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The New FDA Rules for OTC Hearing Aids: What Do They Mean for People with Hearing Loss?

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Editor's Note:

Over the Counter (OTC) have recently become a reality in the United States. Personal amplifiers that could be used as, or in place of, hearing aids have been around almost as long as hearing aids themselves. But in the United States, a series of federal (and in some cases state level) regulations have prevented them from being marketed as hearing aids for people with hearing loss. No such regulations have ever existed in Canada. Up until recently (and for almost a decade), Personal Sound Amplification Products (PSAPs) were allowed in the United States which are sound amplifiers "not" intended for the hard of hearing, but of course, in actual practice were used by many with hearing difficulties. As pointed out by engineer Steve Armstrong (Sounds Good Labs) at the recent Canadian Academy of Audiology conference in Niagara Fall, Ontario, it is not inconceivable that some of the products that were listed previously as PSAPs will be relabeled as OTC hearing aids, but this would require a prior 510(k) approval by the FDA which can be quite an onerous task. In practice, many of the existing hearing aid manufacturers will either create their own device for the OTC market or have an arrangement with other manufacturers such to market them as their own. In essence in Canada, nothing has changed.

One thing that is missing with OTC (and PSAP) products is the verification stage of the hearing aid fitting and this can make the difference between a successful experience or a negative one for our hard of hearing clients. Another is the audiological input and counselling. It may be that hearing aids (of any type) are not required at all. The OTC and PSAP model can potentially be an end-run around the audiologist, but audiologists

may choose to include these devices as part of their clinical programs, and this may have some long-term benefits.

Some manufacturers now offer their own version of a OTC hearing aid (either in-house or from a third party non-traditional hearing aid manufacturer) and other manufacturers have publicly stated that they will have nothing to do with OTC and PSAP hearing aids and will continue to support the professional audiology route solely.

Following is a thoughtful overview of these new American FDA regulations and OTC hearing aids from Karl Strom who has spent many years as the Editor of Hearing Review and now is with HearingTracker.

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The US Food and Drug Administration's rules for OTC hearing aids, announced on August 16, promise sweeping changes for hearing healthcare, creating a new class of more affordable and accessible hearing aids. Hearing aids within this category can be sold online and in stores directly to consumers who have perceived mild to moderate hearing loss without a medical exam or a fitting by a licensed provider.

Effective in mid-October, the new regulations are also designed to increase competition and innovation in the hearing industry, while ensuring the safety and effectiveness of both OTC and prescription hearing aids. Manufacturers have until mid-April 2023 to comply with the rules.

The FDA recently completed the monumental task of reviewing 1,100 public comments and publishing a 200-page rule on OTC hearing aids.

It took over 5 years for the FDA to propose and finalize the OTC hearing aid regulations after Congress and President Trump signed legislation to create them in August 2017. The delay was partly due to the COVID-19 pandemic, which was an "all-hands-on-deck" emergency for the FDA, and the complexity of the OTC regulations, particularly at the state and local levels.

The challenging road to create and finalize the OTC rules involved at least five governmental organizations and committees (FDA, FTC, NIH/NIDCD, PCAST, and NASEM), along with the divergent views of consumer groups, professional organizations, and the hearing aid and consumer electronics industries. Proposed rules for the new OTC classification were issued by the FDA in October 2021, and this generated more than 1,100 written comments—all of which the FDA was obligated to respond to (for more details, see the article and timeline "Over-the-Counter Hearing Aids").

The resulting rule splits air-conduction hearing aids into two groups: **OTC hearing aids** and the traditional **prescriptive hearing aids** we have today. Both are still considered to be either FDA Class I (the lowest risk category regulated by the Agency) or Class II (moderate-risk) regulated devices, with the latter usually reserved for hearing aids that feature wireless streaming and/or tinnitus solutions.

But what do the new rules really mean for consumers? How will things change? Reading the mainstream press, you see rosy predictions of low-cost innovations that will solve all your hearing problems, along with warnings about cheap low-quality devices that will bilk you of your hard-earned cash. This article takes a closer look at the actual FDA rules, while also explaining how they took shape and what they mean.

What has changed with the new FDA rules for OTC hearing aids?

A lot. Boiled down to basics, however, there are two major changes brought about by the new FDA

rules, and both have to do with how the Agency views the professional's role in dispensing hearing aids:

- You can now buy a device that belongs to this **new class of OTC self-fitting hearing aids** without going through a licensed audiologist or hearing aid specialist, and
- The FDA has taken ***all*** **hearing aids off its list of restricted devices**, a list reserved for products that can only be sold through state licensed practitioners or under certain conditions of sale. However, the reality is that state laws will still restrict the sale of prescriptive hearing aids to licensed hearing care professionals only. The removal of hearing aids from the restricted list also changes the governing of warranties and hearing aid returns (addressed later in this article).

