

# One Year Into the OTC Era

## Opinions and Opportunities



**I**t's been roughly a year since the U.S. Food and Drug Administration (FDA) issued a final rule to expand access to hearing aids via over-the-counter sales. The FDA's official press release<sup>1</sup> framed the change as a way to "improve access to hearing aids which may in turn lower costs for millions of Americans."

Aimed at mild to moderate hearing impairment, the rule allows consumers to purchase hearing aids directly from stores or online retailers without the need for a medical exam, prescription, or fitting adjustment from a hearing care professional (HCP). For those who opposed the FDA's move, the battle is over but the war to make it succeed (financially and clinically) continues.

Opportunities and opinions abound, with many

industry experts looking to the future—mostly because the OTC era is still in its infancy and its effects have been limited—at least for now. "It's early," says Brian Taylor, AuD, senior director of Audiology at Signia, a New Jersey-based hearing aid manufacturer. "I've read that about 1% of total hearing aid sales are OTC, so it's been slow to ramp up. At this point, there is no evidence that they [audiologists] have lost market share."

Taylor's estimate of OTC hearing aid sales was borne out by recent national polling commissioned by the American Speech-Language-Hearing Association (ASHA)<sup>2</sup> which confirmed that OTC devices have yet to catch on with the public. ASHA revealed that "only 2% of American adults ages 40 and older who have hearing difficulties reported that they have purchased them,

and only 4% reported that they are likely to purchase OTCs in the next year.” Findings from the ASHA poll of 2,228 U.S. adults ages 40 and older were released on Sept. 12, 2023.

Less than half of poll respondents knew the difference between sound amplifiers and hearing aids. Worse yet, many respondents clung to the debunked analogy between reading glasses and hearing aids.

“Advertisements about OTCs fail to prominently mention whom they are exclusively for, and these ads falsely equate drugstore off-the-rack reading glasses with the devices,” wrote ASHA researchers in a survey summary. “It is not simply a matter of increasing the volume of sound. What is concerning about these findings is that nearly half of respondents with hearing difficulties equated reading glasses with OTCs—and more than half of that group didn’t realize that hearing can be damaged if an OTC is over-amplified.”

In cases where OTC advertisements raise awareness, it has often led to more traffic in the clinic. “At least initially, OTC advertisements have done us a lot of good,” says Salvatore Gruttadauria, AuD, CEO of Diversified Rehabilitation Services, Buffalo, NY. “Our clinics have never been busier, and a lot of them are self-referrals. A lot of this is because of the OTC advertisements. It has made people more aware of hearing loss. People are able to get in front of us and see that there are various options and that the whole field of hearing aids is more complex than putting on an amplifier and sticking it in an ear.”

Gruttadauria admits that there’s no way to know how many people are bypassing the clinic and going straight to the drug store. However, he notes that,

“Out of the offices that we have, I know of only one time where somebody made an appointment and then canceled it saying that they were going to try OTC products first.”

According to Taylor, recent data suggests that typical OTC buyers are five to 15 years younger than the average age of first-time prescriptive hearing aid buyers. That younger (50 to 65) OTC demographic usually contains what Taylor describes as people more interested in the DIY ethos, as well as those who crave “a more convenient buying process with fewer in-person appointments with an audiologist.”

With the knowledge that OTC-leaning buyers tend to skew on the younger side, hearing care professionals can tailor their marketing efforts and target the demographic. “Market to middle-aged adults who are still actively working,” Taylor suggests. “Market to people who have a strong DIY desire and to those who need situational help in noisy social and workplace situations.”

Matt Lang, director of program management at ReSound, a hearing aid manufacturer in Bloomington, MN, agrees with Taylor’s assessment and states: “OTC has accomplished something that the industry has not been able to previously solve, and that is getting patients to consider and accept solutions at a younger age. Part of the reason this is happening is due to the discreet way of accessing support, which is typically through a virtual education and shopping experience—and the self-support of the products through the use of apps.”

That said, Lang contends that the majority of prospective hearing aid users are still choosing to find







a professional for a consultation. “We don’t believe that will change significantly in the coming years,” he says, “but there will potentially be a shift toward a hybrid model utilizing the capabilities of tele-audiology, as well as in-person support.”

Gyl Kasewurm, AuD, believes that tech-savvy baby boomers, perhaps hoping to save money, are more likely to pursue the OTC market. “By contrast, people who have worn aids before are more likely to go straight to audiologists,” adds Kasewurm, owner of Dr. Kasewurm Professional Hearing Services, St. Joseph, MI. “People who have more severe hearing loss, as well as people who value and want ‘the best’ in healthcare, are also more likely to visit an audiologist.”

