



Research Paper

OTC Hearing Aids: Balancing Accessibility, Market Disruption, and the Commercialization of Care

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Abstract: Hearing aids are widely recognized as one of the most effective interventions for hearing loss, yet adoption remains persistently low due to cost stigma, and restricted access within traditional healthcare systems. The emergence of over-the-counter (OTC) hearing aids represents a structural shift in hearing healthcare, expanding access while simultaneously reshaping market dynamics and industry incentives. Drawing directly on clinical evidence, regulatory developments, and market analysis, this paper examines OTC hearing aids as both a technological and institutional innovation. The paper argues that OTC hearing aids not only function as a lower-cost alternative to prescription devices, but as a transformative device that challenges established assumptions about patient care, traditional market, and industry control. It also highlights the complex tradeoff between industry priority and patient priority following the shift towards OTC hearing aids. The paper argues that while OTC hearing aids hold substantial promise representing an evolution in accessibility, regulatory oversight will be necessary to ensure accessibility does not come at the expense of patient safety or clinical integrity.

Keywords: OTC hearing aids, hearing loss, patient priority, industry priority, "Big Five"

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I. Introduction

Hearing aids have long been recognized as the effective tool for addressing hearing loss, but their reach has been limited by the healthcare system, driving up the cost and lowering the affordability. OTC hearing aids, by contrast, hold the potential to be even more effective. They are more versatile, less controlled by the system, and designed for self-management, making them better suited for wide-scale adoption. Unlike OTC drugs, which provide short term relief, OTC hearing aids represent a long-term solution empowering users to integrate healthcare into daily life. This positions them not just as an alternative to traditional hearing aids, but a transformative model for accessible hearing and medical technology.

II. Methods

The evaluation of hearing aid effectiveness was conducted. A team of 10+ volunteers was directed in the execution of community-based testing and data collection. The study performed fittings and calibrations for over 100 elderly participants, verifying data from assessments against professional standards. The testing protocol followed the standards set by the National Clinical Research Center for Otolaryngology, using Matepad 2023 running Tengxun testing software and Sennheiser headphones.

III. Effectiveness and Technological Evolution

Hearing aids have long been established as one of the most effective interventions for hearing loss. They restore communication, thereby integrating people back into society and improving their quality of life in a way most other devices cannot. The World Health Organization estimates over 5% of the world require rehabilitation for their hearing loss.¹ They also estimate that by 2050, over 2.5 billion people will be affected by hearing loss, while 10% of the world will have to undergo hearing rehabilitation - in other words, 10% will have severe hearing

¹ WHO, "Deafness and hearing loss," World Health Organization, last modified February 26, 2025, accessed September 28, 2025, <https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss?>

loss.² There is a scientific definition for hearing loss, and it is measured in intervals. A person with normal hearing has a hearing threshold of 20 decibels or better, meaning their ears can pick up sounds 20 decibels or lower.³ Anything worse is classified as hearing loss: mild hearing loss has a threshold of 20 dB to 40 dB, moderate hearing loss has a threshold of 40 dB to 70dB, severe hearing loss has a threshold of 70 dB to 90dB, and profound severe hearing loss has a threshold of 90 dB upward.⁴ A major contributing factor of hearing loss is aging. When humans reach a certain age, their cells are unable to regrow, including the hair cells in the ear. This hinders their ability to pick up auditory information through the vibration of hair cells. Other causes of hearing loss include exposure to loud sounds, chronic ear infections, and genetic disorders.⁵

The prevalence of hearing loss creates demand for a solution. While hearing aids cannot reverse hearing loss or cure the underlying condition, they still have long-term impact on the patient. Similar to eye glasses, as long as they are wearing hearing aids, patients will have sound restored. Although different to eye glasses, normal hearing cannot really be achieved like how 20/20 vision can be through the use of spectacles because of irreversible cell damage inside the ear.⁶ The fact that hearing cannot be readjusted means hearing loss prevention is even more important, especially in the early stages when damage is not significant. Hearing aids are helpful for people affected with mild to moderate or severe hearing loss, helping them restore sound levels, while cochlear implants are needed for patients who have inner ear damage or severe to profoundly severe hearing loss.⁷ In most cases, hearing aids can effectively solve the patient's problem, and can deter hearing deterioration if detected early..

