U.S. Government Accountability Office

Over-the-Counter Hearing Aids: Information on the New Medical Device Category

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Q&A Report to Congressional Requester

May 7, 2024

Why This Matters

Approximately 38 million American adults have reported some hearing loss, and an estimated 29 million U.S. adults could benefit from using hearing aids, according to the National Institute on Deafness and Other Communication Disorders. Historically, hearing aids have been available only from a licensed professional and are often not covered by health insurance, causing them to be unaffordable for many consumers. As with other types of medical devices, the safety and effectiveness of hearing aids is overseen by the Food and Drug Administration (FDA). In August 2022, FDA finalized a Rule allowing certain hearing aids to be sold without the involvement of a licensed professional—that is, over the counter (OTC)—beginning in October 2022.

We were asked to examine consumer access to hearing loss treatment following FDA's issuance of the OTC hearing aids Final Rule. This report describes what OTC hearing aids are, FDA's rulemaking process for creating the new OTC category for hearing aids, FDA's and other federal agencies' oversight of OTC hearing aids, existing research on the effect of OTC hearing aids on access to hearing loss treatment, and key issues relating to OTC hearing aids.

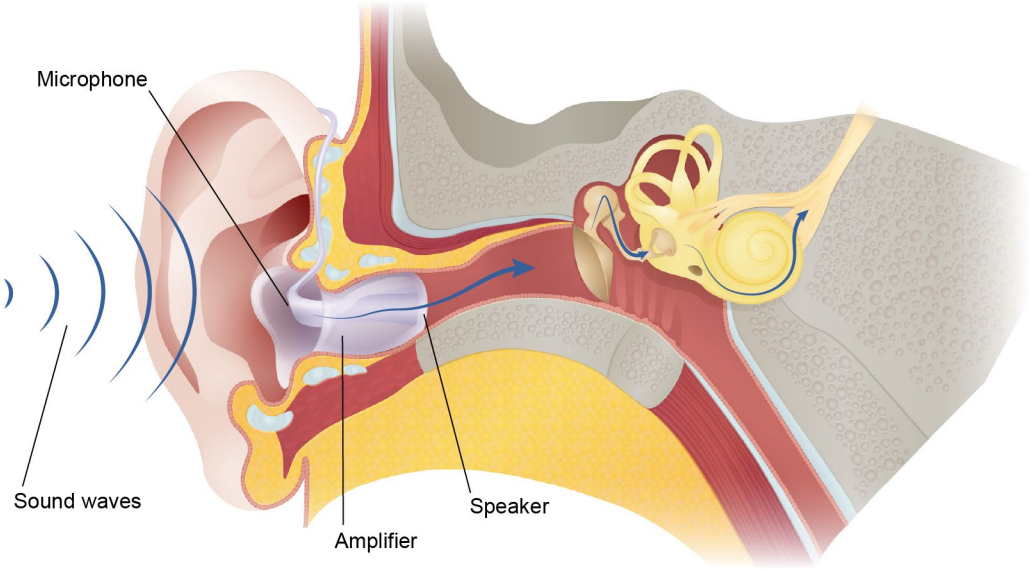
Key Takeaways

- FDA conducts premarket reviews and postmarket oversight of OTC hearing aids in the same manner as it does for prescription hearing aids and other medical devices. For example, FDA monitors OTC hearing aids on the market for performance or safety issues.
- Research, external stakeholder groups, and FDA officials indicated that it is too soon after the implementation of the OTC hearing aids Final Rule to assess the effects OTC hearing aids have had on patient access to hearing loss treatment.
- External stakeholder groups identified issues relating to OTC hearing aids that they believe are important to monitor, including marketing, use by children, and return policies.

What are hearing aids?

A hearing aid is a small electronic device worn in or behind the ear that makes some sounds louder. It allows people with hearing loss to listen, communicate, and participate more fully in daily activities. A hearing aid has three basic components: a microphone, amplifier, and speaker (see fig. 1). The hearing aid receives sound through a microphone, which converts the sound waves to electrical signals and sends them to an amplifier. The amplifier increases the power of the signals and then sends them to the ear through a speaker.[1]

Figure 1: Basic Components of a Hearing Aid



Source: GAO (arrows and labels); Anastasiia Lavrentev/stock.adobe.com (illustration). | GAO-24-106854

Historically, hearing aids were only available from a licensed professional, such as an ear, nose, and throat doctor or an audiologist.[2] These professionals would, among other things, program the device to the individual's specific level of hearing loss (see table 1).

