ISSN: 3049-7159

Review Article

Journal of Business and Econometrics Studies

Hearing at what Cost? The Slippery Slope of Commodifying Hearing Devices

Madison Cain

Lewis Katz Building University Park, PA 16802, USA

Corresponding author
Madison Cain, Lewis Katz Building University Park, PA 16802, USA.

Received: January 08, 2026; **Accepted:** January 19, 2026; **Published:** January 22, 2026

ABSTRACT

Recently the hearing aid industry has been rapidly propelled to the national stage following the introduction of new regulations allowing over the-counter hearings aids to be provided directly to consumers. Once controlled by a handful of manufacturers, the industry has expanded to include tech giants and new entrants eager to capitalize on regulatory changes. At first glance, this shift appears to be a step forward in accessibility. However, the sudden commercialization of hearing aids raises serious concerns about the future of hearing healthcare.

This comment analyzes the hearing aid market before and after OTC legislation. Examining both its benefits and consequences. The influx of corporations—many from outside the healthcare sector—has shifted the focus of hearing care from patient-centered treatment to mass-market consumerism. While innovation is valuable, this shift threatens to deprioritize professional audiological care, leaving individuals with hearing loss to navigate their treatment without expert guidance.

Ultimately, this comment argues that accessibility should not come at the cost of quality hearing healthcare. Furthermore, it argues against commercializing the hearing aid industry and rather focusing on improving access to personalized hearing care services. This comment calls for legal reforms to reinforce access to prescription hearing aids and audiology services, ensuring that hearing loss is treated as a medical condition rather than a mere consumer electronics problem. Without proper oversight, the industry risks moving toward a future where hearing aids are widely available yet fail to provide meaningful solutions for those who need them most.

Introduction

Hearing loss is unique in that it can dramatically change a person's life without making itself readily apparent. It usually starts subtly: missing a few vowels or sounds here and there, nothing noticeable at first. Maybe your S's seem less sharp, or you mispronounce a few words. Then, it becomes entire words or sentences—lost in the noise. At a crowded restaurant, you realize half the conversation passes you by. Frustrated by your repeated "huh?" or "what did you say?" friends and family grow irritated, and you notice.

Slowly, you begin to adapt: avoiding noisy places, declining social gatherings, asking people to text instead of call because phone conversations are too challenging—or maybe you stop answering the phone altogether. Perhaps one day, an alarm fails to wake you up, or worse, you don't hear the fire alarm in your sleep. Yet, for many, there's no dramatic moment of realization. Instead, conversations just feel "irritating" or people seem to "mumble too much." You tell yourself that's just how the world sounds or accept it as a byproduct of aging.

Even in the best-case scenario, where hearing loss remains subtle, your brain knows. You start to withdraw—less connected, less engaged, and increasingly isolated. The insidious nature of hearing loss robs people of connection and safety in ways that are often underestimated, both medically and socially [1].

It would be some solace if this alarming condition had a readily available, quality medical structure to go to for testing, diagnosis, and treatment. Unfortunately, even if you are able to identify a problem with your hearing, you may end up paying an estimated $33 to over $295 just for the hearing test, with

Citation: Madison Cain. Hearing at what Cost? The Slippery Slope of Commodifying Hearing Devices. J Bus Econo Stud. 2026. 3(1): 1-10.
DOI: doi.org/10.61440/JBES.2026.v3.114

the variance subject to the type of test, the insurance See, e.g., National Research Council (US) Committee on Disability Determination for Individuals with Hearing Impairments, Impact of Hearing Loss on Daily Life and the Workplace, NAT'L CTR. BIOTECHNOLOGY INFO.

(Robert A. Dobie & Susan B. Van Hemel eds., 2005), https://tinyurl.com/wjb36c5v ("Although many adults are resilient, acquired hearing difficulties are nevertheless responsible for a high level of general psychological distress for a significant number of people due in part to isolation, loneliness, and withdrawal."). You have, and the provider [2]. Chances are you will likely need or benefit from hearing aids, as about 28.8 million U.S. adults could benefit from using hearing aids [3]. However, in order to get this treatment that could significantly improve your quality of life for the better, you will have to navigate a complex web of options, substantially varying in price and quality. This web has only become even more confusing with a suddenly and rapidly changing market introducing options substantially ranging in price and quality.

Despite the profound impact hearing loss has on individuals and society, it remains an issue plagued by inaccessibility, high costs, and inadequate attention. This Article explores the systemic barriers within the hearing aid industry, examining how these barriers perpetuate isolation for millions while discussing potential avenues for reform.

Background

Overview of Accessibility

Illustrate how common hearing loss is, Diabetes is considered to be a common condition, yet affects only an estimated 11.6% of the US population [4,5]. Yet among adults age 70 and older with hearing loss, fewer than one in three have ever used hearing aids [7]. Among adults ages 20–69 who could similarly benefit, the number is even lower, with only about 16% having ever used them [7]. This stark disparity in treatment is primarily the result of inadequate access to hearing aids [8]. Although hearing loss is certainly not the only medical condition inadequately addressed by the US healthcare system, the barriers to accessing one crucial form of treatment—hearing devices—are unique in their complexity and persistence [9,10]. These barriers include high costs, limited insurance coverage, and the restrictive structure of the hearing aid industry [11].

Structural Challenges in the Hearing Aid Market

Few medical devices in history have experienced such a tumultuous series of circumstances as hearing aids [12]. Numerous factors—such as issues surrounding accessibility, affordability, and innovation—have persistently hindered this essential device [13]. The industry has struggled with lagging innovation, skyrocketing prices, and poor or simply nonexistent insurance coverage [14]. As a result, consumers have been left to navigate these setbacks

58151 (Oct. 20, 2021) (noting that "several barriers likely impede the use of hearing aids in hearing-impaired individuals such as high cost"); Matt Stoller, Silencing the Competition: Inside the Fight Against the Hearing Aid Cartel, BIG (Oct. 21, 2021), https://tinyurl.com/2jdu8nvw.

David Lazarus, Column: High Cost of Hearing Aids Shows (Yet Again) the Insanity of Medical Pricing, LA TIMES (June 8, 2021), https://tinyurl.com/58cn74xy. when trying to access hearing devices [15]. To illustrate, the average cost per pair of prescription hearing aids is an astonishing $4,600—a price tag that puts this essential medical device out of reach for many [16]. Even more startling, the average price of a Behind-the-Ear ("BTE") hearing aid has more than doubled in the last decade, highlighting the industry's growing inaccessibility [17].

