Ensuring the Public Benefits from OTC Hearing Aids Requires a Smart Regulatory Framework with a Strong Focus on Safety and Effectiveness

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Abstract

The key to the "smart" regulation of Over-the-Counter (OTC) Hearing Aids is to promulgate a series of requirements that provide adequate assurances of safety and effectiveness by ensuring OTC devices (1) are used as intended, (2) provide clinically significant positive results for intended users, and (3) avoid unintentionally causing increased confusion among potential users. It is also critically important to establish an effective enforcement mechanism that addresses the potential pitfalls inherent in user-fitted, user-adjusted hearing aids. The introduction of OTC hearing aids could result in the emergence of novice manufactures located throughout the world who will attempt to enter the US market. The key to designing and implementing a smart regulatory program is to recognize immediately that FDA, acting alone, will not have sufficient resources to ensure that all new products meet relevant safety standards. Manufacturers, working with affected consumers, must be involved in the enforcement on a continuing basis.

1. Hearing Loss: A Sideline of Health Care

Making affordable and effective hearing assistance technologies more easily available to consumers is a public health imperative and an economic health necessity. The World Health Organization (WHO) bluntly states that "Unaddressed hearing loss is one of the leading causes of morbidity…" (Chadha, et al. [2018]). In addition, untreated hearing loss is conservatively estimated to cost Americans billions of dollars a year in excess medical costs and lost economic productivity (Huddle, et al. [2017]).

One reason why treatable hearing loss has become such a costly national problem is because auditory health has become a sideline of the health care profession. The National Academies of Sciences, Engineering, and Medicine (NASEM) investigated the growing problem of insufficient hearing health care. The NASEM study was sponsored by Centers for Disease Control and Prevention (CDC), the US Food and Drug Administration (FDA), the Defense Department, the Department of Veterans Affairs, and other agencies and organizations. In stating its purpose, the resultant report, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*[1] explains that the "committee grappled with the questions of how and why hearing loss has been relegated to the sidelines of healthcare."

The report found that major factors which contribute to relegating hearing loss to the health care sidelines include the stigma associated with hearing aids and the fact that most health insurance does not provide coverage of hearing aids. A related factor that helps explain the underuse of hearing assistance devices is the cost. Overall, an estimated "67 to 86 percent of adults who might benefit from the use hearing aids do not obtain them."[2]

[1] National Academies of Sciences, Engineering, and Medicine, Hearing Health Care for Adults: Priorities for Improving Access and Affordability (2016).
[2] National Academies of Sciences, Engineering, and Medicine, Hearing Health Care for Adults: Priorities for Improving Access and Affordability (2016).

2. The Existing Regulatory Framework and Market Dynamics

The federal government has primary regulatory authority for hearing aids in the United States. However, consistent with America's federalist Constitution, State, Local and Tribal governments also play a role in the regulating the dispensing of hearing aids in order to protect the health and the consumer interests of their constituents. At the federal level, the FDA regulates hearing aids as "medical devices" under the Food, Drug, and Cosmetic Act.

FDA regulations classify hearing aids and other medical devices under several different categories based on intended use and risk. FDA has issued multiple regulations which have the aim of ensuring hearing aid safety and effectiveness. One of these regulations, found at 21 CFR 801.420, governs the informative labeling of hearing aids for (1) hearing aid professionals and (2) consumers. Another of these regulations, (21 CFR 801.421(a)), imposes conditions on the sale of certain hearing aids—including "Medical evaluation requirements."

These consumer safety and protection regulations were developed in the mid-1970s, long before OTC hearing aids were a gleam in an inventor's eye. The FDA developed these regulations in response to recommendations from a federal task force and in response to US Senate hearings which discussed the problems resulting from consumers being sold hearing aids without adequate diagnosis and without determination that the product being sold is the correct treatment option. These pro-consumer regulations were also adopted in response to the fact that hearing aids were being marketed to people who did not even need them.[3]

Under the FDA's conditions-for-sale regulation, found at §801.421, the sale of hearing aids are restricted to individuals who have either obtained a medical evaluation from a licensed physician or who voluntarily waive the medical evaluation requirement after being informed that such a waiver is not in the potential user's best health interests. Although OTC hearing aids are exempted from sections 801.420 and 801.421, the consumer protection needs addressed in these regulations remains.