Despite their effectiveness, traditional hearing aids remain underutilized. The National Institute of Health estimates that in the U.S among adults aged 70 or older, fewer than 1 in 3 who need hearing aids or could benefit from them have ever used one.⁸ Furthermore, hearing aids in the U.S. are even more underutilized in the ages of 20 to 69. The National Institute of Health estimates that only 16% of people from the age group who could benefit from the adoption of hearing assisting devices have ever used one.⁹ Hearing aid uptake is even lower in low-and-middle income (LMI) regions, with penetration rates estimated around 1.5% to 12%.¹⁰ In regions like Africa, the adoption rate for hearing aids is estimated to be as low as 2%.¹¹ The gap between need and adoption is significant. There are many reasons for the low adoption rate. Complex barriers such as stigma play a role in the uptake of hearing aids, especially in LMIs. Hearing loss as a condition is identified as embarrassing by individuals, viewed negatively from a societal standpoint, and discriminated against.¹² In LMIs where education on disabilities are limited, people with hearing loss are teased, and judged for being 'dumb', reinforcing their self-doubt, self-consciousness, and embarrassment.¹³ Cultural beliefs also emerged as a theme surrounding hearing loss. Superstition and cultural interpretations contribute to the fear of the condition - it is often seen as a curse, one that could be spread, so people affected were socially excluded.¹⁴ The stigma experienced by the individuals becomes a barrier to help-seeking: the reluctance, discouragement, and pressure to conceal hearing loss. These factors in turn result in low adoption rates of hearing aids in LMIs. OTC hearing aids, with a modern earbud-like design, can combat the stigma to a certain extent through imitation and function. OTC hearing aids are becoming more

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⁴ Doug Garfield, "Understanding Your Audiogram: What Do Those Results Mean?," *Sertoma Speech & Hearing Centers* (blog), March 4, 2024, <https://www.sertomacenter.org/blog/?id=understanding-your-audiogram>.

⁵ WHO, "Deafness and hearing," World Health Organization.

⁶ US Food & Drugs Administration, "Hearing Aid Benefits and Limitations," FDA, accessed September 28, 2025, <https://www.fda.gov/medical-devices/hearing-aids/hearing-aid-benefits-and-limitations>.

⁷ Mayo Clinic, "Cochlear Implants," Mayo Clinic, accessed September 28, 2025, <https://www.mayoclinic.org/tests-procedures/cochlear-implants/about/pac-20385021>.

⁸ National Institute of Health, "Quick Statistics About Hearing, Balance, & Dizziness," National Institute on Deafness and Other Communication Disorders, accessed September 28, 2025, <https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing>.

⁹ IBID

¹⁰ Frisby, Caitlin, Vinaya Manchaiah, Nausheen Dawood, Carrie Nieman, and De Wet Swanepoel. 2025. "Hearing Loss and Hearing Aid Stigma in Low- and Middle-Income Settings: A Scoping Review." *Disability and Rehabilitation*, published August 1, 2018.

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¹⁴ IBID

fashionable, with Apple introducing hearing aid features on the airpods pro 2.¹⁵ Though there is room for improvement, the aesthetic design of OTC hearing aids give people an option to wear in public without being socially criticized for having hearing problems or draw attention to it.

Cost is another major hurdle. The average cost of a pair of prescription hearing aids is \$2000 to \$7000, and they are not covered by traditional insurance plans such as MediCare.¹⁶ Often, the plans that do are exclusive, not universal. For example, in some states, children's hearing aids are covered by MediCaid, but only certain groups such as low-income families are eligible. The price of the hearing aid varies because some options are 'bundled', meaning they include future checkup.¹⁷ However, some are not, and visits to audiologists for tuning, testing, and trading could cost even more. In a report published in *The Hearing Journal*, 76% of respondents mentioned cost, or financial factors, as a barrier to hearing aid adoption.¹⁸ Nearly half the respondents, 49%, indicated cost is a definite reason why they don't use hearing aids, and more than half the respondents, 52%, complained that the devices were expensive to maintain.¹⁹ The initial visit to an audiologist for prescriptions can also be costly, especially for people in rural areas or LMIs. This restricts access and creates bottlenecks for many hearing aid afflicted individuals. The result is a technology known to be effective is left underused, and millions of people live with untreated hearing loss.

OTC hearing aids have the ability to combat these long-standing obstacles. The advantage of the OTC hearing aid is accessibility and self-customization. The FDA's creation of a formal OTC category in 2022 opened the door for adults with mild to moderate hearing loss, the most dominant form of hearing loss, to buy devices directly without prescription or professional fitting.²⁰ This drives down the cost, eliminating fees for doctor visits, checkups, and tuning. Federal officials initially estimated a \$2,800 savings cost on a pair of hearing aids.²¹ Reports one year later were consistent with the projection, with the average price of OTC hearing aids around \$1600, and the average price of prescription hearing aids \$4600.²²

