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January 18, 2022

Janet Woodcock, M.D.
Acting Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Docket No. FDA-2021-N-0555 for "Establishing Over-the-Counter Hearing Aids"

Dear Commissioner Woodcock:

The Hearing Loss Association of America (HLAA) and the undersigned organizations hereby submit comments for the Food and Drug Administration's (FDA) Notice of Proposed Rulemaking Establishing Over-the-Counter Hearing Aids (NPRM on OTC Hearing Aids).

HLAA has been at the forefront of efforts to expand consumer choice of hearing devices for many years. We provided consultation for the President's Council of Advisors on Science and Technology (PCAST) whose 2015 report recommended that the FDA approve a class of hearing aids for over-the-counter sale. In addition, HLAA was the only consumer advocacy organization sponsoring the work of a committee of the National Academies of Sciences, Engineering, and Medicine (NASEM) whose final report in 2016, "Hearing Health Care for Adults: Priorities for Improving Access and Affordability" similarly recommended the FDA create a new category of over-the-counter hearing aids. HLAA was also a visible presence supporting the Over-the-Counter Hearing Aid legislation that became law in 2017 and authorized the agency to promulgate the regulations.

For more than 40 years HLAA has been the voice of consumers with hearing loss. Consumers turn to us for information regarding a wide range of issues related to hearing loss. However, the most common questions we field are regarding the cost of hearing aids. People with hearing loss want to know about their options if they cannot afford a hearing aid. Until this proceeding, there has been precious little to tell them.

Summary

HLAA and the undersigned organizations applaud the FDA's work on the NPRM on OTC Hearing Aids. We welcome the opportunity to provide a consumer perspective on several of the issues raised in this NPRM and urge the FDA to adopt these recommendations.

To address the need for accessible and affordable hearing aids under this NPRM we recommend the FDA:

1. **Classify all over-the-counter hearing aids as self-fitting.**
2. **Require manufacturers to demonstrate safety and effectiveness, especially focusing on usability without professional intervention.**
3. **Add critical labeling information to external and internal packaging, as well as online.**
    a. **Require that information about needed adjunctive technology (such as a smartphone) is included outside the package, inside the package and online.**
    b. **Require that information about compatibility with wireless device use for telecommunications is included outside the package, inside the package and online.**
    c. **Require that information about connectivity to other devices is included outside the package, inside the package and online.**
    d. **Require that information is provided in sufficiently large font outside the package and inside the package to be accessible to all members of the target population.**
4. **Require a free (full refund) 45-day trial period, prohibiting any undisclosed fees.**

Discussion

HLAA and the undersigned organizations collectively advocate for equal access for the over 48 million Americans who are deaf, hard of hearing, DeafBlind, or who have those and additional disabilities. The research organization, DHH-RERC[1], works in conjunction with the other signatories to address the technical challenges faced in securing access to technology.

HLAA and the undersigned speak for consumers with hearing loss, and therefore confine our remarks to consumer issues. Many of those consumers will be empowered by these rules to take control of their own hearing health and the technology they use. We support such changes as long as consumer protections are in place. Further, we support technical performance specifications that ensure the device is fully capable of meeting the hearing needs of the target

[1] These comments were developed in part under a grant from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR grant number 90REGE0013). NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of these comments do not necessarily represent the policy of NIDILRR, ACL, HHS, and you should not assume endorsement by the Federal Government.

end user while also ensuring the user's experience of fidelity and comfort in the output signal received from the device.

Additionally, we seek to highlight the needs of two populations of U.S. consumers that particularly stand to gain from the availability of OTC hearing aids. The first is underrepresented minorities, such as low-income Americans and members of other historically disadvantaged communities, including racial and ethnic minoritized communities, who have historically lacked access to hearing health care.[2] As a result of these barriers to access, members of these populations are more likely to have lower health literacy, defined by the Centers for Disease Control and Prevention "as the ability to find, understand and use information and services to inform health related-decisions and actions for themselves and others."[3] On average these consumers are also less likely to have access to the internet and other technologies including smartphones, than others (the "digital divide") which may hinder access to OTC hearing aids for these communities.