Who will benefit from OTC hearing aids?

Adults (age 18+) with perceived mild-to-moderate hearing loss will see greatly expanded options in terms of safe, affordable, and convenient amplification. Working-age people younger than the typical first-time buyer of hearing aids (age 67), as well as those with financial restrictions, will also greatly benefit from improved access. Professionally fit hearing aids currently range from about $1500-6000 for a set of two. Judging from the current online PSAPs, a set of two decent-quality OTC hearing aids might range from about $300-$2000, with the higher costs largely dependent on product features like Bluetooth streaming, rechargeability, and online professional/technical service and support.

Previous studies have shown that OTC hearing aids are effective for people with milder levels of hearing loss. Research also suggests people are more likely to succeed if they have higher levels of cognitive performance so they can adapt to and self-manage the devices. Other favorable traits for successful use of OTC hearing aids include familiarity with smartphone apps and what is described as having a healthy "locus of control" (ie, individuals who believe they can influence events that occur in their lives).

Ultimately, all US citizens should benefit from OTC hearing aids. **Although hearing loss is a medical problem best treated by hearing care professionals,** OTC hearing aids should allow many more Americans to benefit earlier from amplification. Untreated hearing loss is one of the leading culprits in the epidemic of older persons experiencing social isolation and loneliness, which can lead to negative feelings about self-worth and depression. Hearing loss has been linked to cognitive impairment and dementia like Alzheimer's disease, and has even been shown to reorganize the processing centers of the brain. Researchers have linked untreated hearing loss to a variety of chronic health conditions. Any initiative that results in earlier identification and treatment of hearing loss should save lives and healthcare dollars.

Debby-downer alert! Unfortunately, the new OTC hearing aid regulations do not address some of the most urgent hearing healthcare needs in the United States: it does nothing for people with more severe hearing loss who are most in need of prescriptive hearing aids and must pay large out-of-pocket costs for them. It also does nothing to help children with hearing loss. So there is a lot more to accomplish in terms of improving access to hearing healthcare and hearing aids.

What will the new OTC hearing aids look and sound like?

The term "perceived mild to moderate hearing loss" is a rather vague term because not many

people have a good frame of reference for **how mild or severe** their hearing loss is. But as researcher Larry Humes has pointed out, “large-scale studies have identified self-reported hearing difficulties as one of the strongest predictors of hearing aid uptake and use.” Although people generally know when they have hearing loss, it can take them an average of 4-10 years to act on it. Let’s look at the likely physical and acoustic characteristics of OTC hearing aids:

Physical appearance

Most OTC hearing aids will closely resemble either current hearing aids or earbuds. In fact, the first two FDA-cleared “self-fit hearing aids”—the Bose SoundControl (now the Lexie B1) and the Jabra Enhance Plus—essentially look like receiver-in-the-canal (RIC) hearing aids and earbuds, respectively.

The Bose SoundControl hearing aids and the Jabra Enhance Plus earbuds were the first "self-fitting hearing aids" approved for use by the FDA. (Devices not shown to scale.)

Due to safety concerns, one slight physical difference is that the tip of the receiver (the part that generates the sound like a stereo receiver) of an OTC hearing aid can’t come closer than one centimeter from the eardrum. However, it’s difficult to see how FDA will police this since there is a wide range of ear canal lengths in both men and women.

Loudness limits

A major concern about OTC hearing aids is their potential to damage hearing by over-amplifying sounds for extended periods of time (eg, 12-16 hours/day) in daily use. Loudness limits in OTC hearing aids were the most hotly debated topic because they largely determine how many people can safely use these devices.

For better or worse, after initially following the consumer electronics industry’s recommendations on maximum sound levels, the FDA took a slightly more cautious road. The **FDA lowered the originally proposed maximum sound pressure level (SPL) from 120 dB to 117 dB** for those OTC hearing aids employing “input compression,” a type of circuit technology that can safeguard

your hearing by suppressing loud sounds before they are amplified. OTC hearing aids without this technology are limited to 111 dB SPL—down from 115 dB in the originally proposed rules. This 3-4 dB difference might not seem like much, but decibels are measured on a logarithmic scale, so the sound intensity doubles with about every 3 dB increase. The hearing industry and some hearing conservationists pointed to NIOSH data (used by OSHA) that indicates 120 dB SPL is just too loud to be considered safe. Additionally, at that sound level, certain types of OTC hearing aids could technically address "severe" hearing loss—a use for which they are not intended.

For added safety, the FDA also decided to **mandate a volume control (VC) for *all* OTC hearing aids**. With some advanced hearing aids, the volume is automatically adjusted by the hearing aid's programming. All OTC hearing aids will have a rocker-switch or wheel control to manually turn down the volume if desired (although some people with physical or mental impairments may not be able to use VCs).

