



HOW OTC HEARING AIDS WILL IMPACT THE INDUSTRY

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Executive Summary

Recent developments initiated by President Biden's executive order on classifying over-the-counter (OTC) hearing aids and the forthcoming FDA rules for OTC aids mark a significant turning point for the hearing aid industry. This white paper explores some of the issues and ramifications to the overall market as competition broadens and a race for technological innovation and customized services kicks off.



From a CBS News report on August 6, 2021:

"When the FDA eventually does issue final rules, experts hope it will unleash competition among consumer electronics companies for a global market that some estimate should jump 40% to \$11.6 billion by 2028. Currently, only a handful of specialty device makers dominate the hearing aid market."

"These over-the-counter devices should cost \$200 to \$800. And they'll be produced by companies like Bose, Samsung and maybe Apple," said Dr. Justin Golub, an ear specialist at Columbia University Medical Center in New York. "These are the really innovative companies that always compete to drive costs down, constantly innovate and prove value. So, we're pretty excited about this."

Source CBS News:
<https://www.cbsnews.com/news/hearing-aid-over-the-counter-cheaper-2022/>



A Paradigm Shift Arrives

On July 9, 2021, President Joe Biden released a comprehensive [executive order](#) that addressed the rules on the [classification of over-the-counter \(OTC\) hearing aids](#). President Biden directed the U.S. Department of Health and Human Services to "consider issuing proposed rules within 120 days for allowing hearing aids to be sold over the counter."

The "Over-the-Counter Hearing Aid Act" was originally passed in 2017 but the COVID-19 pandemic delayed the issuance of proposed OTC rules by the FDA by the August 2020 deadline.

In response to the announcement, industry leader and Starkey's President & CEO, Brandon Sawalich, [sent a letter to President Biden](#) and members of Congress commenting on the July 9 executive order. Sawalich's letter stated:

"Even after the FDA finalizes a new category of OTC hearing aids, it has and will continue to be Starkey's belief that individuals with hearing loss are best served by FDA-regulated hearing aids that are fit and adjusted by licensed and trained hearing health professionals. Like a fingerprint, each ear is unique to the individual. Each person's hearing loss requires the convergence of art and science to ensure proper use and to ultimately help them live a healthier life."

Gauging the industry, political, and media response to the executive order and the FDA's forthcoming rules, these developments represent a paradigm shift in the hearing aid industry's competition for consumer market share. In reality, the electronics and technology industries have been encroaching on the hearing aid market and other health care devices for years. Just witness the development of the Apple Watch and AirPods, earbuds, fitness trackers, and related cell phone accessories offering connectivity capabilities and the rapid development of sophisticated devices that can serve health care and medical needs.

Bose sells an \$850 hearing design cleared by the FDA for direct-to-consumer online sales in five states, with plans to expand.

Industry Response

Reactions from manufacturers and audiologists varied -- from vowing to compete directly with electronics firms and produce lower-cost, mass market aids, to seeking ways to embrace the market and bring OTC into a clinic's service environment.

Most audiologists and clinics believe the treatment of hearing loss and fitting of hearing aids require specialized attention, knowledge and training to properly match the devices to the needs of the patient.

Hearing care professionals view their relationships with their patients as a personal and customized experience. They seek to have their patients obtain the best possible outcome and gain the optimal benefit from their aid. These same professionals believe big box retailers and sellers of OTC devices will not provide the evaluation, follow-up, and professional guidance available from clinics and their audiologists.

On the other hand, in a survey conducted by Health Matters, one audiologist said, "I think that this is a very good opportunity, combined with the increased knowledge about the effects of untreated hearing loss, for audiologists to become the most knowledgeable professionals about OTC hearing aids, and to encourage patients to try them earlier than traditional hearing aids would normally be used. We have a great opportunity to expand access and decrease cost, and we should help our patients with hearing loss to understand the advantages and limitations of OTC hearing aids as one of many possible treatments to consider."

How Did We Get Here?

Most competitive movements within industries revolve around pricing and costs. The high costs of hearing aids and services provided by clinics coupled with a lack of adequate insurance coverage left many potential wearers of hearing aids on the sidelines. Add to that the still-present societal stigma attached to the wearing of hearing aids and you're left with a sizable market of underserved customers.