Meghan Abraham, AuD, agrees with Kasewurm that most OTC consumers are likely looking for a lower price, and they are probably experiencing hearing challenges for the first time. “The OTC buyer may have known someone who sought professional treatment and invested thousands of dollars in the process,” says Abraham, who practices at the Audiology Group in Fort Collins, CO. “These individuals may be leery about hearing devices due to friends’ negative or less-than-ideal experiences. I also believe they don’t understand the depths of what hearing healthcare providers do from a care standpoint.”

Ubiquitous online reviews are already starting to pile up, and the cumulative effects of negative OTC reviews may sway prospective patients to avoid OTC

products and seek care from experienced hearing care professionals. “When taking a quick look at Google ratings for OTC hearing aids at the local big box store, there are a lot of complaints about reliability and, ultimately, reports of returning products,” Abraham reveals. “The sustainability of the OTC business model must be questioned because shelf space in these stores is valuable, and the profit margins for products are generally low.

“Returns and time spent by retail employees attending to these situations will likely reduce the OTC market share in the retail sector,” Abraham continues. “With online sales, returns as well as return shipping costs due to dissatisfaction and potentially device malfunction—that we might otherwise easily manage in-office—also cost investors.”

Younger consumers pay attention to bad reviews online, often scouring Google and Amazon to tally influential star-based ratings. Regardless of age, all clients eventually want results. When discomfort, unreliability, and poor hearing form a predictable trifecta of annoyance, people of any age will seek out experts. “Many clinics see some patients who buy OTC elsewhere,” confirms Taylor, “and they need help or service from audiologists.”

### Reducing the Stigma?

Many industry watchers agree that younger individuals are starting their hearing health journeys

earlier, demonstrating a proactive approach and a diminished stigma, possibly due to the widespread acceptance of earbuds. A recent article on Axios.com proclaimed, “Consumer electronics giants like Sony and Bose have staked out a piece of the new market for OTC hearing aids, disrupting a \$10 billion segment that’s been dominated by niche audiology companies.”<sup>3</sup>

Recent ASHA data suggests that the Axios proclamation may be exaggerated, or at least premature. A report compiled by officials at Lucid Hearing, a Fort Worth, Texas-based hearing aid manufacturer, noted, “With technological advances now available, like Bluetooth capability, as well as discreet designs, hearing aids are gaining a ‘hipper reputation’ as OTC lifestyle products and attracting a younger crowd—people in their 30s and 40s.”

One audiologist quoted in the *Wall Street Journal* article “Wait, Are Hearing Aids Cool Now?”<sup>4</sup> remarked, “Members of older generations might feel hearing aids carry stigma, but young Americans routinely use technology to better their health. They can view the new hearing aids as complements to their fitness trackers, their smart scales, and other gadgets—or even as replacements.”

The idea that OTC customers will not be satisfied with the devices, and eventually need (and want) the specialized services of audiologists, is a common refrain. The sentiment has backing with anecdotes and research. Kasewurm points out: “The Humes study showed that for benefit to be optimized, a professional needs to be involved in the process.”

The six-year-old randomized double-blind, placebo-controlled clinical trial referenced by Kasewurm is titled, *A comparison of audiology best-practice services versus an OTC delivery model* (authors: Larry E. Humes, PhD; Christine Herring; Dana L. Kinney, MA; Anna K. Main, AuD; Tera M. Quigley, AuD; and Sara E. Rogers, AuD). In a summary<sup>5</sup> published in *The Hearing Review*, authors demonstrated better outcomes through audiology best practices via several markers.

Kasewurm was not surprised, and six years after the study and one year after the OTC rule, she believes the results are still relevant. “I do not believe that OTCs will negatively affect business,” she says, “because consumers won’t achieve the desired benefits via OTC.”

### Expanding Opportunity?

Stacy O’Brien, AuD, owner of Florida-based Atlantic Hearing Balance and Tinnitus Center, compares the OTC era to a “revolution that promises to make hearing solutions accessible and affordable for all.” But she quickly adds, “As with any revolution, there are casualties, unintended consequences, and a myriad of complexities that often get swept under the rug in the rush for progress.”

Under the casualties and unintended consequences umbrella, hearing care professionals are raising questions about the quality of care and the potential for misuse of OTC devices. However, the concern does not end with HCPs. “Almost every state’s attorney general has issued consumer alerts warning about the potential concerns with purchasing an OTC product,”



says O'Brien. "Florida just reminded its residents with another warning on August 24, 2023 (CONSUMER ALERT: Attorney General Moody Warns About Purchasing Over-The-Counter Hearing Aids)."<sup>6</sup>

The warning is explicit in its clarity, with Attorney General Ashley Moody bluntly stating: "Personal sound amplification products are not alternatives to hearing aids. Personal sound amplification products have different intended uses than hearing aids. Hearing aids are intended to make up for impaired hearing. Personal sound amplification products are intended for people with normal hearing to amplify sounds in certain situations, such as recreational activities like birdwatching or hunting. Personal sound amplification products are regulated as consumer electronics and not medical devices. They may be more variable in terms of product quality compared to hearing aids."