FDA does not limit the sale of traditional hearing aids to certain distribution channels so long as existing regulations are met. However, States and localities may choose to impose specific conditions on the sale of hearing aids, including on whether hearing aids may be sold direct-to-consumers (DTC) by mail or online. Only 10 states either impose restrictions on or prohibit the sale of hearings aids DTC. The result of this situation is that, without medical advice or even basic information, consumers are able to buy hearing aids over the internet that are intended to be dispensed, fitted, and adjusted only by a licensed hearing care professional. Not surprisingly, the result is a great many unhappy consumers and continued public skepticism towards hearing assistance devices that hinders consumer acceptance of professionally prescribed and fitted hearing aids—a situation which harms public health.

In addition to hearing aids, in today's market, consumers also have access to personal sound amplification products (PSAPs). PSAPs are sometimes viewed or presented (albeit inappropriately) as a lower cost alternative to hearing aids. However, unlike hearing aids which are regulated medical devices, PSAPs are non-medical devices that are not intended to assist individuals with hearing impairment. Instead, PSAPs are intended to amplify sounds (such a bird calls) for individuals with normal hearing. The NASEM report made clear that PSAPs do not meet, nor are they designed to meet, the hearing health

[3] Eric Mann, M.D., Current FDA Standards. In Institute of Medicine and National Research Council, *Hearing Loss and Healthy Aging Workshop Summary* (pp. 48-51).

needs of millions of Americans suffering from hearing loss. PSAPs are generally sold direct-to-consumers (DTC) from online vendors without the involvement of a hearing care professional.

3. The Entry of OTC Hearing Aids to Increase Access and Affordability

To redress some of the hearing health care problems that Americans face and provide increased access to hearing aids, the NASEM report recommended that the federal government establish a new category of affordable hearing assistance devices:

> Recommendation 7: The Food and Drug Administration (FDA) should establish a new category of over-the-counter (OTC) wearable hearing devices. This device classification would be separate from "hearing aids." OTC wearable hearing devices would be defined as wearable, OTC devices that can assist adults with mild to moderate hearing loss.

In response to this report, and in an effort to provide greater access to meet the pressing public health need for a new type of hearing assistance device, Congress included the OTC hearing aid provisions in the FDA Reauthorization Act of 2017 (FDARA).[4] This legislation, which was signed into law in August 2017, directs the FDA to:

a. Create over-the-counter hearing aids as a new category of assistive listening devices intended for use by adults with perceived mild to moderate hearing loss.

b. Establish the category's regulatory standards to provide reasonable assurances of safety and effectiveness.

c. Define appropriate device output limits (the maximum level of amplified sound going into a user's ear).

d. Determine whether OTC hearing aids should be subject to a 510(k) premarket notification requirement.

e. Establish any conditions for sale necessary given that OTC hearing aids will be sold without the supervision, prescription, or other involvement of a licensed hearing care professional.

f. Preempt any state and local regulations, that restrict or interfere the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids.

g. Report to Congress two years after the regulations go into effect with an analysis of any adverse reported effects.

4. The FDA Needs to Require Consumers to Take a Self-Administered Hearing Test BEFORE Purchasing OTC Hearing Aids

The WHO and other health authorities have overwhelmingly demonstrated that impaired hearing is a major threat to public health. The record also clearly shows there is substantial reluctance by many people to seek and obtain medically-proper hearing care, in part because of poor consumer experiences with hearing amplification devices which have not been professionally prescribed, fitted, and adjusted. In

[4] Public Law 115-52, FDA Reauthorization Act of 2017, Sec. 709, Regulation of over-the-counter hearing aids.

order for FDARA's hearing health goals to be achieved, the FDA will need to require that consumers take a simple self-administered to determine if they would benefit from the device *before* purchasing it.

If the results of the self-administered hearing test show that the consumer's hearing is not impaired, the consumer would be informed of the results and that he or she has no need for a hearing aid. Conversely, if the consumer's hearing loss exceeds "moderate" hearing impairment, the potential user would then be informed that the OTC device is not intended for their use and that they should seek assistance from a licensed hearing care professional for further consultation. Adult consumers who do have mild to moderate hearing loss would be given an assessment of their hearing and informed that an OTC hearing aid may be right for them.

