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Over-the-Counter Hearing Aids in the United States: A Public Health Perspective after 4 Years

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Readers of CanadianAudiologist.ca likely know that hearing loss has important consequences for health. It is common, and becomes more common with age, impacting two-thirds of adults in the United States (US) over 70 years and more than 90% in those over 85 years. Over the past 15-20 years, public health studies have consistently linked age-related hearing loss to cognitive decline, dementia, social isolation, falls, and health care utilization, among other outcomes important for aging. The 2024 Lancet Commission on dementia prevention attributes 7% of global dementia cases to hearing loss (assuming that hearing loss causes dementia, which we acknowledge is something that is still unknown). However, even if hearing care does not impact outcomes such as cognitive decline and dementia, we know that hearing loss treatment improves communication and quality of life. Recent evidence from the ACHIEVE randomized controlled trial in the US (c.f., Reed et al, 2025) also suggests it reduces declines in social isolation and loneliness over time. Unfortunately, hearing aid use, the primary treatment recommendation for the majority of hearing loss, remains low. Estimates vary, but fewer than 20–30% of US adults with hearing loss use hearing aids, and use is even lower among those with mild loss. Notably, hearing aid use differs markedly by structural and psychosocial factors, including education and income. Taken together, hearing loss is a public health problem, and over-the-counter (OTC) hearing aids were meant to help address it. Now, four years after the implementation of the Over-the-Counter Hearing Aid Act in the US, we review where we are and where we might go next.

The Case for Over-the-Counter Hearing Aids

Reports from the President's Council of Advisors on Science and Technology (2015) and the National Academies of Sciences, Engineering, and Medicine (2016) identified several barriers to hearing care in the US, including high device costs (e.g., an average of roughly $4,700 for a pair), tough-to-access service models with bundling of devices with clinical services, relatively poor

awareness of consequences of hearing loss, and a highly concentrated market in which five manufacturers accounted for more than 95% of global sales. In response, OTC hearing aids were proposed as a market-shaping solution, rather than a subsidy, to close the gap in access and affordability and increase uptake. The hope was that OTC hearing aids would first increase competition and lower prices by allowing new companies into the marketplace. Second, to broaden the offering of devices to meet the needs of different populations. Hearing aid technology has largely advanced vertically, whereby each new generation adds more features (e.g., more channels, better noise reduction, faster processing) at the premium end of the market. OTC hearing aids offer the potential for horizontal advances, meaning different form factors, price points, delivery methods, and even using older technology to meet the needs of people the traditional market was not reaching. Third, engage consumer electronics companies to care more about hearing loss and improve public awareness (e.g., more advertising and visibility of hearing technology).

Inherently, OTC hearing aids align with many public health values and core concepts. The market-shaping approach focuses on the population rather than the individual patient, lowers structural barriers to care, and could encourage earlier intervention among adults with mild hearing loss, who make up the majority of those with hearing loss. Equity was also a key part of the argument, and data on trends in hearing aid use make the point clearly. In nationally representative data from the National Health and Aging Trends Study, hearing aid use among older adults increased from 15.0% in 2011 to 18.5% in 2018. However, among those living below the poverty level, hearing aid use actually decreased over the same period (12.4% to 10.8%), while use increased among those at 200% of the poverty level or above (16.4% to 21.2%). An update through 2022 found a similar pattern: a 54% increase in hearing aid use among higher-income older adults in metropolitan areas, compared with a 7% increase among low-income older adults in metropolitan areas and a 15% decrease among low-income older adults in nonmetropolitan areas, where hearing loss is more common. Overall growth in hearing aid use masked a widening income gap, and lower-cost devices available outside the clinic were seen as one way to reach those being left behind.

The concept wasn’t new. Mead Killion argued for affordable, “one-size-fits-most” hearing aids for years and formally petitioned the US Food and Drug Administration (FDA) in 2003 to create an OTC hearing aid classification. However, adjusting devices to an individual’s hearing still required a dispensing model, as fitting relied on an audiometer, fitting software, and ideally, real-ear verification. By the late 2010s, technological advances made the concept more feasible. For example, in-situ fitting via smartphone apps allowed test tones to be presented through the hearing aid itself while in the ear, which accounts for some of the acoustic properties of the individual’s ear canal. The FDA authorized the first self-fitting hearing aid in 2018, and a later randomized trial reported that outcomes with a self-fitting OTC hearing aid were comparable to an audiologist-fitted hearing aid among adults with mild to moderate hearing loss.