Accurately tracking the effects (and clarity) of OTC marketing is a dicey prospect, but manufacturers such as ReSound tend to be keyed in, with representatives around the country able to get a sense of what's going on.

"Anecdotally we're hearing that there are more conversations about hearing loss from patients due to the OTC legislation and subsequent introductions of OTC products," says Matt Lang at ReSound. "As these OTC manufacturers enter the market, they do so with a healthy advertising budget. Hearing loss solutions are now entering communication channels much more frequently and with different approaches, versus the standard ways this industry has been going to market."

As has long been the case with various types of home medical equipment, officials at Lucid Hearing point out that caregivers are stepping in to purchase hearing aids for their parents and spouses now that hearing tests are not mandatory for OTC purchases. The awareness boost brought about by the entrance of OTC into the hearing aid category has resulted in increased attention by consumers about their hearing health, which also appears to have brought about a surge in hearing aid purchases overall.

According to data generated by the Hearing Industries Association (HIA), 2023 first-quarter hearing aid sales saw a better-than-anticipated increase, with a 9% increase in sales over the same period in the previous year.<sup>7</sup> Prescription hearing aids made up 8% of the increase, while OTC made up 1%.

Down in the Sunshine State with its sizable retiree population, O'Brien has seen the HIA numbers come to life within her seven locations. "While some clinics feared a downturn in business, many report stable or even increased patient numbers," she says. "My clinics in Florida are experiencing new growth every year and we have been able to help more people year-to-date in 2023 than we ever have. The heightened awareness around hearing loss seems to have made the topic more discussable, possibly encouraging more people to seek professional help."

While the 1% OTC number remains steady for now, some manufacturers are betting that it won't stay that way. An article<sup>8</sup> in *The Hearing Review* details efforts by manufacturers, including Lucid Hearing, to embrace the opportunity offered by OTC hearing aids.

"Lucid Hearing began preparing for the possibility of the category launch years ago," the author writes. "That preparation included a robust study of 14 years' worth of audiograms that informed the development of the company's OTC product line."

"We wanted to ensure we were ready and able to offer consumers OTC devices that met our standards of quality at affordable prices," said Tim Schnell, Lucid Hearing's founder and CEO, via *The Hearing Review*. "Our research team worked in conjunction with the University of Texas at Dallas' audiology program to develop pre-set programs that meet the vast majority of consumers' mild to moderate hearing loss needs."

Signia's Taylor also puts a positive spin on the OTC phenomenon, suggesting creative ways to capitalize on it. "OTC is attracting people who have rejected the traditional model of care," Taylor says. "The presence of OTC is an opportunity to offer some unbundled professional services to people who bought OTC elsewhere. Also, some clinics are stocking OTCs to attract a different market segment to their practice. They want to make their counter an OTC counter... Ultimately, OTC is more likely expanding the market."

## The Audiology Difference

As the regulatory and clinical affairs liaison at Intricon Corporation, David Akbari, AuD, has a simple bit of advice for hearing care professionals: Work with the OTC customers who walk in the door. If patients make it that far, they are looking for something more—something better.

"We are doctors," Akbari says. "We go through a lot of school and we have a lot of practical experience. I treat hearing aids sometimes like a black box. You don't necessarily know what the person was thinking when they programmed it, but you can measure it. You can put it in your Real Ear system and see what it's doing for the consumer."

Differentiators are numerous, such as adhering to best practice guidelines using Real Ear verification and using aural rehab and outcome measure questionnaire assessments to tie it together. "Use your synthesis techniques and capabilities as doctors," Akbari adds, "which differentiate us from other credentialed providers."

In the opinion of Salvatore Gruttadauria, communicating the value of audiology in a post-OTC world should not only include what audiologists add, but also what OTC transactions miss.

"There have been many times in my career that we have diagnosed and alerted physicians to the possibility of something like an acoustic neuroma or an acoustic tumor along the auditory pathway,"



Gruttadauria says. “Those are the types of things that are going to be missed, or their diagnosis is going to be very delayed because patients are trying an over-the-counter hearing aid before going to an audiologist.”

O’Brien contends that HCPs can reclaim any potential lost market share by emphasizing their unique value propositions: comprehensive diagnostic tests, personalized treatment plans, and post-purchase support. “Educational outreach can also play a significant role in attracting those who initially consider OTC options,” she says. “Staying abreast of changes, and being prepared to adapt our practices accordingly, can help us maintain our desired market share.”