Existing technology makes it easy to provide consumers with a completely self-administered hearing test. The test could be available as a smartphone app or incorporated into the OTC device itself and used as a mechanism for purposes of self-fitting and calibration. If the device is not right for the consumer, the potential user would then be allowed to return the device and obtain a full refund.

It is important to note that a self-administered hearing test that uses a smartphone app or a testing capability built into OTC hearing aids is fully consistent with the FDARA requirement that the devices be available "without the supervision, prescription, or other order, involvement, or intervention of a licensed person…." By instituting a pre-purchase hearing test requirement, the FDA will protect consumers while improving public health.

5. The Need to Revise Existing Regulations to Ensure Safety and Prevent Consumer Confusion

Traditional hearing aids are currently being sold DTC in about 40 states to consumers in all states without the support or involvement of a licensed hearing care professional. When OTC hearing aids start being sold, they will also be sold to consumers without the involvement of a hearing care professional.

Hearing aids that are sold DTC without the intervention of a trained hearing care professional—irrespective of whether they are are traditional or OTC—are a threat to user's existing level of hearing. It is easy to see how a hearing aid with the volume set too high is going to harm the user's hearing. This is of particular concern with traditional hearing aids that may be designed for individuals for severe hearing loss. If a consumer needs to use a traditional hearing aid, it is critical that the hearing aid be prescribed by a trained professional,who can customize the device for maximum efficacy while ensuring patient safety.

The FDA needs to update its hearing aid prescription regulations. Traditional and OTC hearing aids are different types devices that are regulated distinctly and are intended to treat different conditions in different patient populations. For example, traditional hearing aids may be prescribed to both adults and children who suffer from a wide range of hearing impairments. By contrast, OTC devices are intended only for adults who have mild-to-moderate hearing impairment. However, unless the FDA updates its hearing aid dispensing regulations, consumers are not going to be able to disentangle traditional hearing aids from OTC hearing aids from non-medical PSAPS, all of which are going to be similarly marketed to people who think they there is not what to used to be. Incorrect purchase decisions and failed consumer attempts to improve their hearing will be inevitable. The potential of OTC hearing aids to make broad improvements in public hearing health will not be realized.

To limit consumer confusion between traditional and OTC hearing aids, and the associated mistreatment of hearing loss, the FDA should make minor revisions to 21 CFR 801.420 and 21 CFR 801.421 to establish a requirement that traditional hearing aids may be sold only by licensed professionals, including ear specialists, audiologists, or a hearing aid dispenser (often referred to as hearing instrument specialist, hearing aid specialist, or other similar term in state law) who are licensed under State, Local or Tribal law. The FDA already has the authority to impose this licensure requirement (see, 21 U.S.C. §360j(e)(1)(A)). Under the updated regulations, consumers would continue to be able to purchase traditional hearing aids via DTC, but these small changes will ensure that trained, licensed hearing care professionals are available to help them purchase a device that is safe and effective.

6. Output and Gain Limitations Provide the Minimally Necessary Technical Requirements to Ensure OTC Device Safety and Effectiveness.

The NASEM report stressed the importance establishing strong regulatory controls to ensure safety and effectiveness (NASEM, p. 190). Congress agreed with NASEM in this regard, directing FDA through FDARA to set regulatory "requirements that provide reasonable assurances of the safety and effectiveness of over-the-counter hearing aids," including establishing output limits.

In order to establish a regulatory framework that establishes a minimally necessary level of safety and effectiveness, FDA should limit both output and gain for OTC hearing devices. These technical limitations are paramount to ensuring that OTC hearing aids will not be used by individuals suffering from hearing impairment that exceeds a "moderate" level—individuals that Congress expressly made clear were not intended users of OTC devices.

Output is the upper limit of amplification which is measured in sound pressure level (SPL), referenced in decibels (dB) which is a logarithmic measure of the loudness of sound. For regulatory purposes, the maximum loudness for a device is measured through a process known as Output Sound Pressure Level 90 (OSPL90). This is the output saturation sound level (SSPL) to a 90dB sound input and is measured over a frequency range. A 90dB sound level is equivalent to a screaming child, a very loud sound. The need for regulatory standards on the maximum output of an OTC hearing aid is self-evident since an overly loud sound, even briefly, could cause harm to a person's hearing.