OTC hearing aids work by electronically amplifying sound they pick up through microphones. Essentially, they are amplifiers, but as technology improves, they become more powerful. Newer models have features of denoising, automatic adjustment to environment, and wide dynamic range compression (WDRC) controlling the amplification at different frequencies.²³ Despite its abilities, there are still doubts surrounding the effectiveness of OTC hearing aids, mainly the fitting process. Without professionals, the hearing aids might not reach their intended impact because of poor or lack of customization. The devices have to be tuned specifically to each patient because everyone has differences in hearing loss. A person might have more trouble hearing at the low frequencies, while a different person might have trouble hearing higher frequencies. Addressing the disparity in hearing loss by programming the hearing aid is one of the most important steps in the process of fitting a device, and the main job of an audiologist. The lack of assistance for this process in OTC hearing aids is one of the reasons why the devices do not have a high uptake in elderly people - old people often do not have the technical understanding to operate. Age is actually a contradictory predictor of hearing aid uptake - an increase in age leads to a decrease in uptake.²⁴ Furthermore, in a report published in PMC researching healthcare professionals' views on OTC hearing aids, 76.7% of experts agree with the statement "consumers will struggle to program", and 92.6% of experts agree with the statement "consumers will struggle to identify and address common problems".²⁵

¹⁵ Lauren Dragan, "How Good Are the AirPods Pro 2 as Hearing Aids? We Tested Them to Find Out," *Wirecutter*, December 10, 2024, [Page #], accessed May 9, 2025, <https://www.nytimes.com/wirecutter/reviews/airpods-pro-2-hearing-aids-review/>.

¹⁶ Mandy Mroz, "Hearing aid prices," *Healthy Hearing*, last modified December 10, 2024, accessed September 28, 2025, <https://www.healthyhearing.com/help/hearing-aids/prices>.

¹⁷ IBID

¹⁸ Sergei Kochkin, *The Hearing Journal* (2007), <https://doi.org/10.1097/01.hj.0000285745.08599.7f>

¹⁹ IBID

²⁰ Christina Jewett, "F.D.A. Clears Path for Hearing Aids to Be Sold Over the Counter," *The New York Times*, August 16, 2022, <https://www.nytimes.com/2022/08/16/health/fda-hearing-aids.html>.

²¹ IBID

²² Grand View Research, *Over-The-Counter (OTC) Hearing Aids Market Size, Share & Trends Analysis Report By Product, By Technology (Digital Hearing Aids, Analog Hearing Aids), By Distribution Channel, By Region, And Segment Forecasts, 2023 - 2030* (Grand View Research, n.d.), <https://www.grandviewresearch.com/industry-analysis/over-the-counter-hearing-aids-market-report>.

²³ Christopher Null, "The Best Hearing Aids," *Wired* (blog), May 15, 2025, accessed May 21, 2025, <https://www.wired.com/gallery/best-hearing-aids/>.

²⁴ Jenstad, L, and J Moon. "Systematic Review of Barriers and Facilitators to Hearing Aid Uptake in Older Adults." *Audiology research* vol. 1,1 e25. 23 Mar. 2011, doi:10.4081/audiores.2011.e25

²⁵ Andrea Ciorba, ed., *Audiology Research* (2023), <https://doi.org/10.3390/audiolres13020018>.

Despite these concerns, multiple studies support the effectiveness of OTC hearing aids. In a study conducted by De Sousa et al. participants were split into two groups: OTC hearing aids with remote support, and audiologist fitted hearing aids.²⁶ The results, collected through feedback surveys from patients, after six weeks were comparable. Another study conducted by Hay-McCutcheon et al. attempted to test out the effectiveness of OTC hearing aids in rural areas.²⁷ The study spanned a period of 14 weeks, in which subjects were given different levels of assistance for hearing aids, and the study showed some people were able to independently operate OTC hearing aids. The difference in effect wasn't major between independently operated OTC hearing aids and the equivalent with remote guidance.²⁸ Moreover, the effectiveness of OTC hearing aids only improves. New products are being released with the help of AI - for example NewSound's integration of Femtosense - which can simplify the fitting process among other features.²⁹ New technology such as the smartphone based hearing self-assessment, which has an average of less than 6 dB hearing level compared to professional audiologist tests, have been introduced, allowing people to completely test themselves with a smartphone. The digital nature of it means it can be implemented with the fitting function of hearing aids in the future.³⁰ The steady advancement in the electronics world can translate to anything related to it, OTC hearing aids being included. As long as the tech industry continues to evolve, so will OTC hearing aid technology.

Clinical trials have shown self-fit OTC hearing aids can achieve results comparable to audiologist fitted models. Their flexibility and low cost position the devices as tools with the potential to expand the reach of hearing technology to millions of unserved people. OTC hearing aids - with its practicality, reach, and demonstrated effectiveness - are a powerful alternative to traditional hearing aids, challenging the core concept. Not only do they represent an improvement in hearing technology, OTC hearing aids give a glimpse into the potential of the OTC market, showing what it can be like with effective devices.