Table 1: Degrees of Hearing Loss

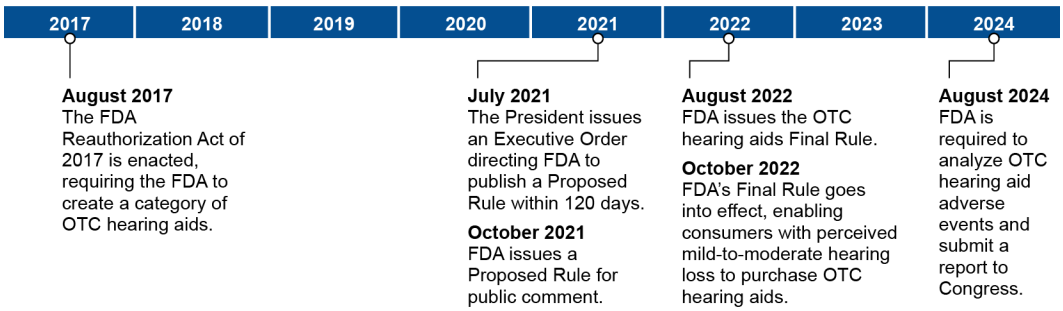
Degree of hearing loss	Effect on hearing
Mild	May hear some speech sounds but soft sounds are hard to hear
Moderate	May hear almost no speech when another person is talking at a normal level
Severe	Will not hear speech when a person is talking at a normal level and only some loud sounds
Profound	Will not hear any speech and only very loud sounds

Source: Centers for Disease Control and Prevention. | GAO-24-106854

What was FDA's process for creating the OTC hearing aids medical device category?

The FDA Reauthorization Act of 2017 required FDA, a department within the Department of Health and Human Services, to create a new medical device category for OTC hearing aids.[3] FDA followed the notice and comment rulemaking process to issue the Final Rule (see fig. 2).[4]

Figure 2: Timeline of the Food and Drug Administration's (FDA) Over-the-Counter (OTC) Hearing Aids Rule



Source: GAO analysis of federal requirements and guidance. | GAO-24-106854

FDA officials told us that, in creating this new category of medical devices, FDA was trying to address an unmet public health need while reasonably assuring the devices were safe, effective, and able to reach as many people as possible. To

draft the Rule, FDA worked with internal experts including audiologists, an ear, nose, and throat doctor, and engineers trained in speech processing, all of whom were already involved with FDA's oversight of hearing aids. In addition, FDA sought input from external stakeholder groups, including experts and associations representing consumers, audiologists and hearing professionals, and the hearing aid industry.[5]

The Final Rule established requirements for OTC hearing aids and other regulatory requirements that apply to hearing aids that require a prescription from a licensed professional. OTC hearing aids use the same fundamental scientific technology as prescription air-conduction hearing aids and are available to consumers without a prescription or the involvement of a licensed professional. While prescription hearing aids can be used to address any degree of hearing loss, OTC hearing aids are intended only for those aged 18 and older with perceived mild-to-moderate hearing loss (see table 2).[6]

Table 2: Differences between Prescription and Over-the-Counter Hearing Aids

	Prescription hearing aids	Over-the-counter hearing aids
Age of intended users	Any age	18 years and older
Level of hearing loss of intended users	Any degree of hearing loss	Perceived mild-to-moderate hearing loss
Conditions for sale	• Prescription from a licensed professional required • Must purchase from licensed seller in some states	• Purchaser must be 18 years or older • No medical exam required • No prescription required • No fitting by licensed professional required • No need for licensed seller

Source: Food and Drug Administration. | GAO-24-106854

FDA's OTC hearing aid regulations limited sound output and insertion depth in the ear canal, set electroacoustic performance specifications, and required certain information on the device labeling.[7] In finalizing the Rule, FDA made the following changes from what the agency had originally proposed in its Proposed Rule.[8] Specifically, the Final Rule did the following.

- **Lowered the maximum sound output.** FDA lowered the maximum sound output, or the output limit, to reduce the risk to hearing from over-amplification of sound. In the Final Rule, FDA lowered the output limit from 115 to 111 decibels of sound pressure level for most devices, and from 120 to 117 decibels of sound pressure level allowable for devices while input-controlled compression is activated. (See table 3 for information about decibel levels.)

Table 3: Common Sources of Noise and Decibel Levels

Everyday sounds and noises	Average sound level (in decibels)	Typical response (after routine or repeated exposure)
Normal conversation	60	Sounds at this level typically do not cause any hearing damage
Motorcycles	95	Damage to hearing possible after about 50 minutes of exposure
Loud entertainment venues (nightclubs, bars, and rock concerts)	105-110	Hearing loss possible in less than 5 minutes
Standing beside or near sirens	120	Pain and ear injury

Source: Centers for Disease Control and Prevention. | GAO-24-106854

- **Revised the design requirements.** FDA revised allowable insertion depth to be at least 10 millimeters from the eardrum and required that all OTC hearing aids have a user-adjustable volume control. In the Proposed Rule, FDA set the insertion depth to an anatomical place in the ear, and several public comments to the Rule characterized this proposal as insufficiently defined and subject to significant variability across individuals. As a result, in the Final Rule, FDA revised the insertion depth to be 10 millimeters from the eardrum, because that depth would minimize the risk from injury from inserting the device too deeply without unduly limiting the device effectiveness.
- **Simplified the required device labeling.** FDA simplified the language of required device labeling to ensure it is easily understood by hearing aid users. FDA regulations require certain information on the outside of the OTC hearing aid box (see text box).