Structural Overview

These exorbitant price ranges and other setbacks can be traced back to the traditionally restrictive underlying structure of the hearing aid industry [18]. The market has long been dominated by a small number of manufacturers—often referred to as the "Big Five"—who collectively controlled more than 90% of the global marketplace for hearing aids [19]. To put this into perspective, the DC Circuit intervened when Microsoft had control over around 90% of the personal computer system market, finding that. Microsoft had engaged in exclusionary and anticompetitive conduct to maintain its monopoly in the market [20]. Furthermore, in 2011, the U.S. Department of Justice blocked the merger of AT&T with T-Mobile USA as four of the largest providers—AT&T, T-Mobile, Sprint, and Verizon—accounted for more than 90% of mobile wireless connections [21]. The merger would have combined two of these four, significantly reducing competition [22].

Judicial and Regulatory Acknowledgement

Despite displaying similarly concerning levels of market concentration and anticompetitive tendencies, the hearing aid industry has remarkably evaded the type of direct government intervention or judicial scrutiny seen in the industries described above [23]. Although the issue has been acknowledged in some legal contexts. For instance, the Cartel Report cited in Energy Transp. Group, Inc. v. William Demant Holding A/S highlighted the hearing aid market's high concentration and exceedingly high profit margins due to limited competition [24,25]. Additionally, as far back as 1975, the Federal Trade Commission (FTC) took action against hearing aid manufacturers for unfair methods of competition and deceptive practices in Beltone Electronics Corp. v. Federal Trade Com [26]. In Beltone, the FTC investigated and issued complaints against several hearing aid manufacturers for misrepresentations and failures to make affirmative disclosures in their advertisements [27].

Failure of Oversight and Oligopolistic Strategies

Despite judicial acknowledgment and FTC intervention in cases like Energy Transport, Beltone, and others, these actions have largely failed to disrupt the hearing aid industry's oligopolistic structure [28]. While these cases addressed anticompetitive practices in the industry such as price-fixing and deceptive advertising, their outcomes did little to curtail the entrenched market dominance [29]. The industry has relied on several sophisticated Virdi, The FDA's New Hearing Aid Won't Solve the Bigger Problems in the strategies to maintain its oligopolistic status [30]. These strategies, which have designated the dominant companies as a "hearing aid cartel," have consisted of patent pools, vertical integration, and a complex network of subsidiaries and audiology services to retain oligopolistic power to the detriment of hearing aid accessibility [31].

Patent pools are one tool the hearing aid industry has used to dissuade competition and maintain market dominance [32]. A patent pool is an agreement between two or more patent owners to aggregate some or all of their patents for the purpose of cross-licensing [33]. In the hearing aid market, the patent pool is centered in a Danish limited partnership K/S HIMPP that provides more than 90% of all hearing instruments worldwide [34]. K/S HIMPP owns an extremely extensive patent portfolio which causes difficulty for new entrants in the market, as the likelihood of infringing on one of the several. Vertical integration is another tool employed by several hearing aid manufacturers. Vertical integration is defined as the acquisition of a company at a different stage of the production process by a firm that already controls another stage; essentially the firm retains control over multiple stages of the supply chain [35-37]. In 2015, the President's Council of Advisors on Science and Technology ("PCAST") expressed concern about vertical integration in the hearing care industry, specifically noting how six companies controlled a high percentage of product sales, and the lack of influx of new innovative companies [38].

Specifically, hearing aid manufacturers have expanded their operations to include various stages of the supply chain, such as distribution, retail, and even health insurance providers, encompassing the production and sale of hearing aids, and the provision of hearing care services [39]. This vertical integration allows these companies to exert influence over nearly every stage of the consumer experience, creating significant barriers for independent competitors and limiting consumer choice [40]. It also places immense pricing power in the hands of a few dominant firms, enabling them to set high prices with little competitive pressure.

Effect on Consumers

Under this extreme concentration of manufacturing power, the hearing aid market experienced unique stagnation with prices continuing to rise and innovation falling behind [41]. For instance, despite advancements in technology over time, costs did not decrease in a manner consistent with other similar tech-heavy markets [42]. Furthermore, despite a recognized need for advancements in features such as battery life, connectivity, and real-time speech recognition, innovation in hearing aids has failed to keep up with consumer demands [43]. Consumers reported that hearing aids that did offer these improvements came with significant price increases even though the improvements were incremental [44]. For example, premium hearing aids that include Bluetooth Connectivity or noise cancellation come with exorbitant price tags, although the same features exist in much less expensive consumer-grade headphones [45]. This stagnation in both price and innovation highlights how the concentrated structure of the hearing aid industry has led to a market that fails to meet the evolving needs and expectations of consumers.

Lack of Insurance Coverage

To complicate matters, most insurances companies do not cover hearing aids, considering hearing loss a "likely risk" rather than a medical necessity [46]. Even when coverage is available, it varies widely across states due to differing mandates and the perception that hearing aids are optional devices or elective devices [47]. This variability reflects broader misconceptions about the impact of untreated hearing loss and the financial concerns of insurers about the potential volume of claims [48]. As stated before, hearing loss is a common condition rising in the United States: it is even expected to double by 2060 [49,50]. Insurance companies worry that if hearing loss testing and treatment were covered by insurance, a large number of people would file claims, significantly increasing costs, particularly in light of rising healthcare expenses [51]. Consequently, many insurance companies consider hearing loss uninsurable [52].

Coverage Across States

Furthermore, only five states—Arkansas, Connecticut, Illinois, New Hampshire, and Rhode Island—mandate insurance coverage of hearing aids for both children and adults [53]. Twenty states require coverage solely for children [54]. However, it's important to emphasize that some insurance plans are entirely exempt from these state mandates, rendering these minimal rules ineffective for a significant portion of individuals [55]. This exemption means that even in states with coverage requirements, requirements can vary significantly regarding coverage, benefit period, and provider qualifications [56]. As a result, millions of individuals may lack access to even the most basic hearing aid coverage, further exacerbating disparities in accessibility and highlighting the inadequacy of current regulatory frameworks.

Coverage by Insurance Programs

Moreover, Medicare does not cover hearing aids at all, leaving individuals to pay entirely out of pocket for these essential devices [57]. Even hearing tests are only covered if ordered by a physician, as they are deemed not "medically necessary" under Medicare guidelines [58]. This is particularly unfortunate considering Medicare is relied on by more than 66 million people ages 65 and older, the age range with the highest prevalence of hearing loss [59,60]. Medicaid, which covers more than 72 million individuals of all ages, only provides hearing care benefits for adults in some states [61]. However, it does cover hearing care and hearing aids for children in all states, emphasizing the significant gap in coverage for the growing population of adults, including those 65 and older who rely heavily on this program [62].

