selection, fitting, and dispensing of these devices;
>
> Does not require an additional professional to take actions, for example, does not in any way require a physician's involvement prior to fitting these devices; and
>
> Does not require an examination of any kind to obtain a prescription hearing aid."[3]

Additionally, the guidance clarified that "FDA's intent is that the same professionals who recommended, selected, fitted, and dispensed restricted hearing aids before the effective date would continue to do so for prescription hearing aids after the effective date."

Many states have begun to update their licensure and dispensing laws and regulations to align with this guidance. None of these states have sought to enact changes different from this guidance because doing so would severely hamper access to prescription hearing aids and would be contrary to the way in which hearing aids have been dispensed over the last 50 years.

Hearing loss is a serious health condition that can be associated with comorbidities of dementia, social isolation, and balance problems. Hearing aid dispensers and audiologists play a critical role in helping those suffering hearing loss obtain the help they need, including identifying whether hearing aids are needed, ruling out other underlying conditions that would impact a patient's hearing, and ensuring that hearing aids are customized to the needs of the patient.

Without this legislation to provide necessary clarification that both licensed audiologists and hearing aid dispensers are authorized to prescribe or order the use of non-OTC hearing aids (again, now regulated by the FDA as prescription medical devices), Maryland remain vulnerable to losing crucial access to hearing care.

Please know I am available at (763) 710-1830 to answer any questions you or your policy staff may have regarding the concerns expressed herein.

Respectively,

Thomas J. Tedeschi

Dr. Thomas J. Tedeschi, AuD., FNAP
Chief Audiology Officer
Miracle-Ear, Inc.

[3] U.S Food and Drug Administration, Dear State Official Letter (October 13, 2022), *available* at https://www.fda.gov/media/163084/download.