FDA Requirements for Information to Be Included on Over-the-Counter (OTC) Hearing Aid Labeling

1) Warnings and additional information regarding hearing health
   - Warning against use in people younger than 18
   - Description of symptoms suggesting perceived mild-to-moderate hearing loss
   - Advice on when to seek heath care services
   - "Red flag" conditions (i.e., when to see a doctor)
   - Notice of contact information
   - Manufacturer's return policy
2) Whether the device is used or rebuilt
3) The words "OTC" and "hearing aid" are prominently displayed on the packaging
4) Information regarding the type and number of batteries and whether batteries are included
5) Whether a mobile phone or remote-control device is necessary to control the OTC hearing aid

Source: Food and Drug Administration (FDA). | GAO-24-106854

To educate consumers on the new OTC hearing aids Rule, FDA released several consumer education resources, including the hearing aid page on the agency's website, a new webpage created for OTC hearing aids, a YouTube video addressing key points in the OTC hearing aids Rule, and a consumer update article on OTC hearing aids.

How does FDA regulate OTC hearing aids?

OTC hearing aids are subject to the same FDA premarket reviews and postmarket oversight as other medical devices. FDA is responsible for ensuring that medical devices sold in the United States provide reasonable assurance of safety and effectiveness and do not pose a threat to public health.[9] Within FDA, the Center for Devices and Radiological Health and the Office of Regulatory Affairs have oversight responsibility for hearing aids.

Premarket reviews

FDA's process for premarket reviews is determined by factors other than whether a hearing aid is available over the counter or by prescription. All OTC hearing aid manufacturers must register their manufacturing facility and list their devices with FDA within 30 days of marketing their devices. Other aspects of premarket review varies by the risk classification of the device—i.e., whether the risk posed to the consumer is low, moderate, or high.[10] Some OTC hearing aids—specifically, hearing aids with self-fitting technology—must go through premarket notification (known as a 510(k)) as they are higher risk.[11] Device manufacturers who are required to submit a premarket notification must do so at least 90 days

prior to marketing the device and demonstrate that the device proposed to be marketed is as safe and effective as a device already legally marketed. All other lower-risk OTC hearing aids (i.e., those without self-fitting technology) are exempt from this requirement.[12]

Postmarket oversight

FDA also conducts surveillance of OTC hearing aids after they are marketed, as it does with other medical devices. These postmarket oversight activities can include requiring that companies complete studies on device performance after marketing and FDA monitoring of reported adverse events (e.g., injury from the device, or performance issues). The agency has distinct codes for OTC and prescription hearing aids, which allow FDA staff to track any differences in reported adverse events between OTC and prescription hearing aids.[13]

When a problem is identified with a device on the market, FDA can request various corrective actions of a manufacturer, such as removing the device from the market, changing the device labeling and instructions for use, or improving user training.

As of February 2024, FDA officials reported the agency had received 12 reports of adverse events involving OTC hearing aids. Officials said the number and types of adverse events for OTC hearing aids were in line with what they would have expected, as they receive complaints for similar issues with prescription hearing aids (e.g., pieces of the hearing aid broke off in the ear, allergic reactions to the device, worsening migraines while using the device). However, the agency officials also noted that these adverse events data are from a passive data surveillance system, which relies on reports (by phone, by mail, or online) from consumers and organizations.[14] Therefore, this number is likely an undercount of adverse events, since not every adverse event is reported to FDA.

How does FDA work with other federal agencies to oversee OTC hearing aids?

FDA coordinates with the Federal Trade Commission (FTC) on trade practices involving hearing aids. FTC has primary responsibility for the truth or falsity of advertising for most medical devices, including OTC hearing aids. Consumers and organizations can submit concerns about false or misleading advertising through FTC's website.[15] FDA and FTC officials stated that the agencies coordinate on an as-needed basis to share advertising concerns and consumer complaints.[16] FTC officials told us that the agency has not seen a spike in advertising complaints following the availability of OTC hearing aids. In addition, FTC has not taken any enforcement actions against hearing aid companies since the Rule took effect in October 2022 but is monitoring the emerging marketplace.

According to FDA officials, FDA coordinates with the National Institute on Deafness and Other Communication Disorders for purposes of developing educational materials consistent with the Final Rule and its regulatory effects. FDA also communicates with the Centers for Medicare & Medicaid Services on device risk-benefit profiles and device performance to inform Centers for Medicare & Medicaid Services decisions regarding health insurance coverage of medical devices. Neither the National Institute on Deafness and Other Communication Disorders nor the Centers for Medicare & Medicaid Services has the regulatory authority to oversee the safety and effectiveness of hearing aids, and FDA does not have regulatory authority over reimbursement or payors.

What is known about how OTC hearing aids have affected patient access to treatment?