Cost as the Largest Barrier to Adoption

A recent study examined how the cost of hearing aids impacts their adoption among individuals with varying degrees of hearing loss [63]. Researchers led by Dr. Virginia Ramachandran found that, despite recent increases in third-party payment options for hearing aids, hearing healthcare remains an out-of-pocket expense that competes with other discretionary expenses for priority [64]. The results of the study demonstrated that for those with moderate to severe hearing loss, eliminating the cost barrier entirely led to a notable increase in hearing aid adoption [65]. In fact, the only group that consistently got hearing aids had insurance that paid for them in full, and participants who had insurance that fully covered the cost of hearing aids were far more likely to obtain them, regardless of the severity of their hearing loss [66]. It is irrefutable that financial coverage of hearing aid significantly influences adoption [67].

Consequences of Accessibility Barriers

Public Impact

With inadequate coverage of hearing care and hearing aids by both public and private insurance companies, a wide gap

continues to exist between those who need or would benefit from hearing device usage and those who actually have access to or use them [68]. If this disparity is left unaddressed, it will have a profound impact on both a personal and national scale, making it a significant public health concern for several reasons. Untreated hearing loss substantially impacts daily interactions, cognitive health and development, and overall well-being [69]. The urgency to address this disparity is further intensified by the projected doubling of hearing loss by 2060, outpacing the overall population growth rate, given the distribution shift toward older adults [70].

Individual Cognitive and Neurological Implications

As this issue grows, the implications of untreated hearing loss become increasingly evident. While some may be able to cope without hearing aids if they only have mild to moderate hearing loss, numerous studies have demonstrated how even a slight hearing deficit can notably impact quality of life [71]. Untreated hearing loss gradually results in auditory deprivation, which further worsens over time [72]. Essentially, hearing is a brain activity: ears deliver sound as electrical impulses via the auditory nerve, and the electrical impulses are translated into recognizable sounds by the brain [73]. Thus, with fewer electrical impulses being delivered, the parts of the brain responsible for hearing get "reassigned" to other tasks, and over time the brain loses the ability to properly process sound [74]. The parts of the brain involved in hearing tend to shrink or atrophy, an effect notably not limited to severe cases of hearing loss [75]. Additionally, the longer the brain persists in improperly processing sound, the more challenging it becomes for it to understand and process information, thereby impacting both neuroplasticity (the brain's ability to change and adapt its structure and function in response to intrinsic and extrinsic factors) and the potential for cross-modal plasticity of the brain (an adaptive phenomenon, in which unaffected regions of the brain take over portions of a damaged sensory region) [76-78].

In a study that tracked 639 adults for nearly 12 years, researchers found that even mild hearing loss doubled dementia risk [79]. Furthermore, moderate hearing loss tripled the risk, and severe hearing loss meant a person was five times more likely to develop dementia [80]. In addition to this significant correlation between hearing loss and poorer cognitive functions, uncorrected hearing loss has been repeatedly proven to facilitate a poorer quality of life overall, related to factors such as isolation, reduced activity, and depression [81]. These findings highlight the critical importance of ensuring everyone has proper access to care for the vital and constantly utilized sense of hearing. The lack of adequate treatment not only affects individuals on a personal level but also carries significant implications for society as a whole.

Over-the-Counter Hearing Aid Act

Legislative Background and Implementation

In 2016, legislation addressing hearing aid inaccessibility was initially introduced and later reintroduced in the 115th Congress as the Over-theCounter Hearing Aid Act of 2017 [82]. This legislation was eventually incorporated into the FDA Reauthorization Act and signed into law in 2017, allowing for the sale of over-the-counter hearing aids [83]. However, the bill required that the Food and Drug Administration issue regulations for this new category of hearing aids [84]. The FDA did not finalize these regulations until October 2022, after President Biden issued an Executive Order titled. Promoting Competition in the American Economy [85]. This order directed the Department of Health and Human Services (HHS) to "promote the wide availability of low-cost hearing aids" and specifically called on the FDA to establish regulations creating a new category of OTC hearing aids to improve accessibility and affordability for consumers [86]. The new regulations finally permitted hearing aids for mild to moderate hearing loss to be sold over the counter without a prescription [87].

Risks Emerging from OTC Hearing Aids

While these actions undoubtedly represent a positive trend in encouraging hearing aid usage, increasing device accessibility, and fostering competition in what has been perceived as an untouchable market, it is crucial to remain vigilant [88]. This means closely monitoring the implementation of these regulations to ensure they truly increase access without compromising the quality of care. More specifically, it is important to recognize the potential for a slippery slope, where the focus on OTC hearing aids may unintentionally pave the way for increased commodification and commercialization of hearing care [89]. Such a shift could prioritize profit-driven models over patient-centered care, ultimately undermining the quality and accessibility of hearing health [90]. Despite the good intentions underlying this legislation and the resulting spike in interest in the hearing aid market, various factors undermine these intentions and suggest a potentially negative trajectory in its progression [91]. For several reasons, this step forward may have shifted the focus on hearing care accessibility off track.

Inadequacy of OTC Hearing Aids

Focusing specifically on OTC hearing aids as a catalyst for the recent surge in activity within the hearing device industry, it's critical to recognize that OTC hearing aids will not be suitable for many individuals. OTC hearing aids are only intended for adults with mild to moderate hearing loss and are v. FTC, 1 F.4th 102 (2d Cir. 2021) (examining the effects of online sales and competition within the contact lens industry). The deregulation of vision care, much like the push for OTC hearing aids, shifted the industry toward commodification, leading to greater accessibility but also raising concerns about quality control and professional oversight. See also 16 C.F.R. § 315 (FTC Contact Lens Rule) (outlining regulatory standards in response to growing market competition). Similar to the hearing aid industry, commercial interests have increasingly influenced the sale and distribution of medical devices traditionally subject to professional oversight. not customized to individual ear shape, which is crucial for enhancing sound quality, amplification, and comfort [92]. This limitation is a significant reason why interest in direct-to-consumer hearing devices has lagged thus far [93].

Moreover, hearing loss is highly individualized: it can be conductive, sensorineural, central, or mixed [94]. It can be unilateral or bilateral and range from mild to profound across various sound frequencies or degrees of residual hearing [95]. As a result, OTC hearing aids carry a genuine risk of under- or over-amplification as they are not tailored to the unique hearing

capabilities of an individual [96]. This can have significant consequences. With over Conductive hearing loss is when sound cannot get through the outer and/or middle ear. Sensorineural hearing loss results from damage to the inner ear or auditory nerve. Central hearing loss is a dysfunction of the central auditory system. Mixed hearing loss is a combination of conductive and sensorineural issues. Types, Causes, and Treatments, HEARING LOSS ASS'N AMERICA, https://tinyurl.com/3w4r5eu9 (last visited Nov. 24, 2024).

amplification, there is the likelihood that damage may be done to the remaining hearing capability, worsening a person's hearing loss [97]. Underamplification raises many of the issues discussed before that correlate with uncorrected hearing loss [98]. Ultimately, it is not feasible for most individuals with hearing loss to have their needs adequately met by OTC hearing aids, given the unique and highly individualized nature of hearing loss [99].

