Standards in Action: Over-the-Counter Hearing Aids

By Kerri Haresign

In 2017, the bipartisan Over-the-Counter (OTC) Hearing Aid Act was passed. This legislation directed the U.S. Food and Drug Administration (FDA) to allow direct-to-consumer and retail-based hearing aid sales. In October 2022, tens of millions of Americans finally gained access to OTC hearing aids after implementation of the FDA’s final rule stemming from the Hearing Aid Act (U.S. FDA 2022). This allows Americans with mild to moderate hearing loss to buy affordable hearing aids the way they buy reading glasses—without a medical exam, from a local store or online.

This moment represents years of advocacy by associations, including the Consumer Technology Association® (CTA), industry partners, and allied organizations. It also stems in part from CTA’s voluntary OTC hearing aid industry standards, which were developed over the last decade and describe minimum performance criteria.

As North America’s largest technology trade association, CTA is the tech sector. Our members are the world’s leading innovators—from startups to global brands—helping support more than 18 million American jobs. CTA owns and produces CES®, the most influential tech event in the world.

The Impact of Access to OTC Hearing Aids

“Ninety-plus percent of adults with hearing loss have needs that can be served by over-the-counter hearing aids,” said Dr. Frank Lin, the director of the Johns Hopkins Cochlear Center for Hearing and Public Health (Span 2022).

Only 20% of people who could benefit from a hearing aid use one, and the new OTC hearing aid category opens a world of sound to Americans with hearing loss. These devices improve accessibility and represent an important, vibrant, and innovative device category for the nearly 40 million adults with mild-to-moderate hearing loss (Gorman 2016).

Many who could benefit from OTC hearing aids wait for symptoms to worsen before seeking a hearing health solution. While ease of access and lower costs may open the door to more people getting devices, increased comfort with hearing products means people may be more open to prescription devices if their hearing loss progresses.

OTC hearing aids aren’t an either-or situation. People under 18, individuals whose test shows more than mild-to-moderate loss, people with compounding health issues, and anyone who isn’t seeing results with existing devices should consult an audiologist.
Driven by Industry Standards

Industry standards are central to this new category, and CTA has been working with the FDA and other stakeholders for years to help establish industry best practices that are driving innovation (and plans to continue that collaboration). Specifically, the final rule cites ANSI/CTA-2051, Personal Sound Amplification Performance Criteria (CTA 2017), which includes technical performance metrics and associated target values for consumer products that provide personal sound amplification and enhancement to a user.

CTA’s Health, Fitness and Wellness Committee recently published ANSI/CTA-2051-A, Wearable Sound Amplifier Performance Criteria (CTA 2022), which updates the original standard but maintains the primary technical performance criteria of the 2017 version. Both ANSI/CTA-2051 and ANSI/CTA-2051-A also reference standards developed by the Acoustical Society of America, the International Electrotechnical Commission (IEC), ISO, and IEEE.

To continue to support the growth of this industry sector through standardization, CTA recently launched new work to identify the elements of standard testing methodology for a consumer-facing hearing metric and to establish a common vocabulary for hearing health for consumer-facing hearing solutions, including OTC hearing aids. This standard is expected to be completed in 2023.

What’s Next?

This is just the beginning for this new device category. Anytime you have novel innovations and new product categories like OTC hearing aids entering the market, conversations open up and increase awareness about hearing health. Working together, we can help improve health outcomes by addressing issues related to hearing loss like dementia and depression (Johns Hopkins 2022).

As we have seen with other digital health technologies, hearing aids have gone from nice to have to a necessity, and this is an exciting moment for hearing health. At CTA, we look forward to the ways that industry standards for these devices will increase the usage and ultimately improve outcomes, lower costs, and enhance consumer experiences.

Kerri Haresign is the director of technology and standards at the Consumer Technology Association. She is responsible for the oversight of a broad range of technology subjects within CTA’s standardization activities, including artificial intelligence, audio systems, health, fitness and wellness technology, and video systems. Additionally, she oversees CTA’s Technology Council. She is vice president of the Society for Standards Professionals (SES) and participates in a variety of other standards activities.
References


U.S. Food and Drug Administration. 2022. “Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids.” Federal Register, August 17.