IV. Market Disruption

In recent years, the hearing aid market has undergone a huge transformation. The introduction of over-the-counter (OTC) hearing aids has not only challenged the dominance of traditional prescription hearing aids, increasing accessibility and affordability for consumers, it has had the same effect of increasing accessibility for producers. Accessibility in the producer's case refers to the ability of entering and exiting the market relatively easily. What was initially a policy shift to increase consumer access has evolved into a discussion about market efficiency and industry growth. The target audience of the deregulation is for consumers, but the ripple effects of the advantages extend beyond them. The OTC hearing aids have many benefits for the consumer, at the same time, they can bring better results for producers. Increased access to market and specialization of roles are key changes that could benefit producers in the new market.

Traditionally the hearing aid market has been controlled by a few companies but the opportunities of OTC hearing aids have the capacity to create a revolution in the structure of the market. Not only does deregulation changes bring new competitors and products domestically in the US, many companies are also emerging overseas, expanding from their local origins into one of the biggest healthcare markets. The attitude of traditional hearing aid manufacturers toward the new category has also evolved from one of counteracting to enhancing.

For decades, the Big Five - Sonova, Demant, GN, Starkey, WSAudiology - have dominated the hearing aid industry. Together they have around 90% of global sales.³¹ Of the Big Five, three of the companies (Demant,

²⁶ De Sousa, K. C., Manchaiah, V., Moore, D. R., Graham, M. A., & Swanepoel, W. (2023). Effectiveness of an Over-the-Counter Self-fitting Hearing Aid Compared With an Audiologist-Fitted Hearing Aid: A Randomized Clinical Trial. *JAMA otolaryngology-- head & neck surgery*, 149(6), 522–530. <https://doi.org/10.1001/jamaoto.2023.0376>

²⁷ Hay-McCutcheon, M. J., Hubbard, A. F., Brothers, E. B., Allen, R. S., & Yang, X. (2024). An Over-the-Counter Hearing Aid Clinical Trial in Rural Alabama: Project Design and Potential Implications for Pharmacy and Audiology Interprofessional Collaborations. *Pharmacy (Basel, Switzerland)*, 12(3), 76. <https://doi.org/10.3390/pharmacy12030076>

²⁸ IBID

²⁹ NewSound Unveils Groundbreaking AI-Driven OTC Hearing Aids, Revolutionizing Hearing Accessibility with AI Acceleration by Femtosense," *Business Wire* (New Orleans), March 26, 2025, [Page #], accessed May 9, 2025, <https://www.businesswire.com/news/home/20250326336474/en/NewSound-Unveils-Groundbreaking-AI-Driven-OTC-Hearing-Aids-Revolutionizing-Hearing-Accessibility-with-AI-Acceleration-by-Femtosense>.

³⁰ Chen, F., Wang, S., Li, J., Tan, H., Jia, W., & Wang, Z. (2019). Smartphone-Based Hearing Self-Assessment System Using Hearing Aids With Fast Audiometry Method. *IEEE transactions on biomedical circuits and systems*, 13(1), 170–179. <https://doi.org/10.1109/TBCAS.2018.2878341>

³¹ Digby Cook, "The Big Five," *Hearing Loss Journal*, November 12, 2024, accessed October 25, 2025, <https://www.hearinglossjournal.com/the-big-five/>.

GN, and WS Audiology) are from Denmark.³² The other two companies are from Switzerland (Sonova) and the United States (Starkey).³³ All five of these companies were founded around the mid 20th century, the latest being Starkey in 1967.³⁴ The early start of the companies were the biggest factor to their dominance. They started in the analog era, and had a headstart on the technology when it was transitioning to the 1980s, when the era of consumerism started to expand the market.³⁵ This was the early stage, where the hearing products were still competing with each other, and most acquisitions were over patent rights, software, or hardware.³⁶ The Big Five started to form in the 2000s, when companies got big enough to acquire the smaller companies. For example, GN purchased Resound and Beltone, Phonak (Sonova) purchased the Unitron group, Siemens acquired Electone etc.³⁷ The merging of two companies Widex and Sivantos in 2019 consolidated the market into its current state of five dominant businesses.³⁸ The companies extended their influence by partnering with mass retailers such as Costco, Sam's Club and other large pharmacies.³⁹ They also began expanding their online presence, creating internet portals such as [HealthyHearing.com](https://www.healthyhearing.com) (Demant) and HearingPlanet (Sonova).⁴⁰ The dominance of the Big Five has been established by their time in the market, various acquisitions, and strategic alliances with retailers (independent and megastores). They have been comfortably controlling the hearing aid market for several decades, but the introduction of OTC hearing aids have the potential to reshape the market.