Analysis an Implications of OTC Hearing Aids

The Blurring Line Between Medical and Consumer Devices

The hearing aid industry is undergoing a rapid transformation, driven by regulatory changes that have opened the market to new players [100]. Once dominated by a few manufacturers, the industry is now seeing an influx of tech giants and startups eager to capitalize on the shift toward OTC hearing aids [101]. At first glance, this surge in competition and innovation may seem like an unequivocal win for accessibility. However, the increasing commercialization of hearing aids brings unintended consequences that could undermine the very consumers it aims to serve [102].

As hearing devices become more integrated into the consumer electronics market, the distinction between medical-grade hearing aids and generic sound amplifiers is fading [103]. Without clear regulatory guardrails, Hearing Aids, 16 NAT'L CTR. BIOTECHNOLOGY INFO. 199, 200 (Aug. 18, 2023), https://tinyurl.com/mpn4xrcn. Kim & Moon stated:

The introduction of OTC HAs by the U.S. FDA has prompted a major transformation in the HA market. This shift has broadened the range of options for individuals with HL, increasing the accessibility of hearing assistive devices—a positive development. However, when selecting a hearing assistive device, it is essential to carefully evaluate its safety and clinical efficacy. Hearing healthcare professionals, such as physicians and audiologists, should thoroughly review the safety and clinical effectiveness of each hearing assistive device.

("The eight external stakeholder groups we interviewed identified several issues relating to OTC hearing aids that they told us should be monitored as the market matures: marketing, children's use of OTC hearing aids, return policies, and gain limits."); Press Release, U.S. Food & Drug Admin., FDA Authorizes First Over-the-Counter Hearing Aid Software (Oct. 13, 2023), https://tinyurl.com/4srsrzaz.

See Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, 21 C.F.R. §§ 800, 801, 808, 874 (2022) (Providing for entry into the market of a variety of devices that may not have been traditionally classified as medical-grade hearing aids); U.S. GEN. ACCT. OFF., GAO-24-106854, OVER-THE-COUNTER HEARING AIDS: INFORMATION ON misleading marketing could lead consumers to purchase ineffective or inappropriate devices, assuming they provide the same level of benefit as professionally fitted hearing aids [104]. The dilution of medical oversight in this space threatens to erode consumer protections and could result in individuals unknowingly forgoing necessary audiological care [105].

Rise of Tech Giants and the Shift Away from Personalized Hearing Care

The entrance of companies like Apple, Bose, and Sony into the hearing aid market reflects a larger shift toward treating hearing devices as another THE NEW MEDICAL DEVICE CATEGORY 8 (2024) https://tinyurl.com/5wvbb77x (Expressing concern with the marketing claims of some OTC hearing aids);

Juliana Kim, FDA Approves Some Apple Airpods to be Used as Hearing Aids, NPR (Sept. 14, 2024, 12:59 PM) https://tinyurl.com/yc3t26y8 (discussing FDA approval of Apple Airpods Pro to function as OTC hearing aids, exemplifying the integration of consumer electronics into the hearing aid market and blurring the lines between medical-grade devices and general sound amplifiers.).

Another major concern with the introduction of OTC hearing aids is the lack of guidance and follow-up care that comes with professionally fitted hearing aids. Hearing aids aren't as easy to use as eyeglasses. The success of the hearing aid fit and their continued use is heavily dependent on the post-care, counseling, and guidance that hearing aid patients receive from professionals such as audiologists and hearing aid dispensing specialists.

Branch of consumer electronics rather than essential medical tools [106]. Apple, for instance, has integrated a hearing aid-like function into its AirPods Pro 2, subtly redefining what consumers think of as hearing assistance [107]. While technological innovation can be beneficial, there is a risk that hearing care is being reduced to a tech feature rather than a critical aspect of medical treatment. The focus on convenience and mass-market appeal could overshadow the importance of individualized audiological care, leading consumers to rely on self-diagnosis and self-treatment rather than seeking professional guidance [108].

Accessibility or Profit Motives?

The influx of new companies raises an important question—why now? While proponents of OTC hearing aids argue that deregulation expands access to hearing care, there is reason to question whether companies are truly prioritizing accessibility or simply capitalizing on a newly deregulated, high-profit market [109]. Historically, industries that undergo rapid commercialization have seen aggressive marketing, misleading claims, and a decline in product quality as companies race to capture market share [110]. The hearing aid industry risks following this same path, prioritizing profit-driven innovation over genuine solutions for individuals with hearing loss [111].

Diminishing Role of Audiologists and Professional Oversight

As more hearing aids are sold over the counter, audiologists and hearing health professionals risk being sidelined [112]. Historically, these professionals played a vital role in diagnosing hearing loss, fitting patients with appropriate devices, and providing necessary follow-up care [113]. With OTC devices, consumers are encouraged to self-diagnose and self-treat, often without understanding the nuances of their hearing loss [114]. This shift not only reduces the quality of care but also increases the likelihood of consumers purchasing ineffective or inappropriate devices [115]. If professional audiological care becomes an afterthought in favor of convenience, consumers could suffer from suboptimal hearing outcomes.

Recommendations for the Future of Hearing Healthcare

Hearing healthcare should not be reduced to a retail transaction. Rather than relying solely on consumer-driven solutions, policymakers should implement legal reforms that strengthen access to prescription hearing aids and audiology services, ensuring patients receive appropriate care tailored to their medical needs. However, achieving this goal is significantly challenging within the United States' fragmented and complex healthcare system.

("Without proper exams and individualized fitting, OTC hearing aids won't target someone's specific hearing loss, which requires an evaluation and calibration for maximum sound benefits. Indeed, experts are advising consumers to consider getting a hearing assessment by a certified audiologist before purchasing a device.").

Legal reforms aimed at improving access to prescription hearing aids and personalized hearing care must take into account the myriad overlapping factors that influence just one sector of healthcare, such as the complexities of public and private insurance coverage, regulatory barriers, provider shortages, and disparities in healthcare access [116].

Extending the ACA's Framework to Hearing Healthcare

As previously stated, the various complexities of the hearing healthcare access issues are unlikely to be addressed by one proposal. However, an invaluable starting point would be to utilize and expand the recently passed Affordable Care Act (ACA)'s framework to include hearing aids. The ACA, through provisions like the Essential Health Benefits (EHB), expanded access to critical health services such as preventative care and treatment for chronic conditions [117]. Specifically, the ACA requires insurance plans to cover certain preventive services without patient cost-sharing, and it a full discussion of the various legal, economic, and regulatory factors affecting access to healthcare—particularly in the context of insurance coverage, provider availability, and regulatory frameworks—is beyond the scope of this Article. For an overview of these complexities see, e.g., Id.

has significantly expanded access to healthcare for millions of Americans [118]. By applying this framework to hearing aids, policymakers could leverage an existing structure to improve access to a necessary medical device that is often overlooked by insurers.

