



**EXPERTS & ADVOCATES AGREE:**

**THE FDA MUST SET SAFE STANDARDS FOR OVER-THE-COUNTER HEARING AIDS**

**More than 90 leading healthcare & consumer organizations support safe standards for OTC hearing aids for those with mild to moderate hearing loss.** Experts have voiced their concerns around the FDA’s draft guidelines for these medical devices, which allow for an output level between 115 and 120 dB and do not put a limit on gain. These amplification limits exceed what is necessary for mild to moderate hearing loss, elevating the risk of permanent hearing loss.

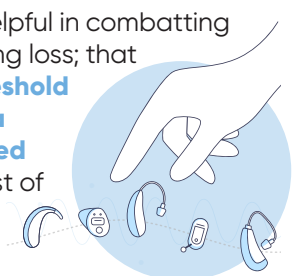
**HERE'S WHAT THEY ARE SAYING:**

“There is broad support from the consumer advocacy community and broader healthcare non-profit organizations around lowering the output limit and establishing a gain limit for OTC hearing aids. **As the FDA finalizes its draft regulations, consumer safety must be considered; we strongly encourage the FDA to lower the output limit to 110 dB and establish a gain limit of 25 dB.**”



– SALLY GREENBERG, EXECUTIVE DIRECTOR, NATIONAL CONSUMERS LEAGUE

“We have a responsibility as audiologists to protect the safety of anyone using hearing devices. For those with mild-to-moderate hearing loss, OTC hearing aids could be helpful in combatting the everyday challenges created by hearing loss; that is, if these devices are safe. **An output threshold of 120 dB is simply too high, and without a gain limit, one’s hearing could be worsened in seconds.** The FDA must act in the interest of patient safety when regulating these medical devices.”



– MARLO B. LAWENCE, AUD, DOCTOR OF AUDIOLOGY

“The FDA’s proposed maximum output levels must be reduced to decrease the risk of harm. **Exposure to sounds at 120 dB can cause pain and hearing injury almost immediately.**”



– ANIL K. LALWANI, MD, COLUMBIA UNIVERSITY MEDICAL CENTER<sup>1</sup>

“The Academy believes that the FDA significantly fell short of ensuring public health protection in the regulations. **Rather than protecting the public health, these regulations as drafted may instead put at risk the very people they are supposed to benefit.**”



– SARAH SYDLOWSKI, AUD, PHD, MBA, ASSOCIATE CHIEF IMPROVEMENT OFFICER, CLEVELAND CLINIC, PRESIDENT, AMERICAN ACADEMY OF AUDIOLOGY<sup>2</sup>

“Our concern is that there will be a percentage of patients who purchase these devices to improve hearing to a better than normal level, but who instead **will be risking damage similar to that which is caused by those who listen to earbuds at excessive volumes.**”



– JAMES C. DENNENY III, MD, CEO, AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY<sup>3</sup>

1. <https://www.regulations.gov/comment/FDA-2021-N-0555-0375>  
 2. <https://www.regulations.gov/comment/FDA-2021-N-0555-0569>  
 3. <https://www.regulations.gov/comment/FDA-2021-N-0555-1053>