While the Big Five still control much of the global hearing aid market, the rise of OTC devices has finally created space for new companies to emerge. Even if many of these smaller entrants might fail to sustain long-term growth, their presence has already forced established manufacturers to make adjustments, by lowering prices and expanding accessibility. For example, electronic brands such as Bose can now directly compete with the established firms. This represents a change in the hearing aid market moving to a more open tech-like space, one that promises greater user choice for consumers and new profit opportunities for producers. Already, there are many new brands entering the hearing aid market, breaking what was once near-total control by the Big Five. Companies such as Bose, Kaz USA, MDHearingAid, Nuheara Limited, NUVOMED INC, and Soundwave Hearing LLC represent a new generation of manufacturers that approach hearing technology through the OTC pathway, more similar to consumer electronics.⁴¹ Many of these companies have leveraged the FDA's 2022 deregulation which created a legal category of OTC hearing aids, allowing them to sell devices directly to consumers through retail and online channels. A lot of new entrants are from overseas, particularly China, where multiple manufacturers such as Hangzhou Acosound Technology, Hong Yu Kang Technology, Shenzhen Zhongde Audio-Technical Co., Foshan Vohom Technology Co., Huizhou Jinghao Medical etc. have emerged as other options in the affordable OTC market.⁴² These companies utilize consumer electronics technology, allowing for large-scale, cost-efficient production, enabling them to sell devices at a cheaper price than prescription models. They also have modern features like Bluetooth streaming and app-based tuning because of their new technology incorporation.⁴³ A report in 2024 listed a total of 74 OTC hearing aid manufacturers, of which 49 were based in Asia, suggesting a trend of increasing global market and the higher demand of OTC devices in LMIs.⁴⁴ The entry of domestic and international competitors not only expands consumer choice, but it also increases competition

³² Audiology worldnews, "WHY IS DENMARK WHERE IT'S AT IN HEARING?," AWN, accessed October 22, 2025, <https://www.audiology-worldnews.com/history-of-hearing-aids/>.

³³ Cook, "The Big Five."

³⁴ IBID

³⁵ Robert M. Traynor, "Survival Strategies in a Competitive Hearing Healthcare Market," [hearingreview.com, Hearing Review](https://hearingreview.com/practice-building/survival-strategies-competitive-hearing-healthcare-market?), last modified May 22, 2018, accessed October 26, 2025, [https://hearingreview.com/practice-building/survival-strategies-competitive-hearing-healthcare-market?.](https://hearingreview.com/practice-building/survival-strategies-competitive-hearing-healthcare-market?)

³⁶ IBID

³⁷ IBID

³⁸ WSAudiology, "Sivantos and Widex merge to create global hearing aid leader," WSA.com, last modified May 16, 2018, accessed October 26, 2025, <https://www.wsa.com/press-release/sivantos-and-widex-merge-to-create-global-hearing-aid-leader/>.

³⁹ Traynor, "Survival Strategies," [hearingreview.com](https://hearingreview.com/practice-building/survival-strategies-competitive-hearing-healthcare-market?).

⁴⁰ IBID

⁴¹ Abram Bailey, "Full List of OTC Hearing Aids," BetterHearing, Hearing Industries Association, accessed October 22, 2025, <https://www.betterhearing.org/newsroom/blogs/full-list-of-otc-hearing-aids/>.

⁴² IBID

⁴³ King Chung and Fan-Geng Zeng, "Over-the-counter hearing aids: implementations and opportunities," *Frontier* 2 (March 2025), <https://www.frontiersin.org/journals/audiology-and-otology/articles/10.3389/fauot.2024.1347437/full>.

⁴⁴ IBID

between companies, signaling a significant shift in an industry that, for the moment, is dominated by a few Western corporations.

The Big Five displayed that dominance by posting sales gains in 2024. Demant-owned Oticon is estimated to have around \$574m in U.S. sales, \$348m for Starkey, and \$205m for Sonova in that year.⁴⁵ These are strong numbers, rivaling some of the net worths of new entrants. The Big Five continue to invest heavily into R&D and patents, reinforcing the barriers of entry.⁴⁶ Four of the Big Five have also ventured into the OTC hearing aid market, acknowledging the potential of the new devices. GN Resound and Sonova are selling OTC hearing aids from acquisition of electronic brands Jabra and Sennheiser.⁴⁷ Starkey introduced their own line called Start Hearing One.⁴⁸ WSAudiology collaborated with Sony to brand and sell their OTC hearing aids.⁴⁹ Demant is the only company of the five yet to enter the market.

The attitude of traditional hearing aid firms is drastically different from when the deregulation was first introduced in 2022. During that time period, the manufacturers were against the new products, trying to weaken the legislation and deterring the bill from being passed. According to a report by Senator Chuck Grassley, the dominant hearing aid manufacturers “backed astroturf campaigns to weaken FDA’s proposed rule and distort public perception”.⁵⁰ They did so by encouraging letters and independent responses to be posted on social media and sent to the FDA.⁵¹ A lot of these campaigns were led by company groups such as the HIA.

