



## FDA Regulation of Over-The-Counter Hearing Aids: Increasing Accessibility and Affordability of Hearing Aids in the U.S.

### Key Points:

- The FDA has developed a separate regulatory classification for over-the-counter hearing aids that are intended for adults with mild-to-moderate hearing loss. These regulations will expand the treatment options available to the 40 million Americans<sup>1</sup> with hearing loss.
- The regulations were mandated by the Over-the-Counter Hearing Aid Act which was championed by Senators Warren and Grassley and passed with bipartisan support in 2017. Previously, Americans could only obtain hearing aids through a licensed provider leading to significant costs and barriers to accessing care.
- The release of these regulations allows for new market entrants and consumer electronic companies to enter the hearing aid market which will increase competition, lower costs, and foster innovation in a stagnant hearing aid market currently dominated by just 5 hearing aid manufacturers.
- Technical specifications for these devices will ensure that OTC hearing aids are safe, effective, and able to meet the hearing needs of adults with mild-to-moderate levels of hearing loss that encompasses >90% of adults with hearing loss. These regulations also include the federal preemption of bureaucratic state-level barriers that could potentially limit the sale of OTC hearing aids.
- The first OTC hearing aids will likely be available for purchase by consumers by late 2022 after FDA approval.

**Newly released Food & Drug Administration regulations for over-the-counter hearing aids improve on the outdated FDA regulations for hearing aids established over 40 years ago.** Those original regulations, written in 1977, did not specifically permit OTC sales of hearing aids because hearing aid technology of that era was only safe and effective if hearing aids were programmed by a hearing care provider<sup>2</sup>. Technological advances since then allow properly designed hearing aids to be safely and effectively used by adults with hearing loss without the need for a provider<sup>2,3</sup>.

**The final regulations for OTC hearing aids will ensure safety and effectiveness.** The regulations for these devices include appropriate output limits and other technical specifications that will ensure OTC hearing aids are safe, effective, and able to meet the hearing needs of over >90% of adults with hearing loss. Clear labeling will also be required indicating the warning signs and symptoms of when a consumer should seek further clinical evaluation. The U.S. is the first country in the world to develop such regulations that will allow consumers to access OTC hearing aids.

**The creation of this regulatory classification for over-the-counter hearing aids is a result of concerted bipartisan action and the Over-The-Counter Hearing Aid Act of 2017.** Initially recommended by consensus reports from the [National Academies](#) and the [White House](#) under President Obama from 2015-16, the bipartisan Over-the-Counter Hearing Aid Act was signed into law by President Trump in 2017. An [executive order](#) from President Biden in 2021 further helped accelerate the timeline for FDA development and release of these regulations. These regulations advanced despite significant opposition efforts funded by the hearing aid industry as identified in a [report from Senators Warren and Grassley](#).

**These regulations will increase Americans' access to hearing aids, foster market competition, and lower costs.** Americans can presently only purchase hearing aids through a licensed hearing care provider. As a result, the average cost for a pair of hearing aids is \$4700 and less than 20% of adults in the U.S. with hearing loss use hearing aids<sup>4</sup>. Outdated FDA hearing aid regulations contributed to this current hearing aid market where only 5 manufacturers control >90% of the world hearing aid marketplace. With the new FDA regulations for OTC hearing aids, consumer technology and other companies will be permitted to enter the market and sell hearing aids directly to consumers, thereby increasing market competition and lowering costs for consumers.

**Creating an OTC hearing aid category addresses an urgent public health need.** Growing public health evidence over the past decade has linked hearing loss with increased dementia risk and other adverse health outcomes. With the release of these regulations for OTC hearing aids, the FDA directly fulfills a recommendation of the 2021 update to National Plan to Address Alzheimer's Disease ([Action 6.B.2](#)) to increase Americans' access to hearing aids. Ongoing public health efforts from the Johns Hopkins Bloomberg School of Public Health through its [Know Your Hearing Number](#) campaign seeks to build public awareness of hearing and when to consider using OTC hearing aids and other hearing technologies and strategies.

## References

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At the [Johns Hopkins Cochlear Center for Hearing and Public Health](#), we are training a generation of clinicians and researchers to study the impact that hearing loss in older adults has on public health, and to develop and implement public health strategies and solutions for hearing loss in the US and globally.

We approach our work with the foundational understanding that strategies and solutions that allow older adults with hearing loss to communicate and effectively engage with their environment are fundamental to optimizing human health and aging.

For more information:

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