Hearing Health and Technology Matters (HHTM), an online resource on topics related to hearing, surveyed audiologists on OTC hearing aids and found:

65%

of audiologists surveyed believe OTC hearing aids will have either a "negative" or "very negative" impact on audiology's future.

61%

of respondents see consumer electronics companies like Apple, Samsung, and others as being the greatest beneficiaries of the OTC hearing aid legislation that was recently passed in the House and Senate.

52%

of audiologists surveyed felt that OTC hearing aids would likely *hurt* their clinic, compared with **9%** that said OTC hearing aids would *help* their clinic.



Market Potential:

Where are we now—where are we headed?

Measuring the Scope of the Market

- According to Debra L. Tucci, M.D., M.S., M.B.A., the director of the National Institute on Deafness and Other Communication Disorders (NIDCD), part of the National Institutes of Health, approximately 15% of U.S. adults report some degree of hearing loss.
- Data from the UN puts the number of people at advanced ages is increasing exponentially. The global population aged 80 years or over is projected to triple between 2017 and 2050, increasing from 137 million to 425 million. In 2050, older individuals are projected to account for one in five people globally.
- A market research report entitled “Hearing Aids Market, 2021-2028” from Fortune Business Insights projects the global hearing aid market to reach 11.02 billion dollars by 2028, a compound annual growth rate (CAGR) of 7.4% during the forecast period. Driving the growth will be increasing innovations in hearing technologies and expanded roles for connected devices.

The surging global growth of the geriatric population is expected to create increased demand for hearing devices and implants. In concert with that growth, there is a significant demand suppressed by COVID-19’s dramatic effect on the healthcare sector, leading to the postponement of non-compulsory surgeries such as needed for cochlear implants and audiological diagnostic devices. In 2020 alone, the Hearing Industries Association (HIA) found unit sales of hearing devices in the U.S. declined 18%.

In a report by Reuters, William Demant Holdings, one of the world’s largest hearing aid manufacturers, said it could start producing less expensive over-the-counter (OTC) hearing aids for the U.S. market if demand increases after the OTC legislation goes into effect. North America represents the largest and most lucrative market for Demant, the parent company to well-known hearing aid brand Oticon.

“I do not expect any significant change in the U.S. market, but should sales of products like these become substantial ... we will produce some as well,” said Soren Nielsen, CEO of William Demant.

Starkey and Demant are just two of the major hearing industry players to comment publicly on possible plans to produce OTC devices. Other major industry players already have plans to ensure they do not lose significant market share in North America in the coming years as the hearing aid market faces continued pressure from the consumer electronics industry.

Source: <https://www.reuters.com/article/us-william-demant-h-results-idUSKCN1AUoSP>