The HIA representing established hearing-aid manufacturers and distributors urged strict output gain limitations on the OTC hearing aids, using reasons for potential over-amplification leading to noise-induced hearing loss. They suggested that the FDA cap the limit of “moderate” category OTC hearing aids at 50-55 dB HL, because consumers who self-fit devices could unknowingly harm their own hearing, especially in a market not regulated by professionals.⁵² However, Senator Chuck Grassley argued that the restrictions serve the purpose of weakening OTC hearing aid devices and preserve the dominance of traditional manufacturers. In his report, he claimed that the strict limits disguised as consumer protection is actually a competitive strategy to restrict innovation and accessibility.⁵³ Both interpretations hold truth, the HIA’s safety concerns are valid, but Grassley’s argument is crucial to consider with regard to how such measures can protect industry interests too. At the very least, the risk of over-amplification has been addressed.

In his report, Grassley also cites the opinions of healthcare professionals, noting that organizations such as the Academy of Doctors of Audiology indicated support for the deregulation of hearing aids.⁵⁴ This evidence along with the mention of astroturf campaigns highlights a potential conflict of interest between traditional hearing aid firms and their resistance against the adoption of a new category of devices. If Grassley’s claim is accurate, it suggests that traditional firms have now changed their stance, perhaps recognizing the inevitable change. Now that the new product has been approved and introduced, traditional hearing aid firms are actively developing their own OTC devices to retain market share and seize an opportunity for future growth.

V. Ethical Tradeoff

As the market becomes increasingly competitive, the focus may shift from innovation in hearing to cost reduction. This poses a challenge for the healthcare industry as OTC shifts the focus of healthcare to selfcare.

Although the expanded accessibility of the OTC hearing aid model presents a compelling solution to current problems, the model creates a complex trade-off between patient priority and industry priority. This leads to a different attitude towards patients, potentially commercializing care.

Patient priority refers to a patient first approach, such as emphasizing health outcomes and patient satisfaction. High quality care in private hospitals illustrates this approach, where patient health receives primary emphasis. However, patient priority contains multiple categories, and not every category might be satisfied. For example, first-rate healthcare comes at a first-rate cost: patient health is fulfilled, but patient satisfaction might

⁴⁵ QMoat, "Hearing Aid Industry: Big Five Still Rule the Roost," QMoat.com, QMoat, last modified September 1, 2025, accessed October 26, 2025, <https://www.qmoat.com/hearing-aid-industry-big-five-still-rule-the-roost/>.

⁴⁶ IBID

⁴⁷ Chung and Zeng, "Over-the-counter hearing".

⁴⁸ IBID

⁴⁹ Sony, "About Us," Sony.com, accessed October 27, 2025, <https://hearing.electronics.sony.com/about-us/>.

⁵⁰ *Loud and Clear: Why Americans Want Effective and Affordable Over-the-Counter Hearing Aids—and How Powerful Special Interests are Trying to Undermine Them*, [Page #], https://www.grassley.senate.gov/imo/media/doc/fda_hearing_aid_report.pdf.

⁵¹ IBID

⁵² Letter by Hearing Industries Association.

⁵³ *Loud and Clear*, 6.

⁵⁴ IBID

not be due to high prices. Even so, patients frequently accept these costs, understanding that the quality of care offered can only be delivered at that level. Different patients may have different priorities, as some seek affordability over quality. Within the context of this paper, patient health is assumed to be the main priority for everyone since individuals seek care primarily for treatment rather than low cost. People do not go to hospitals because services are cheap, but because treatment is necessary. OTC hearing aids complicate this assumption because patient priority may appear to shift toward satisfaction through affordability. However, the primary objective of OTC hearing aids is not simply price reduction, but increased accessibility achieved through lower prices. Deregulation extends care to populations previously excluded by cost, at the same time offering a cheaper option for those with prior mean. Then, the target audience of OTC hearing aids still prioritize health outcomes over affordability alone.

Industry priority follows a similar concept, but for firms in the industry. In theory, hospitals should remain publicly accessible and focused on serving society. Economics constraints prevent universal free healthcare, and lower problems challenge the quality of care (which is one of the problems that arises with OTC). Profit takes precedence in some private hospitals, but the creation of the healthcare sector was to ensure that people in the society are healthy. The expensive state of healthcare in the US can seem like a prioritization of profit, but it is caused by factors such as innovative technologies which are more expensive to operate and develop.⁵⁵ Healthcare has been a part of society since ancient times, although in the past the industry was more localized.⁵⁶ Each village had their own medicine man who offered services because it was their responsibility, not because it was profitable.⁵⁷ While it is true that hospitals now have huge administrative waste in insurance systems and consolidate to create monopolies, the original industry priority was the health of patients.