Gain, the second key aspect of hearing aid performance that needs to be regulated, is the difference between the SPL of the incoming sound and the output. In short, gain helps determine clarity when the sound is amplified. Modern hearing aids perform sophisticated audio processing to maximize the device's effectiveness in a wide range of settings and situations. Controlling gain is a key part of this processing and hearing aids often offer automatic gain control. Moreover, advanced hearing aids may provide different levels of gain in different frequency ranges to meet the specific hearing needs of each user. However, if the gain is too high in relation to the output, the amplifier will not be able to properly reproduce the incoming audio signal and the result is distortion. The distortion would sound like a stereo speaker with too much volume going through it. This type of distortion would reduce the effectiveness for the hearing device. A secondary concern is that this leads to very poor understanding in noise. Full On Gain (FOG), which is "the gain when the volume control is set to maximum" is measurement used to describe the gain found in a hearing device.

Regarding OTC hearing aids, different organizations have different recommendations for output and gain limits. For example, the four leading hearing health professional associations recommend output be restricted to 110 dB SPL and that the maximum FOG be 25dB.[5] Consumer electronics manufacturers favor limiting output to 120 dB SPL and do not recommend any specific gain limitation. However, based on peer reviewed information, the better recommendation to provide reasonable assurances of safety and effectiveness would be for FDA to establish an OSPL 90 limitation of 110 dB and FOG limitation of 25 db. This is confirmed by real-world data from audiograms of over 28,000 adults that show commercially-available hearing aids programmed according to parameters typical of those used for individuals with mild-to-moderate hearing loss yield output and gain levels that are well within the recommended limits (110 dB SPL output and 25 dB gain) of the four leading professional hearing care associations and endorsed by the Hearing Industries Association (HIA), the national association representing hearing aid manufacturers.[6]

7. 510 **Premarket Notification: The Foundation for a Smart Regulatory Enforcement Program**

Before a company is allowed to sell a medical device intended for human use, it needs to first demonstrate to FDA that the device is a safe and effective for a recognized medical condition. FDA has established three classes of medical devices (I, II, and III) with more stringent regulatory controls placed on the higher device classes.

Class I medical devices include many low risk items commonly found in doctors' offices such as tongue depressors, canes, and various types medical tables and chairs. These items are generally exempt from regulatory review unless they are going to be sold for novel uses. Class II and III devices are subject to greater oversight.

For novel devices or novel uses of an approved device, the agency requires an extensive Premarket Approval Application process. However, most new medical devices are substantially equivalent to at least one device which has already been approved. These "me to" devices can go through the FDA's "510(k)" process, which is used to demonstrate that the device to be marketed is as safe and effective as a substantially equivalent legally marketed device.

Traditional non-implantable hearing aids may be regulated as (1) Class I devices that are exempt from premarket review and clearance before marketing per 21 CFR 874.3300(b)(1), (2) Class II devices which require premarket review and clearance by FDA before marketing per 21 CFR 874.3300(b)(2) and 21 CFR 874.3950 or (3) Class II devices that are[7] exempt from premarket review and clearance before marketing (21 CFR 874.3305). Thus, some but not all, Class II devices are exempt from the 510(k) substantial equivalence process.

With respect to OTC hearing aids, Section 709(b)(3) of FDARA directs the FDA "to determine whether" these devices should be required to go through the 510(k) premarket process. In 2019, the FDA

[5] American Academy of Audiology (AAA), Academy of Doctors of Audiology (ADA), American Speech-Language-Hearing Association (ASHA), International Hearing Society (IHS), Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness (Aug. 2018), *available at* https://www.asha.org/uploadedFiles/Consensus-Paper-From-Hearing-Care-Associations.pdf (last visited Oct. 30, 2020).

[6] Tedeschi T., Jones C., and Stewart. Real World Evidence on Gain and Output Settings for Individuals with Mild-to-Moderate Hearing Loss. *The Hearing Review* (July 2020).