In the less than 2 years since consumers could purchase OTC hearing aids, there has been limited research examining their effect on patient access to hearing loss treatment. However, early research has suggested that OTC hearing aids can be as effective as prescription hearing aids and, as a result, may expand access for those with mild-to-moderate hearing loss. We conducted

a literature search to identify peer-reviewed research on patient access to hearing loss treatment following the market availability of OTC hearing aids in October 2022. We identified 12 relevant research studies (see app. I).

In these studies, researchers discussed the potential for OTC hearing aids to increase patient access to hearing loss treatment. For example, one study suggested that OTC hearing aids may have the potential to afford easier access to hearing health care for residents of rural areas, a traditionally underserved segment of the population.[17] Another study found that survey respondents who reported lower household incomes or were unsure about their insurance coverage were likely to consider using OTCs instead of a prescription device.[18]

However, four studies noted the lack of research on OTC hearing aids and the need for additional studies. For example, one 2023 study found that there is limited research on all aspects of OTC hearing aids currently on the market and concluded that high quality, independent research must be prioritized to supplement evidence provided by the OTC hearing aid manufacturers for regulatory approval purposes.[19]

FDA officials said the agency had not studied the effect of the OTC hearing aids Final Rule on consumer access to hearing aids but was open to working with other federal agencies to conduct such a study in the future. FDA officials and six external stakeholder groups we spoke with said it was too early after implementation of the Rule to have data on its effects.[20]

What is the effect of OTC hearing aids on consumer interest in hearing treatment?

Research and external stakeholder groups reported that consumer interest in hearing loss treatment initially increased following issuance of the OTC hearing aids Final Rule. One study found that online searches for hearing aids increased following FDA's Final Rule, particularly searches focused on OTC hearing aid vendors, cost, and reviews of specific device brands.[21] According to an additional article, the majority of audiologists surveyed reported that the volume of patients they saw did not significantly increase or decrease when OTC hearing aids became available; however, some practitioners reported working with patients who requested help with OTC hearing aids.[22]

Six external stakeholder groups we spoke with noted that, anecdotally, there was a small initial increase in consumers accessing hearing health care following implementation of the OTC hearing aids category. For example, two groups said there was an increase of consumers in the audiologists' offices due to media attention immediately following the Rule. One group said the traffic has leveled out, but the other group said the foot traffic to audiologists' offices has continued.

What barriers remain for access to hearing treatment?

Research and external stakeholder groups reported barriers to accessing hearing loss treatment even with the availability of OTC hearing aids, namely consumer preferences and professional concerns, difficulty assessing hearing loss, and affordability.

Consumer preferences and professional concerns

Research and external stakeholder groups found consumer preferences and professional concerns could be a barrier to OTC hearing aids improving access to hearing loss treatment.

- One study of consumers found that there is a strong consumer preference (84 percent of respondents) for working with a hearing health care professional in person to identify the need for a health care product or service, as opposed to doing so online.[23]

- Another study found that most of the hearing health care professionals surveyed expressed concerns related to OTC hearing aid safety (e.g., medical red flags could be missed without professional oversight), counseling, and audiological care (e.g., consumers not receiving education on realistic expectations for the devices).[24]
- Similarly, a study of pharmacists, who may be responsible for advising OTC hearing aid patients in their communities, found that two-thirds of survey respondents did not have the necessary knowledge to counsel patients on OTC hearing aids.[25]
- Four external stakeholder groups we interviewed expressed concern with the lack of medical intervention when consumers purchase OTC hearing aids. Medical intervention could include, for example, professional advice on whether a device will work for the consumers' hearing needs, whether the device is appropriately adjusted, and proper device use.

Difficulty assessing hearing loss

Research and external stakeholder groups found that inaccurate assessment of hearing loss may prevent consumers from receiving appropriate hearing loss treatment.

- A study published prior to the availability of OTC hearing aids found that about 13 percent of its participants had underestimated their hearing loss while approximately 5 percent overestimated it when they self-reported hearing difficulty.[26] OTC hearing aids do not require a hearing test by a licensed professional prior to purchase, but consumers may take a self-assessment to assess their approximate level of hearing loss prior to purchase or to program their OTC hearing aid.
- In a study of hearing health care professionals, almost 90 percent of survey respondents agreed with the statement that they were concerned that consumers are "not able to accurately predict hearing loss."[27]
- Three external stakeholder groups noted that actual hearing loss is often not consistent with perceived hearing loss, so consumers may not be able to accurately assess their level of hearing loss without medical intervention.
- Four groups noted that hearing loss self-assessments are often insufficient to assess hearing loss because there are many factors for which the test cannot account, such as the technology savviness of the user or earwax buildup.

