"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

"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

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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.

"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

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"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

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-0555-1063