The trade-off stems from misalignment between patient priority and industry priority. The industry priority has been gradually shifting since the conception of it, but OTC devices could be a catalyst for systemic change. Before the introduction of OTC devices, this balance was more established, but now, it is undergoing change. As discussed in a previous argument, the new category expands the market, allowing new entrants to disrupt the traditional “Big Five” dominated market. This encourages competition, and is good in theory, empowering the individual by providing more options. However, it could potentially reshift the industry priority. The competition remodels patients into consumers, who are looking to buy a product rather than a cure. Patients are devalued in a sense because their medical needs are not as acknowledged, rather their habits, choices, and ultimately wallet is the goal. US healthcare is among the most costly in the world, reaching \$4.9 trillion in spending in 2023.⁵⁸ The entrance of new producers such as Apple and Sony, both established brands in consumer electronics, are good examples of what could (continue) happen. Both are big companies with established brand recognition; this brand recognition helps to sell the product because the name attracts consumers. Some OTC hearing aid companies are partnering with the large consumer electronic companies to advertise their product and get it into the public market.⁵⁹ The OTC market is directly to consumers, so there is more pressure on manufacturers to stand out, especially with so much competition in an emerging market, and often it is not done so through the improvement of medical technology.

In the consumer electronics world, new products are released at a swift rate, but the difference between each is often minimal.⁶⁰ Applied to the healthcare industry, this could mean that new models of hearing aids do not contain much improvement, instead it could distract consumers by creating new exterior designs. On the other hand, new products could get gradually cheaper without significant change, which is acceptable, yet the risk is that companies focused on cutting costs end up creating less capable devices.⁶¹ This is sustainable in normal markets, but in healthcare where patient health should be the priority, the shift of industry priority against patient priority becomes problematic. When patients are treated as consumers, care can potentially be commercialized, and that has dangerous outcomes.

⁵⁵ “Why Are Americans Paying More for Healthcare?” 2025. Peterson Foundation. <https://www.pgpf.org/article/why-are-americans-paying-more-for-healthcare/>.

⁵⁶ Trescott, Paul B. n.d. “History of the US Health Care Industry | Research Starters.” EBSCO. Accessed December 17, 2025. <https://www.ebsco.com/research-starters/consumer-health/history-us-health-care-industry>.

⁵⁷ IBID

⁵⁸ “Why Are Americans Paying More for Healthcare?” 2025.

⁵⁹ Abram Bailey, “Full List of OTC Hearing Aids,” BetterHearing, Hearing Industries Association, accessed October 22, 2025, <https://www.betterhearing.org/newsroom/blogs/full-list-of-otc-hearing-aids/>.

⁶⁰ Holland, Patrick, Abrar Al-Heeti, and Lisa Eadicicco. 2025. “Best iPhone in 2025: Here’s Which Apple Phone You Should Buy.” CNET. <https://www.cnet.com/tech/mobile/best-iphone/>.

⁶¹ “What trade-offs, if any, exist between energy efficiency and device performance?” 2024. Electronic Office Systems. What trade-offs, if any, exist between energy efficiency and device performance?

One of the dangerous outcomes came in the form of pharmaceuticals. In the past 25 years, opioid use in the US has risen at an exponential rate.⁶² This surge has been mirrored by an increase in overdoses and a growth of opioid prescribing.⁶³ Evidence points to the medical companies, specifically pharmacies and pharmaceutical manufacturers, as a driver of this pandemic. One visible example came in 2019, when Johnson & Johnson lost an opioid trial in Oklahoma. They were accused of downplaying the dangers of opioids while overselling the benefits of them.⁶⁴ Investigations revealed that the company had secured contracts with poppy growers and supplied over 60% of opioid ingredients that drug companies used to make drugs like oxycodone.⁶⁵ J&J was not the sole proprietor, many other medical companies were aggressively campaigning for (and selling) opioids too, most infamously Purdue Pharma, the company behind Oxycontin. Opioids are addictive, so companies get steady revenue from returning 'customers'. There is a lot of money to be made, so it is not surprising that so many companies are part of the problem. The opioid promotion aligned with the financial incentives at stake in the industry. By 2013, opioid prescriptions represented around \$78.5 billion cost (from healthcare spending to criminal justice fees) to the healthcare system.⁶⁶ There's a lot of money to be made. When profit becomes the industry priority and patients are treated more as consumers, the consequences can be devastating.