Affordability

None of the studies in our literature search examined affordability. Three external stakeholder groups indicated that the cost of OTC hearing aids was too high for the average consumer to afford.[28]

- A study, from before the hearing aids Final Rule went into effect, found that nearly 17 percent of adults with hearing loss may be unable to afford OTC hearing aids costing $500.[29] The reported cost of prescription hearing aids can range from $1,000 to $6,000 per pair, and OTC hearing aids can range from around $200 to over $1,000, depending on the device's technology.[30]
- In addition, health insurance coverage often excludes hearing loss treatment, including OTC hearing aids. Three studies and four external stakeholder groups discussed the lack of insurance coverage, particularly Medicare coverage, as a barrier to patients accessing hearing loss treatment. As of February 2024, Medicare allowed beneficiaries to receive a hearing exam annually for certain hearing conditions, but the coverage excluded exams for the purpose of fitting hearing aids. (See table 5.)

Table 5: Summary of Potential Health Insurance Coverage for Prescription and Over-the-Counter (OTC) Hearing Aids, as of February 2024

Type of health insurance	Prescription hearing aid coverage	OTC hearing aid coverage
Traditional Medicare	No	No
Medicare Advantage Plans (supplemental)[a]	Varies	Varies
Medicaid[b]		
Children	Yes	Varies
Adults	Varies	Varies
Private health insurance[c]	Varies	Varies
TRICARE (active military members and their families)	Yes	No
Department of Veterans Affairs[d]	Yes	No

Sources: Centers for Medicare & Medicaid Services; Hearing Loss Association of America; American Speech-Language-Hearing Association; National Council on Aging; Department of Defense; Department of Veterans Affairs. | GAO-24-106854

Note: Many health insurance plans require that a beneficiary meet certain clinical criteria and receive a prescription from a licensed professional before covering a hearing aid. Thus, it is unlikely that many of these plans would cover an OTC hearing aid unless one was recommended by a licensed professional. In addition, health plans would not cover OTC hearing aids for children under 18 years old because the devices were not intended for this age group.

[a]Medicare Advantage plans may choose to cover prescription and OTC hearing hearings as supplemental benefits. GAO previously reported that 90 percent of Medicare Advantage plans we reviewed offered hearing aid coverage, and approximately 82 percent offered at least one over-the-counter item benefit. See GAO, *Medicare Advantage: Plans Generally Offered Some Supplemental Benefits, but CMS Has Limited Data on Utilization,* GAO-23-105527 (Washington, D.C.: Jan. 31, 2023).

[b]Medicaid covers hearing services, including prescription hearing aids, for Medicaid beneficiaries under 21 years old. According to the Hearing Loss Association of America, more than half of states provide some prescription hearing aid coverage to adult Medicaid beneficiaries. Medically necessary hearing aids meeting the definition of medical supplies, equipment, and appliances must be covered under the mandatory Medicaid Home Health benefit. 42 C.F.R § 440.70(b)(3)(ii)(2023). According to Centers for Medicare & Medicaid Services officials, states have the option to decide if they want to cover OTC hearing aids. If a state decides to cover OTC hearing aids, the ordering requirements of the home health benefit must be met.

[c]According to the American Speech-Language-Hearing Association, 20 states require health insurance plans operating in their states to cover prescription hearing aids for children. They also note that five states require health plans to cover prescription hearing aids for children and certain specified adults. Requirements vary by state for ages covered, amount of coverage, benefit period, and provider qualifications. Some plans may partner with certain hearing aid companies or offer consumers an allowance to purchase OTC products. Individuals also may use their Health Spending Accounts or Flexible Savings Accounts to pay for OTC hearing aids.

[d]The Department of Veterans Affairs procures hearing aids for its beneficiaries through national contracts with select vendors. According to agency officials, as of February 2024, the Department of Veterans Affairs had not procured OTC hearing aids for its beneficiaries as the cost of prescription hearing aids through the agency's contracts are, in most cases, less than the cost of an OTC hearing aid.

What issues did stakeholders identify in the OTC hearing aid market?

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. We discussed these issues with FDA officials.

- **Marketing.** Three of the eight external stakeholder groups expressed concerns with the marketing claims of some OTC hearing aids, including some that claim to help with severe hearing loss. One group noted that patients could get discouraged if a hearing aid does not work as expected and opt not to use it. This can have long-term health consequences, as research has found hearing aid use to be associated with decreased risks of depression in older adults.[31] FDA officials noted that, while OTC hearing aids are intended to treat mild-to-moderate hearing loss, there is overlap between perceived moderate and severe hearing loss. The officials said that FDA would not advise an individual with severe hearing loss to use an OTC hearing aid as the individual would not achieve the optimum benefit.

