BUILDING A BETTER OTC HEARING AID:

AREAS FOR IMPROVEMENT IN FDA'S PROPOSED RULE

Protect the Health and Safety of Hearing Aid Users

Congress carefully restricted the OTC hearing aid category to users over the age of eighteen with "perceived mild to moderate hearing loss." The proposed rule would give the FDA few tools to enforce these restrictions and would define the new device in a way that poses safety risks to the public. The proposed rule trusts users to self-diagnose "mild-to-moderate" hearing loss based on labeling but there is no indication that the FDA has validated the labeling to show that users self-diagnose accurately. Similarly, the proposed rule leaves it to retailers and purchasers to abide by the age requirement, without requiring verification. This lack of guardrails is particularly concerning because the FDA has allowed amplification in OTC hearing aids of up to 120 dB, about the noise level of a chainsaw. Combined, these decisions pose a safety risk not only to those with severe hearing loss, who may be incentivized to use an OTC product rather than seeking medical care, but also to American consumers with near-normal hearing, who may overcorrect by using powerful new OTC products. Further, teenagers may use the products for reasons unrelated to hearing loss, such as to amplify music or games. There is nothing to prevent manufacturers from combining OTC hearing aids with other wearable consumer technologies, potentially expanding use of the product well beyond adults with mild-to-moderate hearing loss.

To minimize risks to the public, the FDA should impose a gain limit of 25 dB and an overall output limit of 110 dB. In addition, if the FDA will not implement stronger protections to ensure use only by those over 18 with perceived mild to moderate hearing loss, at a minimum, the FDA should validate the proposed labeling statements to ensure users can accurately self-diagnose their level of hearing loss.

Preserve State and Local Public Health and Consumer Protections

Currently, all fifty states have hearing professionals licensing requirements, and many have important protections for hearing aid consumers, such as mandatory warranties and returns and advertising restrictions. In addition, since 1980, the FDA has granted exemptions from preemption to allow state and local rules that provide enhanced consumer protections, such as professional requirements when fitting hearing aids for minors. The proposed rule would repeal virtually all the exemptions from preemption for state and local rules, even though the exemptions relate exclusively to non-OTC hearing aids. This means that the continued effect of such state and local laws will be unclear and may be decided in the courts.

First, the FDA should make clear that state and local requirements relating to the sale of hearing aids to minors—which, by definition, involve non-OTC hearing aids—would not be preempted. Further, the FDA should state that many enhanced consumer protection requirements, such as mandatory returns, generally do not "restrict or interfere with" commercial activities related to OTC hearing aids, and thus would also not be preempted. Second, the FDA should not repeal the existing exemptions from preemption without any analysis and should address which state and local requirements currently exempted from preemption will remain valid under the final rule. Third, the final rule should encourage use of existing processes where state or local governments can seek advisory opinions about the new preemption provision and emphasize that the FDA will find against preemption when consistent with the statutory language and "in the public interest."

Protect Hearing Aid Consumers

Hearing aids differ from most generally used consumer electronic devices. They will only become more widely used with the creation of a category of OTC hearing aids. Yet, as the proposed rule throws into question state and local consumer protections, it would create minimal federal protections for OTC hearing aid consumers. Further, the proposed rule would weaken longstanding protections for non-OTC hearing aids by ceding FDA's authority to act against false and misleading advertising, such as unsubstantiated claims about the benefits of a manufacturer's hearing aids.

The final rule should require warranties and returns as conditions of sale for all hearing aids. Such conditions are more, not less, critical with the creation of an OTC category of hearing aids. Yet, after forty years of regulating hearing aids as restricted devices, the FDA has proposed to do away with restricted device protections, abandoning its oversight of hearing aid advertisements. The final rule should retain restricted device status for OTC and non-OTC hearing aids to ensure a consistent, federally mandated standard of protection, allowing additional, complementary protections to continue at the state and local level.

We Urge the FDA to Listen Carefully

LISTEN CAREFULLY