The Over-the-Counter Hearing Aid Act and FDA Regulation

The Over-the-Counter Hearing Aid Act of 2017 (S. 670 and H.R. 1652, 115th Congress), led by Senators Elizabeth Warren and Chuck Grassley, passed as a rider on the FDA Reauthorization Act of 2017 (H.R. 2430, Section 709; Public Law 115-52). The law directed the FDA to create a regulatory category of OTC hearing aids for adults with perceived mild to moderate hearing loss by 2020. The regulations were delayed, and following a 2021 White House executive order, the FDA released its final rule in August 2022. By October 17, 2022, OTC hearing aids were available

for sale to adults 18 years and older.

The technical specifications were relatively broad. The rule limits maximum output to 111 dB SPL (or 117 dB SPL with input-controlled compression and a user-adjustable volume control), requires that no part of the device sit closer than 10 mm to the eardrum, and sets labeling and basic electroacoustic requirements (e.g., distortion, latency, and self-generated noise). Notably, there is no gain limit. Most OTC hearing aids fall under classifications that are exempt from the 510(k) premarket notification process. A 510(k) is a submission in which a manufacturer demonstrates to the FDA that a new device is substantially equivalent to a device already legally on the market. Being 510(k) exempt essentially means a manufacturer registers the device with the FDA and attests that it meets the requirements. In Canada a Class II Medical License is required from Health Canada but no supporting data is required unless requested by federal authorities. This drastically lowers the bar for entry, and enforcement is difficult for the FDA (and Health Canada) because it requires reporting from others, action from legal systems, and resource-intensive market surveillance. However, a non-exempt category exists for devices labeled as “self-fitting,” which require 510(k) clearance and must meet special controls, including clinical validation of the self-fitting approach (e.g., a full clinical trial showing that self-fitting is as good as a professional fit). This means a consumer could pick up two “OTC hearing aids” backed by very different levels of evidence and have no way of knowing it.

What Has Happened Since?

Four years in, we don’t have much high-quality evidence on OTC hearing aid uptake, and much of what we do have comes from industry surveys. However, none of the available data suggests a revolution in hearing aid uptake that the introduction of OTCs was meant to start. In the 2025 MarkeTrak survey, a major, nationally representative study run by the Hearing Industries Association since 1988, OTC hearing aids made up a small share of hearing aid ownership among adults with self-reported hearing difficulty, smaller than the share using earbuds with hearing features. There are some encouraging signs (e.g., roughly 70% of OTC buyers were first-time hearing aid owners, and the FDA authorized hearing aid software for Apple and Samsung earbuds in 2024 and 2026, respectively). At the same time, several companies, including Sony, Sennheiser, and Jabra, have left the market, and in July 2026, LXE Hearing, the parent company of early OTC brands Eargo and Lexie, announced it was winding down its US operations.

Consumers also seem confused, both about device quality and about what FDA status actually means. A 2026 study of 138 OTC hearing aid listings on Amazon found that two-thirds were marketed as “OTC hearing aids,” but only about one in four could be verified as FDA registered or cleared. Notably, verified devices cost an average of roughly $700 compared with less than $200 for unverified devices. Some listings were marketed to adults with severe hearing loss, outside the target consumer population for OTC hearing aids, and product descriptions were written at a college reading level. In 2025, the Nevada Attorney General even issued a consumer warning about sellers posting official-looking “FDA Registration Certificates” alongside their products.

For consumers, it’s alphabet soup (e.g., OTC, PSAP, self-fitting, preset, FDA registered, FDA cleared). And in Canada, health care is delivered provincially so these devices may be labelled differently from region to region. In many ways, it’s like how chicken is labeled at the grocery store. Most consumers don’t know what terms like “free range” or “no hormones added” actually mean. For example, “no hormones added” applies to all chicken sold in the US, as federal rules don’t allow hormones in poultry. “FDA registered” on a hearing aid box is much the same; it tells a

consumer very little about whether the device is any good.

Is Consumer Education or Insurance Coverage the Answer?

Others have argued that consumer education, portable audiograms, paid consultations with hearing care professionals, and health insurance coverage of OTC hearing aids are necessary to realize their benefits. While reasonable and potentially helpful to some, these concepts somewhat defeat the purpose of a robust OTC market. OTC hearing aids were intended to be simple enough to purchase without professional help and affordable enough that insurance coverage wouldn't be needed. If consumers need professional education to select a device, we have largely recreated the dispensing model, but with fewer protections for the consumer. Likewise, if insurance coverage requires a prescription or a preferred vendor, we have recreated the prescription pathway under a different name.