- **Children's use of OTC hearing aids.** Five of the eight external stakeholder groups discussed the long-term risks that OTC hearing aids pose to children. OTC hearing aids are only intended for use in adults (18 years and older). However, three of these groups had heard reports of children wearing OTC hearing aids. FDA officials said that the labeling is clear that OTC hearing aids are not intended for those under 18. In the Final Rule, FDA said it assessed the risks of children accessing OTC hearing aids and the agency determined that the public health was better served by not imposing age verification requirements as the requirements could act as a barrier to access (e.g., for those without identification).
- **Return policies.** Two of the eight groups discussed the importance of OTC hearing aid return policies allowing enough time for the patient to adjust to the device before the return window closes. FDA requires that an OTC hearing aid label include the manufacturer's return policy and a statement in the inside packaging that it may take weeks for the consumer's brain to adjust to the device. FDA officials said the agency does not require a specific return policy because such policies are not necessary for FDA to reasonably assure the safety and effectiveness of OTC hearing aids, and return policies are typically regulated by the states. FDA officials stated that return policies can be a factor in market competition, in that those devices with more generous return policies would benefit in the market.
- **Gain limit.** Three of the eight groups we spoke with expressed concerns that FDA did not implement a gain limit (i.e., the amount of amplification added to incoming sounds resulting in sound output) on OTC hearing aids. In its Final Rule, FDA lowered the output limit from the Proposed Rule but did not require a gain limit. However, one group said that limits are needed for both output and gain to minimize the risks of damaging consumers' hearing with over-amplification. FDA wrote in the Final Rule that the agency did not require a gain limit because it wanted to maximize access to OTC hearing aids for the full range of intended users with perceived mild-to-moderate hearing impairment. Without a gain limit, FDA said that consumers have greater flexibility to customize their hearing aids to their needs, listening preferences, and communication goals. In addition, FDA said that, because of the output limit, a gain limit is not necessary to provide reasonable assurance of safety and effectiveness.

What are the next steps for FDA's regulation of OTC hearing aids?

As of February 2024, FDA did not have any plans to revise its OTC hearing aid regulations. However, FDA officials said the agency may issue technology specific regulations and guidance as new hearing technologies are approved and cleared by FDA. In addition, FDA is required to analyze OTC hearing aid adverse events and submit a report to Congress by August 2024. This analysis and report may have implications for the agency's oversight of OTC hearing aids.

Agency Comments

We provided a draft of this report to the Department of Health and Human Services for review and comment. The agency provided technical comments, which we incorporated as appropriate.

How GAO Did This Study

To do this work, we conducted a literature search for studies in peer-reviewed journals that were published after the Final Rule took effect. We searched various databases, such as EBSCO platform, ProQuest platform, and SCOPUS. We performed these searches to identify studies published from October 17, 2022, through November 22, 2023 (see app. I for search criteria and identified studies).

In addition, we interviewed FDA and FTC officials and a selection of eight external stakeholder groups representing consumers, audiologists and hearing professionals, and the hearing aid industry regarding FDA's and other federal agencies' oversight of OTC hearing aids, the issues relating to the OTC hearing aid market, and the known effects of the OTC hearing aids category on patient access (see app. II for a list of the groups). We selected the eight groups by identifying professional, industry, and consumer protection groups that 1) submitted public comment on FDA's Proposed Rule, 2) conduct relevant work on hearing loss treatment and technology, and 3) provide a diverse perspective on hearing health issues. The views of these stakeholders are not generalizable to other stakeholders.

We conducted this performance audit from May 2023 to May 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Addressee

The Honorable Charles E. Grassley
Ranking Member
Committee on the Budget
United States Senate

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services and other interested parties. In addition, the report will be available at no charge on the GAO website at https://www.gao.gov.

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Appendix I: Research Studies Identified in our Literature Search

We conducted a literature search to identify research studies that met the following criteria: (1) issued after October 17, 2022, when the over-the-counter (OTC) hearing aids category took effect; (2) contained information on OTC hearing aids; (3) contained information on patient access to hearing loss treatment; and (4) published in a peer-reviewed journal.[32] For each of the journal articles, we reviewed the study methodologies and determined that they were suitable for examining patient access to hearing loss treatment following the

market availability of OTC hearing aids in October 2022. We identified 12 studies that met our criteria.

Borre, Ethan D., et al. "Potential Clinical and Economic Outcomes of Over-the-Counter Hearing Aids in the US." *JAMA Otolaryngology-Head & Neck Surgery* (May 18, 2023).

Boven, Christopher, et al. “In-situ hearing threshold estimation using Gaussian process classification.” *Scientific Reports* (Sept. 6, 2023).

De Sousa, Karina C., et al. “Effectiveness of an Over-the-Counter Self-fitting Hearing Aid Compared With an Audiologist-Fitted Hearing Aid: A Randomized Clinical Trial.” *JAMA Otolaryngology-Head & Neck Surgery* (Apr. 13, 2023).

Jorgensen, Lindsey E., and Rachel E. Barrett. “Relating Factors and Trends in Hearing Device Adoption Rates to Opportunities for Hearing Health Care Providers.” *Seminars in Hearing* (Dec. 1, 2022).

Manchaiah, Vinaya, De Wet Swanepoel, and Anu Sharma. “Prioritizing research on over-the-counter (OTC) hearing aids for age-related hearing loss.” *Frontiers in Aging* (Mar. 23, 2023).