The ACA also provides a foundation for integrating hearing care into broader health coverage, aligning it with the medical necessity of audiology services [119]. Expanding coverage for hearing aids could help reduce the out-ofpocket burden on patients, which would alleviate a major burden on hearing aid access–the price. Including hearing aids under the ACA would also recognize hearing aids as medical devices that require professional assessment and treatment, not mere consumer products [120]. By addressing hearing care through the lens of comprehensive health coverage, this solution would also ensure the preservation of high-quality, individualized care, avoiding the pitfalls of an over-commercialized, profit-driven model.

Integrating ACA and Medicare Solutions

Expanding Medicare alongside the ACA to include hearing aids would likely more comprehensively–albeit imperfectly–address the complexities of hearing aid access. Fortunately, a proposal for Medicare expansion already has some support in Congress [121]. In January of 2025, the bipartisan Medicare.

Hearing Aid Coverage Act was reintroduced [122]. This legislation would expand Medicare coverage to include hearing aids for beneficiaries and would address the needs of the senior population, who are disproportionately affected by hearing loss but often face significant out-of-pocket costs for these devices [123]. These two proposals, while targeting different groups, could work synergistically to enhance access to hearing healthcare for a broader portion of the population.

By addressing both the ACA and Medicare, policymakers would create a more unified, consistent healthcare approach that ensures individuals of all ages have access to affordable, high-quality hearing care. Moreover, the success of one solution, such as the expansion of ACA coverage, could generate momentum for broader reforms in Medicare, leading to a more

Conclusion

Hearing healthcare is too often overlooked in broader healthcare discussions, yet its impact on millions of Americans is profound. As the rates of hearing loss continue to rise, the importance of ensuring equitable access to quality treatment will only become more urgent. We are living through a pivotal moment in the history of hearing aids. The current transformation of the hearing aid market presents both opportunities and significant risks—without proper oversight, the industry may prioritize profit over patientcentered care, leaving individuals to navigate hearing loss without adequate support [124-135].

Therefore, it is crucial to remain vigilant to ensure that, even as the dust settles and the excitement in the industry fades, access to quality prescription hearing aids—access which is currently limited—improves and hearing care becomes more widely available to those who need it. The focus must not shift to mass-producing new devices without considering the unique needs of those they are meant to help. True accessibility means more than simply increasing the availability of devices; it requires ensuring that individuals receive proper evaluation, guidance, and high-quality devices tailored to their needs.

Given the complexities of the United States healthcare system, it is important to acknowledge that there is likely no perfect solution to this issue.

Nonetheless, this Article advocates for extending the ACA's framework to include hearing healthcare and expanding Medicare coverage through the Medicare Hearing Aid Coverage Act. This twofold approach would better meet the needs of a broader segment of the population, and meaningful progress on either front would benefit the healthcare system as a whole. Ultimately, any meaningful progress will depend on continued advocacy and policy reform. The future of hearing healthcare hinges on our commitment to prioritizing patient needs over corporate interests, ensuring that innovation in the industry leads to better, not just more, hearing solutions.

References

1. Prevalence of Hearing Loss and Gaps in Treatment. Hearing loss is not a rare condition. Approximately 15% of American adults (37.5 million) ages 18 and over report some trouble hearing, and about 13% of Americans ages 12 and older have hearing loss in both ears.
2. Potomac Audiology News, POTOMAC AUDIOLOGY, https://tinyurl.com/bdzpzz6r (last visited Feb. 2, 2025).
3. Quick Statistics About Hearing, NAT'L INST. ON DEAFNESS & OTHER COMMC'N DISORDERS (Mar. 4, 2024), 4. Id.
4. National Diabetes Statistics Report, CDC (May 15, 2024) https://tinyurl.com/3yxram2d. Quick Statistics About Hearing, supra note 3. Id.
5. See Over-the-Counter Hearing Aid Act of 2017, Sen. 670, 115th Cong. (2017) (noting that only a small share of Americans with hearing loss— around 14 percent—use assistive hearing technologies, primarily because they cannot afford to buy costly hearing aids).
6. See, e.g., 2023 National Healthcare Quality and Disparities Report, AGENCY FOR HEALTHCARE RSCH. & QUALITY, https://tinyurl.com/3tt679dc (last reviewed May 2024).
7. See generally, Over-the-Counter Hearing Aid Act of 2017, supra note 8. See FDA, Proposed Rule: Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, 86 Fed. Reg. 58150, See, Jaipreet Virdi, The FDA's New Hearing Aid Won't Solve the Bigger Problems in the Market, WASHINGTON POST (Aug. 25, 2022, 6:00 AM), https://tinyurl.com/yvpkm2kr (arguing that the FDA's new OTC hearing aid regulations fail to address affordability, accessibility, and monopolistic control in the industry); See also Over-the-Counter Hearing Aid Act of 2017, S. 670, 115th Cong. (2017) (noting the historically limited accessibility of hearing aids and the need for reform); Delivering Over-the-Counter Hearing Aids Now Act, S. 4043, 117th Cong. (2022) (seeking to expedite the implementation of OTC hearing aid regulations in response to ongoing accessibility challenges).
8. See Kristen Knight, Is There a Hearing Aid Price Bubble? AUDICUS (Mar. 17, 2023), https://tinyurl.com/bp8h69w4.
9. See, Rohit Bhisey, Hearing Aids Market to Exceed US$7 bn by 2026, Rise in The Prevalence of Hearing Loss to Drive the Market, BIOSPACE Mar. 8, 2022) (reporting that the global hearing aids market is oligopolistic);
10. See, e.g., Timothy Noah, A Hearing Aid Oligopoly Is Trying to Strangle Cheap Over-the-Counter Competitors, NEW REPUBLIC (June 30, 2022), https://tinyurl.com/4tv4vbyj.
11. Donya Currie, Reasons for Low Hearing Loss Treatment, NAT'L COUNCIL ON AGING (Sept. 17, 2024), https://tinyurl.com/2rke78m9.
12. NAT'L ACADS. OF SCIS., ENG'G & MED., HEARING HEALTH CARE FOR ADULTS: PRIORITIES FOR IMPROVING ACCESS AND AFFORDABILITY at 207, 209 (Dan G. Blazer, et al. eds., 2016), https://tinyurl.com/2338xhfn.
13. See, e.g., Timothy Noah, A Hearing Aid Oligopoly Is Trying to Strangle Cheap Over-the-Counter Competitors, NEW REPUBLIC (June 30, 2022), https://tinyurl.com/4tv4vbyj. Id.
14. United States v. Microsoft Corp., 253 F.3d 34, 58 (D.C. Cir. 2001).
15. Complaint at 2–3, United States v. AT&T Inc., No. 1:11-cv-01560 (D.D.C. Aug. 31, 2011).
16. Complaint at 2, United States v. AT&T Inc., No. 1:11-cv-01560 (D.D.C. Aug. 31, 2011).
17. See United States v. Microsoft Corp., 253 F.3d 34, 58 (D.C. Cir. 2001); United States v. AT&T Inc., No. 1:11-cv-01560 (D.D.C. filed Aug. 31, 2011).
18. Energy Transp. Grp., Inc. v. William Demant Holding A/S, 697 F.3d 1342, 1355 (Fed. Cir. 2012).
19. Energy Transp. Grp., Inc. v. William Demant Holding A/S, 697 F.3d 1342, 1355 (Fed. Cir. 2012).
20. Beltone Elecs. Corp. v. FTC, 402 F. Supp. 590, 594(N.D. Ill. 1975). Id. at 594.
21. See Energy Transp. Grp., 697 F.3d 1342, 1347; Beltone Elecs.
22. Corp., 402 F. Supp. 590, 592; see also Dictograph Prods., Inc. v. Fed. Trade Comm'n, 217 F.2d 821, 822 (2d Cir. 1954); Reiter v. Sonotone Corp., 442 U.S. 330, 335 (1979).
23. See Matt Stoller, Silencing the Competition: Inside the Fight Against the Hearing Aid Cartel, BIG (Oct. 21, 2021), https://tinyurl.com/2jdu8nvw; Kristen Knight, Is There a Hearing Aid Price Bubble? AUDICUS (Mar. 17, 2023), https://tinyurl.com/bp8h69w4; Jaipreet
24. Market, WASHINGTON POST (Aug. 25, 2022, 6:00 AM), https://tinyurl.com/yvpkm2kr.
25. See Matt Stoller, Silencing the Competition: Inside the Fight Against the Hearing Aid Cartel, BIG (Oct. 21, 2021), https://tinyurl.com/2jdu8nvw. Id.
26. Kevin Closson, Patent Pools, SPIE (Sept. 30, 2009), https://tinyurl.com/y2mjh2az.
27. About HIMPP, HEARING INSTRUMENT MANUFACTURERS PATENT PARTNERSHIP, https://tinyurl.com/y72rszzp (last visited Nov. 24, 2024). patents is much higher.35 This acts as a substantial deterrent to new entrants as infringement means the payment of licensing fees, which could be significant.36
28. Market, WASHINGTON POST (Aug. 25, 2022, 6:00 AM), https://tinyurl.com/yvpkm2kr.
29. See Matt Stoller, Silencing the Competition: Inside the Fight Against the Hearing Aid Cartel, BIG (Oct. 21, 2021), https://tinyurl.com/2jdu8nvw. Id.
30. Kevin Closson, Patent Pools, SPIE (Sept. 30, 2009), https://

