

Dept. of Justice: AG Kaul urges FDA to preserve state regulation of over-the-counter hearing aids

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MADISON, Wis. – Attorney General Josh Kaul recently 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 hearing aids.

The FDA is currently considering a proposal that would establish for the first time a new category of over-the-counter hearing aids that would allow such devices to be sold directly to consumers without a medical exam or fitting by an audiologist.

“Making hearing aids more affordable and accessible by allowing them to be sold over the counter is a great step, but it doesn’t need to come at the cost of consumer protection,” said Attorney General Kaul. “The FDA should make it clear that its proposed rule won’t interfere with the enforcement of state consumer protection rules.”

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.

The attorneys general further urge the FDA to strengthen age verification processes to protect children under 18 and make it clear that over-the-counter 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.

Joining Attorney General Kaul in the comment letter are the attorneys general of Arizona, Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Guam, Hawaii, 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, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Virginia, and West Virginia.