[7] See, Sec. 2, Hearing Aids https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products-draft-guidance

determined that self-fitting hearing aids would be subject to the agency's 510(k) process. This decision was made in response to a De Novo product application requested by a consumer electronics manufacturer to establish a new generic category of hearing aids of the type that potential users would have the ability to self-fit but for which there was no substantially equivalent product in the market.

The FDA explained, in its Final Order establishing this new generic category of hearing aids called "self-fitting air-conduction hearing aids" (as regulated under 21 CFR 874.3325), that manufacturers of devices that similarly incorporate self-fitting technology, including software, enabling users to independently derive and customize their hearing aid fitting and settings could use the 510(k) process to obtain premarket clearance. Because OTC hearing aids will incorporate technology analogous to the De Novo device, they too should be subject to a 510(k) premarket notification requirement. This will serve as the basis for a strong enforcement program.

8. Strong Enforcement Program is Necessary

In its FY 2021 budget request to Congress, the FDA and its Center for Devices and Radiological Health (CDRH) emphasized that it is moving rapidly toward its long-standing goal of ensuring the safety of medical devices through "an active surveillance system that relies on real-world evidence and timely receipt of robust safety information."[8] An effective post-market active surveillance system for medical devices must allow (1) consumers to report any suspected problems and (2) encourage manufacturers to be rapidly aware of any device-related problems so that they can be addressed as quickly as possible. The 510(k) process provide the necessary database for achieving these goals.

The FDA currently places approvals of 510(k) filings online and provides a searchable database. However, the search tools are not user friendly and the database does not provide access to all 510(k) information. In order for FDA to comply with its statutory mandate to "submit to Congress a report analyzing any adverse events relating to over-the-counter hearing aids" two years after the final regulation is issued, and to meet the agency's own post-market surveillance goals, it should place all 510(k) information for OTC hearing aids online in a dedicated, consumer-friendly database.

Furthermore, FDARA requires that the OTC hearing aid labels include "information on how consumers may report adverse events." To meet this directive, FDA must first develop an effective reporting mechanism. This can be achieved by developing a dedicated, consumer-friendly database for OTC hearing aids that allows consumers to report adverse events or submit complaints, both of which the FDA should utilize to as part of a strong enforcement program to ensure safety and effectiveness is achieved.

SUMMARY AND RECOMMENDATIONS

1. **Output and gain limits**. To ensure that OTC hearing aids are safe, effective, and used only by individuals with mild to moderate hearing impairment, as required by FDARA, the FDA should impose technical requirements that limit OTC devices to:
    a. 110 dB output limit (OSPL90); and
    b. 25 dB Full on Gain limit.

[8] Department of Health and Human Services, Food and Drug Administration (HHS/FDA), "Fiscal Year 2021Justification of Estimates for Appropriations Committees.

2. **Mandatory self-administered hearing tests should determine intended users.** In order for potential users to adequately determine whether or not OTC hearing aids are intended for their use, the FDA should require potential users to undergo an evaluation of their hearing loss through a self-administered hearing test. If the results of the self-administered hearing test show that a potential user's hearing loss exceeds "moderate" hearing impairment, the potential user should not be permitted to use an OTC hearing aid but should instead be directed to seek help from a licensed physician (one specializing in the diseases of the ear), an audiologist, or hearing instrument specialist.

3. **Licensure requirement to dispense traditional hearing aids.** To ensure that the new OTC hearing aid category remains distinct from the traditional hearing aid categories, the FDA should revise its existing hearing aid regulations to limit dispensing of traditional non-OTC devices (874.3300, 84.3305, and 874.3325) to ear specialists, audiologists, and dispensers as defined by FDA and licensed under state law.

4. **Use the 510(k) Process as the Basis for Market Surveillance, Strong Enforcement and Congressional Reporting**. Consistent with the policy established by the FDA in its establishment of the "Self-Fitting Air-Conduction Hearing Aid," OTC hearing aid manufacturers should be required to obtain premarket clearance through the 510(k) process to market their device. The FDA should place all 510(k) substantial equivalence information for OTC hearing aids in an online publicly available database. This database, along with any reported adverse events or complaints, should be used as the basis for a strong enforcement program to protect the public and to report to Congress on any OTC hearing aid adverse events.

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