tinyurl.com/y2mjh2az.
31. About HIMPP, HEARING INSTRUMENT MANUFACTURERS PATENT PARTNERSHIP, https://tinyurl.com/y72rszzp (last visited Nov. 24, 2024). patents is much higher.35 This acts as a substantial deterrent to new entrants as infringement means the payment of licensing fees, which could be significant.36
32. See About HIMPP, HEARING INSTRUMENT MANUFACTURERS PATENT PARTNERSHIP, https://tinyurl.com/y72rszzp (last visited Nov. 24, 2024); Stoller, supra note 30.
33. See generally FTC v. Procter & Gamble Co., 386 U.S. 568, 574– 75(1967).
34. President's Council of Advisors on Science and Technology, Letter to the President on Hearing Technology (Oct. 25, 2015), https://tinyurl.com/5n6py3p9.
35. See 7.7 List of Significant Companies, SONOVA, https://tinyurl.com/bdu27fma (last visited Nov. 24, 2024) (listing Connect Hearing Inc. as a subsidiary of Sonova; Connect Hearing is a network of hearing aid clinics providing hearing healthcare services and hearing aids).
36. See Matt Stoller, Silencing the Competition: Inside the Fight Against the Hearing Aid Cartel, BIG (Oct. 21, 2021), https://tinyurl.com/2jdu8nvw; David Lazarus, Column: High Cost of Hearing Aids Shows (Yet Again) the Insanity of Medical Pricing, LA TIMES (June 8, 2021), https://tinyurl.com/58cn74xy.
37. Kristen Knight, Is There a Hearing Aid Price Bubble? AUDICUS (Mar. 17, 2023), https://tinyurl.com/bp8h69w4.
38. See NAT'L ACADS. OF SCIS., ENG'G & MED., HEARING HEALTH CARE FOR ADULTS: PRIORITIES FOR IMPROVING ACCESS AND AFFORDABILITY., 206— 209 (Dan G. Blazer, et al. eds., 2016), https://tinyurl.com/2338xhfn. President's Council of Advisors on Science and Technology, supra note 38.
39. Catherine Roberts, What You Need to Know About Hearing Aids, PSAPs, and 'Hearables', WASHINGTON POST (July 2024, 2023, 2:00 PM), https://tinyurl.com/ys5xdrhc.Id.
40. Why Don't Insurance Companies Cover Hearing Aids?, PRO.
41. HEARING CTR., https://tinyurl.com/3ys8ad42 (last visited Nov. 2, 2024).
42. Amber Willink et al., Dental, Vision, And Hearing Services: Access, Spending, And Coverage for Medicare Beneficiaries, NAT'L CTR.
43. BIOTECHNOLOGY INFO. (Feb. 1, 2020), https://tinyurl.com/bd99wf6h.
44. See Erika Shakespeare, Why Doesn't Medicare Cover Hearing Aids?, AUDIOLOGY & HEARING AID ASSOC.'S (Apr. 26, 2024), https://tinyurl.com/4vb7x7kb; Why Don't Insurance Companies Cover Hearing Aids?, PRO. HEARING CTR., https://tinyurl.com/3ys8ad42 (last visited Nov. 2, 2024).
45. See discussion infra, Section I.A.1.
46. Nicole Hernandez, Hearing Loss Statistics 2024: More Common Than You Might Think, NAT'L COUNCIL ON AGING (Nov. 7, 2023), https://tinyurl.com/3azw3pza.
47. See, e.g., Why Don't Insurance Companies Cover Hearing Aids?, PRO. HEARING CTR., https://tinyurl.com/3ys8ad42 (last visited Nov. 2, 2024).
48. See, e.g., Jen Christensen, Hearing Loss an 'Invisible,' and Widely Uninsured, Problem, CNN HEALTH (Sept. 12, 2016, 1:20 PM), https://tinyurl.com/3nzaxrdc (noting the lack of private insurance coverage for hearing loss and explaining that, when private insurance does provide coverage, it "typically covers the cost of an exam to assess hearing loss, and that's about it.").
49. State Insurance Mandates for Hearing Aids, AM. SPEECHLANGUAGE-HEARING ASS'N, https://tinyurl.com/445fby6x (last visited Nov. 25, 2024).
50. Cara Everett, Does Medicare or Insurance Cover Hearing Aids in 2024?, NAT'L COUNCIL ON AGING (Nov. 14, 2024), https://tinyurl.com/4z7xzm3y.Id.
51. About Us, MEDICARE.GOV, https://tinyurl.com/455urrpm (last visited Nov. 2, 2024).
52. Quick Statistics About Hearing, NAT'L INST. ON DEAFNESS & OTHER COMMC'N DISORDERS (Mar. 4, 2024), https://tinyurl.com/5tb7af3v. ("22% of those ages 65-74 and 55% of those who are 75 and older have disabling hearing loss.").
53. July 2024 Medicaid & CHIP Enrollment Data Highlights, MEDICAID, https://tinyurl.com/y5da36ve (last visited Nov. 24, 2023); State Insurance Mandates for Hearing Aids, supra note 53.
54. State Insurance Mandates for Hearing Aids, supra note 53.
55. Virginia Ramachandran et al., Reducing Hearing Aid Cost Does Not Influence Device Acquisition for Milder Hearing Loss, but Eliminating it Does, 64 HEARING J. 10 (May 2011), https://tinyurl.com/45826axn.Id. at 10.
56. Id. (finding that cost remains a major barrier to hearing aid adoption for those with moderate to severe hearing loss.).
57. See, e.g., Quick Statistics About Hearing, NAT'L INST. ON DEAFNESS & OTHER COMMC'N DISORDERS (Mar. 4, 2024), https://tinyurl.com/5tb7af3v.
58. See NAT'L ACADS. OF SCIS., ENG'G & MED., HEARING HEALTH CARE FOR ADULTS: PRIORITIES FOR IMPROVING ACCESS AND AFFORDABILITY. 17, 27.
59. (Dan G. Blazer, et al. eds., 2016), https://tinyurl.com/2338xhfn; The Hidden Risks of Hearing Loss, JOHN HOPKINS MED., https://tinyurl.com/3823sf9a (last visited Sep. 21, 2024); Basics of Sound, the Ear, and Hearing, in DISABILITY DETERMINATION FOR INDIVIDUALS WITH HEARING IMPAIRMENTS (Robert A. Dobie & Susan B. Van Hemel eds., Nat'l Rsch. Council, 2005), NAT'L CTR. BIOTECHNOLOGY INFO., https://tinyurl.com/495z8nx2.
60. Adele M. Goman, Addressing Estimated Hearing Loss in Adults in 2060, 143 JAMA OTOLARYNGOLOGY HEAD & NECK SURGERY 733 (Mar. 2, 2017), https://tinyurl.com/55kscs49.
61. See, Stig Arlinger, Negative Consequences of Uncorrected Hearing Loss—A Review., INT. J. AUDIOLOGY 17–20 (2003), https://tinyurl.com/4rdhbfkc; The Hidden Risks of Hearing Loss, JOHN HOPKINS MED., https://tinyurl.com/3823sf9a (last visited Sept. 21, 2024); see also Rosemary Queenan, Amplifying Their Voices: Equity and Assistive Technology for Children with Disabilities, 127 DICK L. REV. 1, 4, 16–17 (2022).
62. Madeleine Burry, Understanding Auditory Deprivation: Why Untreated Hearing Loss is Bad for Your Brain, HEALTHY HEARING, https://tinyurl.com/2hh87ayd