One of many intangibles in any one-year assessment of the OTC landscape is the overall level of concern. For HCPs who tend to worry, C. Scot Frink, AuD, has some advice. “It’s much ado about nothing,” says Frink, a private practice audiologist at Salem Audiology Clinic, Salem, OR. “Certain types of OTC hearing products have existed for decades, and they really have not had that much effect on the market. What I see coming into my office isn’t too much different than what I saw in the past. I personally don’t think that OTC devices can beat what we have...so at this point OTC is not an issue at all.”

Frink illustrates the point with the real-world example of a recent patient who came to his Salem office with a set of well-known brand of OTC hearing aids purchased online. The patient had normal hearing in the low frequencies and moderate high frequency loss. “He was overwhelmed with those power domes on the OTC device,” Frink explains. “The gain was next to nothing, and he felt that they did not even help him. I did Real Ear testing on him, and it actually showed he had net insertion loss, meaning that the hearing aids were plugging his ears more than they were actually helping him.”

Frink put a set of stock devices on the patient, ran the test with the manufacturer software, and “nailed” the Real Ear target. “The patient said, ‘Wow, I can really hear better with these, but I probably can’t afford them.’” Frink patiently explained the services, follow-up, and troubleshooting. By the time they factored in the OTCs’ cost (not to mention time wasted on an ineffective product), the patient was grateful for the expertise and readily purchased the hearing aids—and the all-important audiologist guidance.

Whatever happens in the next five to 10 years, manufacturers and hearing care professionals seem ready to pivot if necessary. On the manufacturer side, Matt Lang at ReSound predicts that the environment will be “noisy” with new patients entering the market at a younger age and new products introduced. “After the initial dust settles, we think everyone will be able to win in the sense that patient preferences will have been identified,” Lang muses. “From there, we can adjust to those preferences with solutions and support.”

Audiologist and consultant Gyl Kesewurm bases her optimism on demand and an enduring value proposition that the profession has consistently maintained. “I’m as positive and optimistic about audiology as I was when I entered the field many years ago,” she says. “People are acquiring hearing loss at younger ages and living longer. I can’t foresee any shortage of people with hearing loss in the near or distant future. In fact, everything I have read indicates that we need more hearing healthcare professionals to handle the number of patients who need and *want* our services.”

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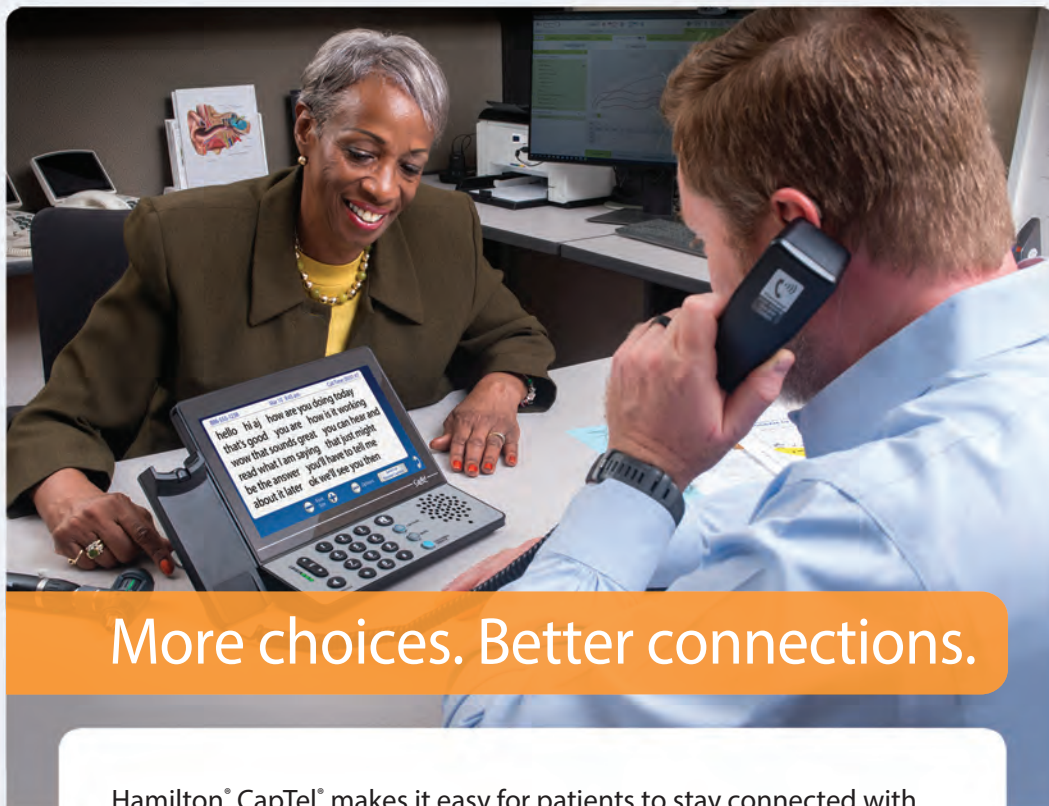
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