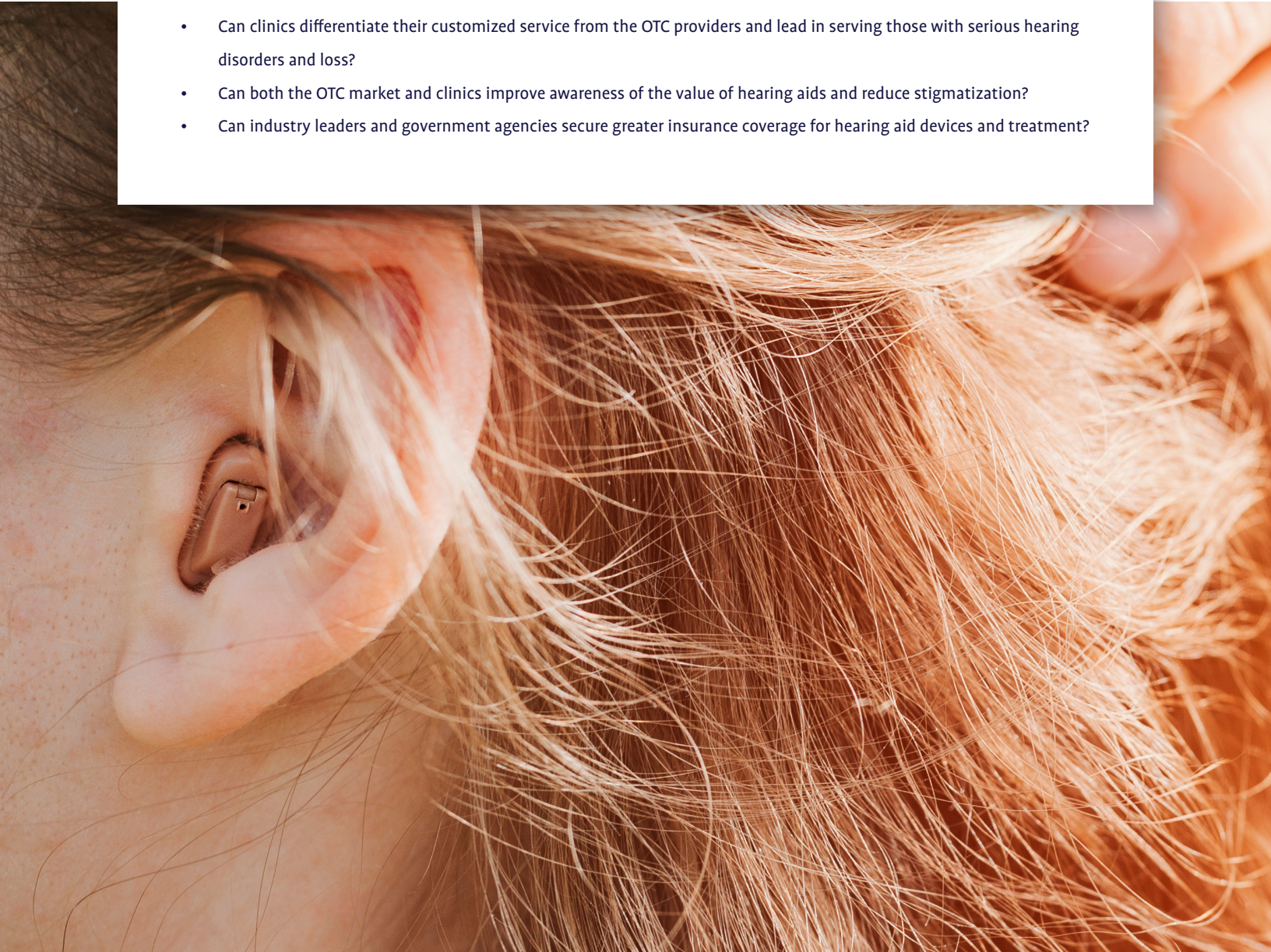


What it all Means

Clearly, the development of an OTC market for hearing aids is one that industry players cannot ignore or dismiss lightly. Clinics and manufacturers are developing plans for meeting the OTC challenge through adaptations in their services, marketing strategy, and distribution channels. Some may pursue joint ventures with electronics companies and big box retailers, while others will look for alternative avenues to compete on price and service. Below, we look at some important questions to consider about the impact of OTC hearing aids.

Key Questions about the OTC hearing aid market

- Will the hearing aid industry, already burdened by third-party payer contracts, further evolve its ecosystem with the proliferation of OTC hearing aids?
- Can electronic companies compete with the intricacies that hearing aid manufacturers have been dealing with for decades? How will they manage repairs and services, for example?
- Will clinics embrace the OTC market and look to serve it?
- Can clinics differentiate their customized service from the OTC providers and lead in serving those with serious hearing disorders and loss?
- Can both the OTC market and clinics improve awareness of the value of hearing aids and reduce stigmatization?
- Can industry leaders and government agencies secure greater insurance coverage for hearing aid devices and treatment?



Additional Resources:

Sycle, a software management platform serving the audiology industry, hosted the webinar, [*Over the Counter \(OTC\) Hearing Aids: Their Impact on the Marketplace*](#), as part of the company's Thought Leadership Series. Taking part in the panel discussion was RiseENT Executive VP **Kyle Acker**, AuD; **Matt Dearing**, VP of Marketing at My Hearing Centers; Eargo Hearing Aids COO **Bill Brownie**, Hearing Review Editor in Chief **Karl Strom**, and moderated by Sycle Co-Founder and CTO **Sean Shoffstall**. The panel discussion focused on key questions that impact all hearing clinics.

To watch the webinar on-demand, visit: <https://web.sycle.net/panel-discussion-otc/>

Further information can be found at:

- [Hearing Review](#)
- [Hearing Matters](#)
- [NIH: National Institute on Deafness and Communication Disorders \(NCID\)](#)



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