(Dec. 22, 2022). Id.

63. Burry, supra note 72; Marie Simon, et al., The Impact of Early Deafness on Brain Plasticity: A Systematic Review of the White and Gray Matter Changes, 14 FRONTIERS IN NEUROSCIENCE 206, 1–2, 9–12 (2020), https://tinyurl.com/4nvnzrdc.
64. Andrej Kral & Anu Sharma, Crossmodal Plasticity in Hearing Loss, 46 TRENDS IN NEUROSCIENCES 377, 377–93 (2023), https://tinyurl.com/dw78hehk.
65. Caroline Levine, Cross-Modal Plasticity, BRITANNICA (Oct. 27, 2024), https://tinyurl.com/b3579atf.
66. The Hidden Risks of Hearing Loss, JOHN HOPKINS MED., https://tinyurl.com/3823sf9a (last visited Sep. 21, 2024).
67. See Arlinger, supra note 71; See also National Research Council (US) Committee on Disability Determination for Individuals with Hearing
68. Impairments, Impact of Hearing Loss on Daily Life and the Workplace, NAT'L CTR. BIOTECHNOLOGY INFO. (Robert A. Dobie & Susan B. Van Hemel eds., 2005), https://tinyurl.com/wjb36c5v.
69. Over-the-Counter Hearing Aid Act of 2017, Sen. 670, 115th Cong. (2017).
70. Food & Drug Administration Reauthorization Act, Pub. L. No. 11552, 131 Stat. 1005 (2017).
71. Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, 21 C.F.R. §§ 800, 801, 808, 874 (2022); Exec. Order No. 14,036, 86 Fed. Reg. 36,987, 36,989 (July 9, 2021).
72. Exec. Order No. 14,036, 86 Fed. Reg. 36,987, 36,989 (July 9, 2021).
73. Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, 21 C.F.R. §§ 800, 801, 808, 874 (2022).
74. See Matt Stoller, Silencing the Competition: Inside the Fight Against the Hearing Aid Cartel, BIG (Oct. 21, 2021), https://tinyurl.com/2jdu8nvw.
75. See, e.g., Fairness to Contact Lens Consumers Act, 15 U.S.C. §§ 7601–7610 (mandating that eye care professionals provide patients with prescriptions, facilitating third-party sales and increased commercialization of contact lenses); 1-800 Contacts, Inc.
76. v.FTC, 1 F.4th 102 (2d Cir. 2021) (examining the effects of online sales and competition within the contact lens industry). See supra note 89.
77. Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, 21 C.F.R. §§ 800, 801, 808, 874 (2022).; see Rohima Badri, OTC Hearing Aids: The Good, the Bad, and the Ugly, HEARING HEALTH FOUNDATION (Oct. 6, 2022), https://tinyurl.com/2vzj84x.
78. See Esther Landhuis, Why Aren't More People Buying Over-TheCounter Hearing Aids? UNDARK MAGAZINE (Dec. 27, 2023), https://tinyurl.com/2rav29ub. Hearing Loss, MAYO CLINIC (Mar. 30, 3023), https://tinyurl.com/326am8wn; Id. Unilateral hearing loss is when one ear is affected; bilateral means both ears are affected. Types, Causes, and Treatments, HEARING LOSS ASS'N AMERICA, https://tinyurl.com/3w4r5eu9 (last visited Nov. 24, 2024).
79. See Rohima Badri, OTC Hearing Aids: The Good, the Bad, and the Ugly, HEARING HEALTH FOUNDATION (Oct. 6, 2022),
80. https://tinyurl.com/2vzj84x; Over-the-Counter (OTC) Hearing Devices, YALE MED., https://tinyurl.com/mtjhkmxr (last visited Oct. 31, 2024).
81. Over-the-Counter Hearing Aids (OTCs) 1 Year Later, AM. SPEECHLANGUAGE-HEARING ASS'N (Sep. 12, 2023), https://tinyurl.com/3cj2554z.
82. See Badri, supra note 96.
83. See Hearing Loss, MAYO CLINIC (Mar. 30, 3023), https://tinyurl.com/326am8wn; Badri, supra note 96; Over-the-Counter Hearing Aids (OTCs) 1 Year Later, supra note 97.
84. See discussion, infra II.C.1.
85. See U.S. Hearing Aids Market Size & Trends, GRAND VIEW RSCH., https://tinyurl.com/3areppcw (last visited Feb. 2, 2025); Ga-Young Kim & Il Joon Moon, Changes in the Hearing Aid Market Due to Over-the-Counter
86. Kim & Moon, supra note 101 at 200.
87. See Rohima Badri, OTC Hearing Aids: The Good, the Bad, and the Ugly, HEARING HEALTH FOUNDATION (Oct. 6, 2022), https://tinyurl.com/2vzj84x; U.S. GEN. ACCT. OFF., GAO-24-106854, OVER-
88. THE-COUNTER HEARING AIDS: INFORMATION ON THE NEW MEDICAL DEVICE CATEGORY 8 (2024) https://tinyurl.com/5wvbb77x