Manchaiah, Vinaya, et al. “Hearing Healthcare Professionals’ Views about Over-the-Counter (OTC) Hearing Aids: Analysis of Retrospective Survey Data.” *Audiology Research* (Mar. 1, 2023).

Midey, Elizabeth S., et al. “National Survey of Pharmacist Awareness, Interest, and Readiness for Over-the-Counter Hearing Aids.” *Pharmacy* (Nov. 12, 2022).

Panth, Neelima, et al. "Over-The-Counter Hearing Aids: Trends in Information-Seeking Behavior.” *American Academy of Otolaryngology-Head and Neck Surgery Foundation* (Jun. 27, 2023).

Picou, Erin M. “Hearing Aid Benefit and Satisfaction Results from the MarkeTrak 2022 Survey: Importance of Features and Hearing Care Professionals.” *Seminars in Hearing* (Dec. 1, 2022).

Singh, Jasleen and Sumitrajit Dhar. “Assessment of Consumer Attitudes Following Recent Changes in the US Hearing Health Care Market.” *JAMA Otolaryngology-Head & Neck Surgery* (Jan. 19, 2023).

Swanepoel, De Wet, et al. “Comparing Hearing Aid Outcomes in Adults Using Over-the-Counter and Hearing Care Professional Service Delivery Models.” *American Journal of Audiology* (Jun. 2023).

Venkitakrishnan, Soumya., Dana Urbanski, and Yu-Hsiang Wu. “Efficacy and Effectiveness of Evidence-Based Non-Self-Fitting Presets Compared to Prescription Hearing Aid Fittings and a Personal Sound Amplification Product.” *American Journal of Audiology* (Nov. 2023).

Appendix II: External Stakeholder Groups

We interviewed eight external stakeholder groups representing consumers, audiologists and hearing health professionals, and the hearing aid industry regarding the known effects of the over-the-counter (OTC) hearing aids category on patient access and FDA’s regulation of OTC hearing aids. The views of these stakeholders are not generalizable to other stakeholders.

American Academy of Audiology

American-Speech-Language-Hearing Association

Consumer Healthcare Products Association

Educational Audiology Association

Hearing Industries Association

Hearing Loss Association of America

National Consumers League

National Council on Aging

Endnotes

[1]National Institutes of Health, National Institute on Deafness and Other Communication Disorders, *Hearing Aids,* accessed February 1, 2024, https://www.nidcd.nih.gov/health/hearing-aids.

[2]Prior to the creation of the OTC hearing aids medical device category, hearing aids were restricted devices, requiring interaction with a licensed professional. FDA has the statutory authority to restrict the sale, distribution, or use of a device. A restricted device can only be sold on oral or written authorization by a licensed practitioner or under conditions specified by regulation.

[3]FDA Reauthorization Act of 2017, Pub. L. No. 115-52, 131 Stat. 1005 (2017).

[4]Rulemaking is the policy-making process, governed by various statutes, for executive agencies of the federal government. Agencies use this process to develop and issue Rules (also referred to as "regulations"). An agency cannot issue a Rule unless granted authority to do so by law. Rules are published in the Federal Register and made publicly available.

[5]FDA also considered reports on hearing health care from the President's Council of Advisors on Science and Technology and the National Academies of Sciences, Engineering, and Medicine. Both reports encouraged FDA to create a new category of medical devices for OTC hearing aids, among other recommendations. See Executive Office of the President, "Aging America & Hearing Loss: Imperative of Improved Hearing Technologies" (Oct. 2015); and National Academic of Sciences, Engineering, and Medicine, "Hearing Health Care for Adults: Priorities for Improving Access and Affordability," *The National Academies Press* (2016).

[6]87 Fed. Reg. 50,698 (Aug. 17, 2022). FDA finalized guidance in August 2022 to clearly distinguish between OTC hearing aids and personal sound amplification products. The latter, also available over the counter, are electronics that amplify sound for non-hearing-impaired consumers in situations such as hunting and bird watching. In contrast, as noted in the report, OTC hearing aids are intended for consumers with mild-to-moderate hearing loss. See Food and Drug Administration, *Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products: Guidance for Industry and Food and Drug Administration Staff* (Aug. 17, 2022).

[7]FDA regulations limit the output of a hearing aid, which includes the incoming sound plus the gain added by the hearing aid. Gain is the amount of amplification that the hearing aid adds (i.e., the difference between the input level and the output). 87 Fed. Reg. 50,698.

[8]86 Fed. Reg. 58,150 (Oct. 20, 2021).

[9]21 U.S.C. § 360c.

[10]FDA classifies each medical device type intended for human use into one of three classes based on the level of risk it poses to the patient or the user and the controls necessary to reasonably ensure its safety and effectiveness. See 21 U.S.C. § 360c(a)(1) and 21 C.F.R. § 860.3(c) (2023).

[11]Self-fitting hearing aids have greater customization through technology such as hearing tests, software, and smartphone applications.