Here is a HearingTracker video from an experienced hearing aid user in the UK who provides his perspectives on the Bose SoundControl self-fitting hearing aid. Closed captions are available on this video. If you are using a mobile phone, please enable captions clicking on the gear icon.

Will the new FDA rules ensure high-quality OTC hearing aid products?

OTC hearing aids must meet some basic electroacoustic standards (e.g., distortion and self-generated noise controls, latency, frequency response, etc.), but this does *not* necessarily ensure high quality or effectiveness. However, the standards should help.

Currently, there are less than a dozen **good online self-fit hearables** in the form of personal sound amplification products (PSAPs)—amplification devices not intended to compensate for a hearing loss but can do just that for people with milder losses. But, beyond these few PSAPs, **today's online amplification marketplace is a cesspool of rip-off products**. The FDA will continue to regulate all hearing aids as Class I and Class II devices and the new baseline standards and good manufacturing practices (GMPs) for OTC hearing aids should provide at least some quality assurances.

Additionally, **OTC hearing aids that rely on apps and/or computers during the self-fitting process are required to be premarket approved by the FDA**, which means the first product a company sells must be cleared through a fairly rigorous **510(k) application process**. Historically, this has weeded out sketchy companies. The downside, however, is it limits competition only to players who have the resources to apply for a 510(k). Simpler "wear-and-go" type hearing aids that don't rely on computers or apps for self-fitting do not need a 510(k).

Even with these quality standards, it's almost certain there will be lots of corner-cutting and substandard OTC hearing aids found online and on the shelf. Buyer beware!

A few examples of hearables include the Nuheara IQbuds2, the Apple AirPods Pro when using the transparency mode and personalized hearing functions, as well as numerous app-based headphones like those offered by Bose.

Will prescription hearing aid prices decrease due to competition from OTC hearing aids?

Probably not, although we could see continued downward price pressure on some (e.g., basic or essential level) prescription hearing aids. Average sales prices of hearing aids have been trending downward in the past decade, probably due to competition from Costco and other mass merchandisers. But it's the medical model of hearing care that is most responsible for the higher cost of hearing aids.

Hearing healthcare shares similarities with dentistry and optometry, where the products sold are not nearly as important as the professional who fits and customizes them to work well for the patient's individual needs. In hearing care, audiologists hold advanced academic degrees, while hearing aid specialists most often obtain their training through hybrid (in-person and online) education programs. Both usually must pass a licensing exam and they must maintain regular continuing education credits. Both use specialized and expensive audiological equipment for testing hearing and fitting hearing aids in private-practice or retail settings, and patients generally require 2-6 return office visits. Additionally, audiologists can also work for ENT clinics, hospitals, VA centers, and school districts and may specialize in cochlear implants, tinnitus treatment, vestibular (balance) rehab, and pediatric audiology.

All this requires substantial investments and fixed costs. On average, about one-half to two-

thirds of the cost of professionally dispensed hearing aids originates from professional services and related overhead. Unless OTC radically changes this "medical model" of care, it's unlikely prescription hearing aid prices will decrease substantially. In fact, a recent video by audiologist "Dr. Cliff" Olson makes the opposite case: he believes prescription hearing aid prices could *increase* due to OTC hearing aids and basic supply-and-demand factors.

What about hearing aid returns and warranties and the FDA taking hearing aids off its list of restricted devices?

One consequence of the FDA taking hearing aids off their list of restricted devices is some aspects of consumer protection—notably warranties and return-for-credit policies—will now largely flow through individual state laws and the professional licensure requirements in those states.

So why did the FDA decide to take hearing aids off this list? The answer is that so many states have so many different laws governing hearing aid sales that it would be a total mess to do anything else. Understanding all this requires some background knowledge about the history of hearing aid regulation.

In February 1977, the FDA mandated that anyone purchasing a hearing aid must first undergo a medical evaluation or sign a "**physician waiver**" form. Later, in August 1977, the FDA placed hearing aids on their **restricted devices** list, meaning hearing aids could be prescribed only by a licensed professional under special "conditions of sale," much like prescription drugs can only be dispensed by a doctor.

Along with a set of 1970s regulations from the Federal Trade Commission (FTC), these two regulatory actions are now collectively known as the "**Hearing Aid Rule**." At the time, the rule was strongly opposed by both the hearing industry and hearing aid dispensers who had been establishing their own regulations and state licensing laws since the late-1950s. These regulations continued to evolve and largely dictated how hearing aids were sold in each state.

In late-1993, the FDA held hearings to ***tighten* the Hearing Aid Rule** and further restrict who could dispense hearing aids, but the FDA backed off this proposition after a turf war ensued between ENTs, audiologists, and hearing aid specialists, leading to bad press and reduced use of hearing aids. Ten years later, in 2003, Citizen's Petitions were filed by two prominent audiologists to get rid of the "physician waiver" system and create an OTC hearing aid classification. By this time, the industry and professionals had adapted their businesses to a medical model and generally opposed the petitions which were ultimately denied by the FDA.