89. See FTC Settlement Turns Down the Volume on Deceptive Sound Amplifier Ads, FEDERAL TRADE COMM'N (May 2, 2018), https://tinyurl.com/jaynmnhz; Donya Currie, How to Avoid Over-the-Counter Hearing Aid Scams in 2025, NAT'L COUNCIL ON AGING (Sept. 19, 2024) https://tinyurl.com/3k8p5tpd.
90. Badri, supra note 102. In her piece, Badri provides:
91. See Ga-Young Kim & Il Joon Moon, Changes in the Hearing Aid Market Due to Over-the-Counter Hearing Aids, 16 NAT'L CTR. BIOTECHNOLOGY INFO. 199, 199–200 (Aug. 18, 2023), https://tinyurl.com/mpn4xrcn.
92. Juliana Kim, FDA Approves Some Apple Airpods to be Used as Hearing Aids, NPR (Sept. 14, 2024, 12:59 PM) https://tinyurl.com/yc3t26y8.
93. See Jaipreet Virdi, The FDA's New Hearing Aid Won't Solve the
94. Bigger Problems in the Market, WASHINGTON POST (Aug. 25, 2022, 6:00 AM), https://tinyurl.com/yvpkm2kr; Rohima Badri, OTC Hearing Aids: The Good, the Bad, and the Ugly, HEARING HEALTH FOUNDATION (Oct. 6, 2022), https://tinyurl.com/2vzj84x.
95. See Katherine N. Menon et al., Over-the-Counter Hearing Aids Challenge the Core Values of Traditional Audiology, NAT'L CTR. BIOTECHNOLOGY INFO. 657–58, 666 (Feb. 8, 2024), https://tinyurl.com/mv3j4mfb; U.S. FOOD & DRUG ADMIN., REGULATORY
96. IMPACT ANALYSIS FOR MEDICAL DEVICES; EAR, NOSE, AND THROAT DEVICES;
97. ESTABLISHING OVER-THE-COUNTER HEARING AIDS; FINAL RULE, Docket No. FDA-2021-N-0555 (Aug. 17, 2022) (noting potential economic impacts, including market shifts and profitability considerations for manufacturers entering this newly deregulated space).
98. See generally Andrew Kolodny, How FDA Failures

Contributed to the Opioid Crisis, AMA J. ETHICS (Aug. 2020), https://tinyurl.com/msrkrmtz (discussing how companies engaged in aggressive marketing tactics and misleading claims.); In re Nat'l Prescription Opiate Litig., 458 F. Supp. 3d 665 (N.D. Ohio 2020) (demonstrating how corporate-driven commercialization can negatively impact public health).

99. See generally S. COMM. ON FINANCE, DECEPTIVE MARKETING PRICES FLOURISH IN MEDICARE ADVANTAGE (2022), available at https://tinyurl.com/4kb4x7dd (offering insight into how aggressive marketing and profit-driven priorities in a healthcare sector can undermine genuine consumer welfare); In re Nat'l Prescription Opiate Litig., 458 F. Supp. 3d 665 (N.D. Ohio 2020). See supra note 105.
100. See generally Health Insurance Coverage and Access to Care, U.S. DEP'T HEALTH & HUM. SERV.'S, https://tinyurl.com/2dh8rxkd (last visited Feb. 2, 2025); AGENCY FOR HEALTHCARE RSCH. & QUALITY (AHRQ), 2021 National
101. Healthcare Quality and Disparities Report (Dec. 2021), https://tinyurl.com/3fy85try; NICOLE HUBERFELD ET AL., THE LAW OF A117. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified at 42 U.S.C. § 18001 et seq.).
102. MERICAN HEALTH CARE (3rd ed. 2023). 132. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified at 42 U.S.C. § 18001 et seq.); Jennifer Sullivan et al., Entering Their Second Decade, Affordable Care Act Coverage
103. Expansions Have Helped Millions, Provide the Basis for Further Progress,CTR. ON BUDGET & POLICY PRIORITIES 1–2 (Mar. 25, 2024), https://tinyurl.com/5n8xvt54.
104. U.S.C. § 18022 (2023); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified at 42 U.S.C. § 18001 et seq.).
105. H.R. 500, 119th Cong. (2025).
106. Social Security Act, Title XVIII, 42 U.S.C. §§ 1395 et seq. (2018); H.R. 500, 119th Cong. (2025); Kathleen E. Bainbridge & Virginia
107. Ramachandran, Hearing Aid Use among Older United States Adults: TheNational Health and Nutrition Examination Survey, 2005–2006 and 2009–2010, NAT'L CTR. BIOTECHNOLOGY INFO. 6, 8 (May 2014), https://tinyurl.com/4mcswb6c. integrated, comprehensive hearing healthcare system that meets the needs of all Americans.