[12]FDA has exempted almost all class I (low to moderate risk) devices from premarket notification requirements. Certain class II (moderate to high risk) devices are also exempt. FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues.

[13]Each medical device is assigned a specific product code that allows FDA to identify the generic device category. QUF, QUG, and QUH are the product codes for OTC hearing aids. ESD, OSM, and QDD are the equivalent product codes for prescription hearing aids.

[14]Consumers can report problems to FDA on their website (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program) or by calling 1-800-FDA-1088.

[15]https://reportfraud.ftc.gov/.

[16]GAO, *Medical Advertising: Federal Oversight of Devices,* GAO-23-106197 (Washington, D.C.: Sept. 8, 2023).

[17]Neelima Panth et al., "Over-The-Counter Hearing Aids: Trends in Information-Seeking Behavior," *American Academy of Otolaryngology-Head and Neck Surgery Foundation* (Jun. 27, 2023).

[18]Jasleen Singh and Sumitrajit Dhar, "Assessment of Consumer Attitudes Following Recent Changes in the US Hearing Health Care Market," *JAMA Otolaryngology-Head & Neck Surgery,* (Jan. 19, 2023).

[19]Vinaya Manchaiah, De Wet Swanepoel, and Anu Sharma, "Prioritizing research on over-the-counter (OTC) hearing aids for age-related hearing loss," *Frontiers in Aging* (Mar. 23, 2023).

[20]The two other external stakeholder groups discussed anecdotal information that the OTC hearing aids Final Rule increased visits to the audiologists' offices, but the groups were unaware of supporting data or research relating to the effects of the Final Rule on patient access.

[21]Neelima Panth et al., "Over-The-Counter Hearing Aids: Trends in Information-Seeking Behavior," *American Academy of Otolaryngology-Head and Neck Surgery Foundation* (Jun. 27, 2023).

[22]Jerry LaMartina, "Audiology's Not-So-Scary Future With OTC Hearing Aids," *The Hearing Journal* (Oct. 2023).

[23]Jasleen Singh and Sumitrajit Dhar, "Assessment of Consumer Attitudes Following Recent Changes in the US Hearing Health Care Market," *JAMA Otolaryngology-Head & Neck Surgery,* (Jan. 19, 2023).

[24]Vinaya Manchaiah et al., "Hearing Healthcare Professionals' Views about Over-the-Counter (OTC) Hearing Aids: Analysis of Retrospective Survey Data," *Audiology Research* (Mar. 1, 2023).

[25]Elizabeth S. Midey et al., "National Survey of Pharmacist Awareness, Interest, and Readiness for Over-the-Counter Hearing Aids," *Pharmacy* (Nov. 12, 2022).

[26]Ji Eun Choi et al., "Discrepancies between self-reporting hearing difficulty and hearing loss diagnosed by audiometry: prevalence and associated factors in a national survey," *BMJ Open* (2019).

[27]Vinaya Manchaiah et al., "Hearing Healthcare Professionals' Views about Over-the-Counter (OTC) Hearing Aids: Analysis of Retrospective Survey Data," *Audiology Research* (Mar. 1, 2023).

[28]Ethan D. Borre et al., "Potential Clinical and Economic Outcomes of Over-the-Counter Hearing Aids in the US," *JAMA Otolaryngology-Head & Neck Surgery,* (May 18, 2023).

[29]Anna Marie Jilla and Carole E. Johnson, "Population-Based Perspectives on Affordability of Hearing Aids," *The Hearing Journal* (Dec. 2020).

[30]Vinaya Manchaiah et al., "Over-The-Counter Hearing Aids: What Do Consumers Need to Know," *The Hearing Journal* (Feb. 2023).

[31]David J. Mener et al., "Hearing Loss and Depression in Older Adults," *Journal of the American Geriatrics Society* (Sept. 12, 2013).

[32]A research librarian conducted searches in August 2023 and November 2023 in the following databases: BIOSIS Previews®, Embase®, EMCare®, MEDLINE®, PAIS International, SciSearch®, and Social SciSearch® in ProQuest Dialog; Coronavirus Research Database, Criminology Collection, Education Database, ERIC, Global Newsstream, Health & Medical Collection, Policy File Index, ProQuest Dissertations & Theses Global, PTSDPubs, Publicly Available Content Database, Research Library, SciTech Premium Collection, and Sociology Collection in ProQuest; AgeLine, Business Abstracts with Full Text (H.W. Wilson), Business Continuity & Disaster Recovery Reference Center, Business Source Corporate Plus, CINAHL Plus with Full Text, local holdings eBook Collection, EconLit with Full Text, Finance Source, Index to Legal Periodicals Retrospective: 1908-1981 (H.W. Wilson), Leadership & Management Source, Newswires, Risk Management Reference Center, and Web News in EBSCOhost; Scopus; OCLC FirstSearch; Policy Commons; and Harvard Think Tank Search.