In 2016, with the advent of OTC self-fit hearing aids seemingly "a given," the Agency announced it would no longer enforce its physician waiver requirement. However, most state licensure laws still require it. So, in practical terms, the federal **Hearing Aid Rule has stood basically unchanged for 45 years**. In that timespan, most states also created "lemon laws" that offer consumer protections for a wide range of products including hearing aids, while the professions of audiology and hearing aid specialists created their own separate sets of regulations through *several hundreds* of state licensure laws.

Given all these disparate state laws and other factors, the FDA's most practical solution for creating an OTC Hearing Aid Rule was to take hearing aids off its restricted list. However, doing so creates a patchwork of different rules, particularly for product warranties and returns. At this

point, it doesn't appear FDA wants to get involved in how states regulate and make laws governing the sale of hearing aids—as long as those laws don't "restrict or frustrate" the intent of the OTC Hearing Aid Rules and its other regulations.

This means the **smart consumer should look carefully at the warranty and return provisions** which are often stated in the "fine print."

Product returns and warranty policies should be read more carefully due to some of the rule changes.

Are hearing aid warranties and return policies really such a big deal?

They can be. Hearing aids are small head-worn electronic devices used for up to 16 hours per day that regularly encounter harsh environments, including rain, sweat, dust, wind, heat/cold, etc. Although there are myriad reasons hearing aids are returned to the manufacturer—with malfunction being only one of them—the return-for-credit rate for traditional hearing aids has hovered around 15-20% for decades. Returns are considered a major "built-in" factor in the cost of manufacturing prescription hearing aids.

Probably the most frequent "trouble-shooting" task audiologists encounter is earwax or debris clogging the hearing aid receiver opening (port). Most hearing aids use wax guards to prevent this from occurring, but none are completely effective. When wax clogs the receiver port, loudness is greatly reduced and/or the aid can "go dead." For prescription hearing aids, this is a relatively easy fix for a professional with the right equipment and replacement parts.

For OTC hearing aids, however, it could be a trickier problem to solve. Of course, it's possible OTC hearing aid manufacturers will devise clever ways to address clogged receiver ports, but some in the hearing industry fear this could cause reliability problems and erode consumer satisfaction with OTC hearing aids.

The Hearing Loss Association of America (HLAA) recommends consumers look for return policy details on the OTC hearing aid box and online before purchasing the device. If you're having

major problems with the hearing aid and aren't getting help from the supplier, you can file a complaint with the FDA or call 1-800-FDA-1088.

Will OTC Hearing Aids foster new innovations and greater competition among hearing aid manufacturers?

Competition will almost certainly intensify as more OTC hearing aids become available. Most hearing aid manufacturers and many consumer electronics companies will be vying to get their products into a dominant position in the OTC hearing aid market. The NIDCD estimates 28 million people could benefit from hearing aids, so the market has great potential. OTC is also a logical entry point for consumers to experience the benefits of amplification, and then progress to prescription hearing aids when they need them. With this greater competition, branding will also become more important in marketing hearing healthcare products.

At HearingTracker, we believe we'll see accelerated innovations in the new OTC devices, apps, and speech-in-noise and self-fitting solutions. But the mainstream press, members of Congress, and others have largely missed the fact that innovation has already been progressing rapidly in hearing aids. They routinely insinuate that only companies outside the hearing industry can transform hearing aid technology.

The evidence doesn't support this idea. Many world-class companies and start-ups with impressive resources—ranging from Panasonic, J&J (Songbird), Doppler, and more recently Bose—have entered the US hearing aid market and failed. This certainly doesn't mean an Apple or Google (or a smaller start-up) won't come along with a groundbreaking idea and seriously accelerate innovation. However, developing a tiny hearing aid with great sound quality, speech-in-noise capabilities, comfort, and a battery life of 16+ hours/day—with rechargeability and Bluetooth connectivity for more advanced aids—is a lot harder than people think.

A new era of hearing healthcare

The FDA's new OTC hearing aid rules should provide more affordable and convenient options for adults (age 18+) with mild to moderate hearing loss. The new rules open up hearing aid sales to online and retail stores and provide basic safety and quality standards that will hopefully reduce the number of substandard devices found on today's market. The new rules, however, do require consumers to be more informed about warranties and return policies, as the regulations governing them have largely been shifted to the states.

OTC hearing aids have great potential to get amplification into the ears of people earlier than before, and this provides a golden opportunity for improved healthcare in the United States. They should also increase competition and may accelerate innovation for a new era of consumer-driven hearing care.