Was the Regulation the Problem?

Education and coverage may help with some of the downstream problems, but they don't address why the market is confusing to begin with. Instead, one might argue that the regulation itself was the problem. The low bar for entry (e.g., 510(k) exemption and minimal technical specifications) made it relatively quick and inexpensive to register an OTC hearing aid. Within about a year of the final rule, the FDA registration database included well over a hundred hearing aid listings from over fifty manufacturers, many of them startups, and that doesn't include the many unregistered products marketed as hearing aids online. Some good products are on the market. However, the low bar left the market open to many players with products that aren't, which created consumer confusion.

This regulatory scheme runs counter to basic consumer protection principles. In a dispensing model, the consumer is protected by the dispenser, whose license and reputation are on the line with each device provided. In an OTC model, the dispenser is removed, and the consumer's protection must instead rely on higher regulatory standards for the device itself. In the US, we removed the dispenser and set a relatively low bar for the device. In some sense, the 510(k) exemption created a behavioral nudge towards a worse market, as the easiest path for a new company is the exempt category rather than the more costly self-fitting pathway that requires clinical trial evidence. When consumers can't easily distinguish high- and low-quality devices, good products end up competing on price with poor ones, what Akerlof (an Economist at Georgetown University) famously called a "market for lemons." We can't prove this is what happened, but the exit of several well-regarded brands fits the pattern.

A better alternative would be a market with five or six large companies offering clinically validated OTC products, strong customer support, and a clear pathway to prescription hearing care as a patient's hearing needs change. While a higher bar for entry would reduce the number of competitors, competition among a smaller number of high-quality products may serve consumers better than competition among hundreds of products of unknown quality and, therefore, result in a robust OTC hearing aid market that protects consumers.

Impact on Consumers Who Need Hearing Care

We worry about people who are confused by the market, buy a device that doesn't meet their needs, and then never purchase hearing aids again because they feel they wasted their money.

Adults already wait an average of about four years from noticing hearing difficulty to obtaining hearing aids. A poor first experience with a device that whistles, sounds tinny or hollow, overamplifies low-frequencies, and doesn't help in noisy places could convince someone that hearing aids don't work. We have little data on how often this occurs, but from a public health perspective, it could push people further from hearing care, and could prevent some from seeking care again. Importantly, this risk is unlikely to be distributed evenly as the consumer most likely to choose a $150 device over a $700 device or $4700 prescription hearing aids, is likely the person for whom cost is the deciding factor. For that person, losing that money matters, and they may not be able to afford a second try or have an audiologist nearby, let alone the means to see one. Ironically, low-income older adults, whom OTC hearing aids were partly meant to help, may be most likely to end up with the worst products on the market.

Where Do We Go From Here?

It is still early, and the evidence is limited. Yet, several directions are worth considering for the future. First, other countries, including Canada, that are weighing their own OTC pathways could set a higher regulatory bar from the start. If the professional is removed from the purchase, standards for the device should increase to compensate (e.g., premarket review and clinical validation for all devices sold as hearing aids, not just those labeled as self-fitting, along with clear, standardized labeling). This means considering consumer protection when setting technical and use standards for products to meet an OTC definition. Second, consumers would benefit from education provided by trusted third parties without a product to sell, such as professional societies or hearing loss advocacy organizations. For example, a simple, publicly available list of devices that meet a meaningful quality standard would give consumers somewhere to check before they buy. Similarly, under this umbrella, third parties need to help consumers understand hearing well enough to know when to seek change. This may mean promoting campaigns that shift how we talk about hearing loss from all-encompassing phrases like 'hearing loss' or 'mild/moderate hearing loss' to numeric metrics or more detailed descriptions that matter to consumers. Third, and perhaps the hardest to achieve, the US could revisit the regulation itself, for example by requiring clinical evidence for all OTC hearing aids. Working with online retailers to pull listings that misrepresent FDA status, or that market OTC devices to people with severe hearing loss, would also help.

OTC hearing aids were built on sound public health principles, and they remain an important part of the hearing care market. However, the first four years suggest that increasing access to devices does not automatically translate into better hearing care for a larger number of adults. Consumer protection, particularly for those with the fewest resources, should be the focus moving forward. Consumers need regulations that give them confidence that the device they purchase will actually help them hear better and, keep them connected to hearing care as their needs change.

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