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January 14, 2022

Food and Drug Administration, HHS

*Submitted electronically*

Re: Docket No. FDA-2021-N-0555 for Establishing Over-the-Counter Hearing Aids

We, the undersigned State Attorneys General, submit this comment in response to the Food and Drug Administration ("FDA") request for comments on its proposed rule for Establishing Over-the-Counter Hearing Aids.[1] Currently, all 50 states have hearing professional licensing requirements, and many have important protections for hearing aid consumers, such as mandatory warranties, returns and advertising restrictions. In considering the final rules related to Over-the-Counter (OTC) Hearing Aids, the FDA should ensure that states maintain a role as regulators in this emerging market.

As primary enforcers of our respective states' consumer protection laws, state attorneys general ("State AGs") have regulated the hearing aid market in concert with the FDA's labeling and dispensing requirements. Traditionally, the FDA has treated state requirements for hearing aids as complementary to its regulatory framework. Since the 1980s, the FDA has granted many state petitions for exemption from federal preemption for the following requirements aimed at protecting consumers in our respective states, such as:

- Enhanced physician expertise to fit hearing aid users under the age of 18;
- Disclosures concerning medical attention for certain medical conditions;

[1] *See* request for Comments, Medical Devices; Ear, Nose and Throat Devices: Establishing Over-the-Counter Hearing Aids, 86 Fed. Reg.

- Mandatory information and disclosures on hearing aid receipts;
- Recordkeeping requirements; and
- Written notice of money-back guarantees.

While the FDA's proposed rule offers consumers much needed relief in the form of more affordable and accessible hearing aids, it could have unintended negative consequences on our constituents. The proposed rule includes broad language that could be interpreted to repeal virtually *all* the state-requested exemptions from preemption issued by the FDA since 1980 – even those related exclusively to non-OTC hearing aids. Such language could create unneeded confusion and the potential for unnecessary litigation.

We respectfully request the FDA consider the following three proposals to clarify the impact of the proposed rule on state regulations related to all hearing aids, including OTC hearing aids.

*First,* the FDA should define preemption terms in a way that recognizes the important role state and local entities play in protecting consumers. The FDA should define the language "restrict or interfere" to pertain only to state and local laws that prevent or create an obstacle to a commercial activity involving OTC hearing aids. Thus, a state warranty requirement for OTC hearing aids should not be preempted merely because it *pertains* to the commercial activity of servicing when it does not prevent or create an obstacle to servicing. The same would be true of other consumer protections, such as mandatory disclosures, returns, and written notice of money-back guarantees.

*Second,* the FDA should state explicitly the type of state requirements that the final rule ***would not*** preempt. The existing regulation on device preemption, 21 C.F.R. § 808, lists types of state and local requirements that are generally not preempted. The final rule should expand this list with examples pertaining to hearing aids. For example, it should explicitly identify state and local requirements that relate to the sale of hearing aids for users under 18 years of age as *not* preempted.
*Third*, the FDA should explicitly state in the final OTC Rule: (a) that the existing processes in place in 21 C.F.R. §808.20 to petition the FDA for a preemption determination will continue to apply; and (b) that the FDA will find against preemption when consistent with the statutory language and "in the public interest."

Ultimately, it is unacceptable for us as primary enforcers of our respective states' consumer protection statutes to step aside and cede the responsibility for protecting consumers that use hearing aids to the companies supplying the

product. We must be allowed to continue with our traditional consumer protection role and we strongly encourage the FDA to make that clear in the final OTC Rule. Additionally, we are concerned with the inadequate age verification processes mandated and deficient labeling requirements. Without these proper guardrails to protect consumers' health, OTC hearing aids could result in hearing loss or other consumer harm. The FDA should mandate age verification processes to protect those under 18 and ensure proper labeling to make clear that OTC hearing aids are only for those with mild to moderate hearing loss.

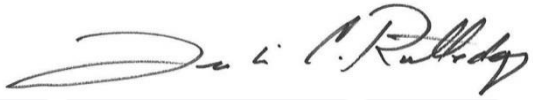
We appreciate the FDA's willingness to listen to and consult with the State AGs with respect to regulating these sophisticated medical devices. We hope the FDA will continue to recognize the important role that states play in the healthcare device market and that the FDA will incorporate the ongoing feedback provided in this letter.

Sincerely,

William Tong
Connecticut Attorney General

Dave Yost
Ohio Attorney General

Mark Brnovich
Arizona Attorney General



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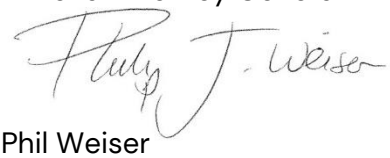

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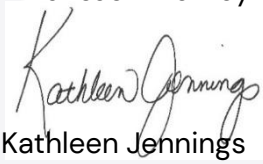

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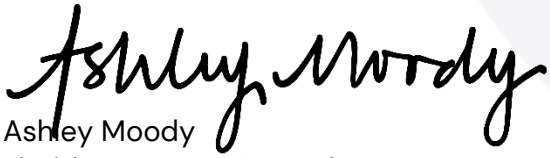

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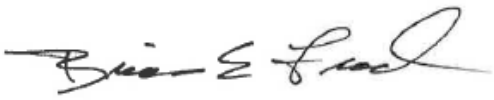

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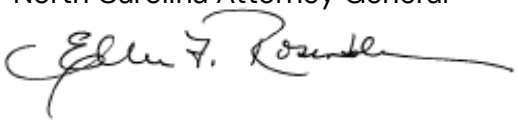

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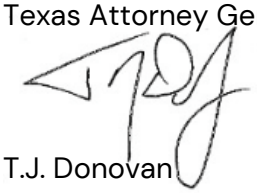

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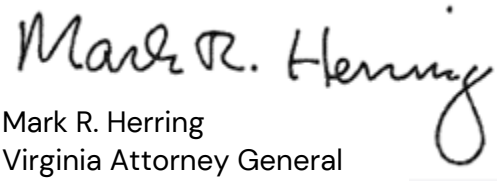

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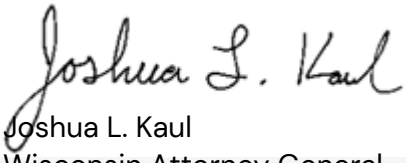

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