



DEPARTMENT OF THE ATTORNEY GENERAL

DAVID Y. IGE
GOVERNOR

HOLLY T. SHIKADA
ATTORNEY GENERAL

For Immediate Release
January 20, 2022

News Release 2022-05

ATTORNEY GENERAL SHIKADA URGES FDA TO PRESERVE STATE REGULATION OF OVER-THE-COUNTER HEARING AIDS

HONOLULU – Hawai'i Attorney General Holly T. Shikada joined a bipartisan coalition of 42 states and territories urging the U.S. Food and Drug Administration to preserve state authority to enforce their consumer protection laws in connection to the sale of over-the-counter (OTC) hearing aids.

The FDA is currently considering a proposal that would establish for the first time a new category of OTC hearing aids that would allow such devices to be sold directly to consumers without a medical exam or fitting by an audiologist, and making amendments to update the regulatory framework for hearing aids.

Currently, all 50 states have hearing professional licensing requirements and many have important protections for hearing aid consumers, including mandatory warranties and returns and advertising restrictions. The attorneys general caution that rules currently under review by the FDA may unintentionally hinder or repeal those important consumer protection authorities, undermining states' abilities to ensure safe and affordable access to hearing aids. The attorneys general urge the FDA to make explicit that their federal rule will not preempt these critical state consumer protections.

"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," the comment letter states.

"Although we support more affordable and accessible options for hearing aids, it shouldn't be at the expense of the public's safety and well-being," Attorney General Shikada said. "It is key to maintain the State's ability to regulate hearing professional licensing requirements, so the people of Hawai'i have important protections for its hearing aid consumers."

The attorneys general further urge the FDA to strengthen age verification processes to protect children under 18 and make it clear that OTC hearing aids are only appropriate for those with mild to moderate hearing loss.

“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,” the attorneys general state.

The comment letter was led by Connecticut Attorney General William Tong and Ohio Attorney General Dave Yost, and joined by Attorney General Shikada and the attorneys general of Arizona, Arkansas, Colorado, Delaware, Florida, Georgia, Guam, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Virginia, West Virginia, and Wisconsin.

Click [here](#) to access the letter.

#

For more information, contact:
Gary H. Yamashiroya
Special Assistant to the Attorney General
Email: ATG.PIO@hawaii.gov
Web: <http://ag.hawaii.gov>
Twitter: [@ATGHlgov](https://twitter.com/ATGHlgov)