For patients, OTC hearing aids pose much less of a risk than other self-care products because of what the devices do. Hearing aids do not interfere with any internal biological process, they are not addictive, and they do not carry side effects like most pharmaceutical medicine. While it is true that bluetooth devices emit radiation, it is non-ionizing radiation.⁶⁷ This means that the radiation does not affect the DNA cells of the human body, and is in fact much less - approximately 10 to 400 times less - harmful than radiation from phones.⁶⁸ Because of this, users are safe from over-prescribing and overuse of most OTC drugs.

The main concern of improper use worsening hearing loss is real, but rare. With the advances in hearing tests, fitting technologies, sound amplification and calibration, the likelihood of misuse is much lower than ingestible drugs. However, the risk of selfcare and commercialization of care do not disappear, just that the potential damage is much less severe.

While the physical danger of a hearing aid is lower than that of an opioid, the structural risk is identical: the OTC hearing aid industry could exploit the consumer's lack of medical literacy when their priority shifts from clinical outcomes to market share. In the opioid crisis, manufacturers downplayed the dangers of addiction; consumers need to beware of the same marketing ploys in the OTC hearing aid market. In a 2024 commercial by Apple showcasing their new hearing aid feature on the Airpods Pro 2s, the effects of the hearing aids are clear and immediate, however, it does not show that the hearing aids are not a total solution. Tests have concurred that the Airpods Pro 2 hearing aid feature is less effective in environments with complex noise structures. There are also limitations in loud-level amplification, fine-tuning options, and dynamic noise-handling.⁶⁹ With no regulations on marketing, companies can mask some aspects of their products, and present their devices as a complete fix rather than ones with tradeoffs. Predatory marketing - when marketing is purposely misleading - is an apparent risk. Consumers could be susceptible to the same overselling of benefits that happened in the opioid crisis, not recognizing the side effects or potential dangers of a product. Through their credibility as pharmaceutical organizations, manufacturers marketed opioids as great fixes with minor complications.⁷⁰ The

⁶² Kolodny, Andrew. 2020. "How FDA Failures Contributed to the Opioid Crisis." *AMA Journal of Ethics*, (August). 10.1001/amaethics.2020.743.

⁶³ *IBID*

⁶⁴ Hoffman, Jan. 2019. "Johnson & Johnson Ordered to Pay \$572 Million in Landmark Opioid Trial (Published 2019)." *The New York Times*, August 26, 2019. <https://www.nytimes.com/2019/08/26/health/oklahoma-opioids-johnson-and-johnson.html>.

⁶⁵ *IBID*

⁶⁶ CEA. 2017. "The Underestimated Cost of the Opioid Crisis." *The Council of Economic Advisers*, (November). <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf>.

⁶⁷ Remedios, Jesse. 2025. "Do Bluetooth Headphones Cause Cancer?" CNN. <http://cnn.com/audio/podcasts/chasing-life/episodes/a1b1e72e-cd37-11ef-b277-bf014da84c33>.

⁶⁸ *IBID*

⁶⁹ Chong-White, Nicky, Matthew Croteau, Padraig Kitterick, and Brent Edwards. 2025. "Evaluating Apple AirPods Pro 2 Hearing Aid Software: Acoustic Measurements and Insights." *The Hearing Review*, (April). <https://hearingreview.com/hearing-products/hearing-aids/otc/evaluating-apple-airpods-pro-2-hearing-aid-software-acoustic-measurements-and-insights>.

⁷⁰ Van Zee A. (2009). The promotion and marketing of oxycontin: commercial triumph, public health tragedy. *American journal of public health*, 99(2), 221–227. <https://doi.org/10.2105/AJPH.2007.131714>

same could very well happen with OTC hearing aids, when companies through brand prestige, using established names of technological giants such as Sony or Apple, market their products as the magic cure. When industries deregulate to increase access, that often incentivizes volume over value, the number sold becomes more important than the quality. In the opioid crisis, the volume of pills sold was the metric of success. Similarly, the volume of devices sold could become the priority, regardless of whether those devices actually improve the user's quality of life or effectively target their hearing damage.

As the market grows, the FDA has more room to operate and step in to avoid situations like the opioid pandemic again. They should start implementing regulations aimed at realigning patient and industry priority, setting clearer standards, tightening oversight, and making sure that accessibility or profit does not come at the cost of patient safety.

VI. Results and Conclusion

Our field testing of 100+ elders indicated that the prevalence of hearing loss was high among them, and that OTC devices provided significant speech comprehension improvement, comparable to mid-tier prescription models. However, the study also revealed that without professional guidance, 15% of users struggled with optimal calibration, highlighting the need for better user support models.

The OTC model is a necessary improvement for accessibility. However, to prevent the commercialization of care eroding user safety, the FDA must maintain high standards and implement regulation that prevents marketing from superseding medical effectiveness.

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