The second population is older Americans, who have a high need for hearing health care. Approximately 50% of those with mild to moderate hearing loss are age 65 and over.[4] This population also faces a digital divide (only 60% of those over 65 own a smart phone).[5] In addition, older Americans are more likely to have low vision, and so may struggle to read small print text. They may have limited manual dexterity and may have difficulty using small devices that require fine motor skills to manipulate.

Our expectation is that the expense of OTC hearing aids will be less than professionally-fit hearing aids, but still will be substantial for many Americans, particularly for the groups discussed above. To create a vibrant and inclusive market for OTC hearing aids, it will be important to protect consumer interests and anticipate consumer beliefs and capacities that reflect the realistic needs of a diverse population while minimizing financial risk.

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[2] Committee on Accessible and Affordable Hearing Health Care for Adults; Board on Health Sciences Policy; Health and Medicine Division; National Academies of Sciences, Engineering, and Medicine. Hearing Health Care for Adults: Priorities for Improving Access and Affordability. Blazer DG, Domnitz S, Liverman CT, editors. Washington (DC): National Academies Press (US); 2016.

[3] Centers for Disease Control and Prevention. What is health literacy? https://www.cdc.gov/healthliteracy/learn/index.html

[4] Goman AM, Lin FR. Prevalence of hearing loss by severity in the United States. American Journal of Public Health. 2016;106(10):1820-2.

[5] Pew Research Center. April 7, 2021. Mobile fact sheet. https://www.pewresearch.org/internet/fact-sheet/mobile/

RECOMMENDATIONS

1. **Classify all over-the-counter hearing aids as self-fitting.**

HLAA and the undersigned organizations recommend removing "self-fitting" from the hearing aid classification and explicitly defining the OTC classification as self-fitting.

We also recommend the application of the special controls already in place for self-fitting hearing aids as currently defined, specifically clinical data evaluating the self-fitting strategy, for all OTC devices.

The FDA welcomes comments on the definitions pertinent to the regulation of OTC hearing aids. In particular, the FDA seeks comments on the clarity of the definitions and ways to improve the definitions to encourage and support the broad availability of safe and effective devices. (*See* NPRM on Over-the-Counter Hearing aids, pp. 28, 69-71, 112-113).

The FDA is proposing that "Self-Fitting" be a classification under "Air Conduction Hearing Aids," while at the same time considering self-fitting hearing aids to be eligible for regulation as OTC hearing aids. Characterizing self-fitting devices as a subgroup of the broader OTC category creates an artificial distinction among devices that all require consumers to self-adjust them and then determine if the result is both suitable and appropriate for their needs. The FDA seems to be making a distinction between: 1) devices that have controls (e.g., a volume control) and presets (e.g., a limited number of settings for different types of frequency responses), which users can select from to customize, but not fully individualize, their listening experience; and, 2) devices that have interactive software to obtain behavioral measures, which in turn are used to determine specific, individualized targets for the output of the hearing device. This distinction is subtle, and therefore, likely confusing for the consumer.

The range of user interfaces consumers may interact with to adjust OTC devices is large, from selecting among common presets at one extreme to utilizing an interface shown to result in audiologist-equivalent fittings at the other extreme. However, this does not alter the fact that for all OTC devices it is still the end-user making these selections and adjustments themselves in order to achieve their desired goal.

The universal, underlying characteristic of all OTC devices is that they are self-fit, and as such HLAA and the undersigned organizations recommend removing "self-fitting" from the hearing aid classification and explicitly define the OTC classification as self-fitting OTC. We also recommend the application of the special controls already in place for self-fitting hearing aids as currently defined, specifically clinical data evaluating the self-fitting strategy, for all OTC devices.

2. **Require manufacturers to demonstrate safety and effectiveness, especially focusing on usability without professional intervention.**

HLAA and the undersigned organizations recommend that manufacturers of OTC hearing aids demonstrate safety and efficacy the way that self-fit hearing aids are defined under § 874.3305, focusing, in particular, on (iv) usability testing.

For OTC hearing aids, usability is a crucial, yet different, aspect of device efficacy than hearing assistance benefits. To achieve and maximize hearing assistance benefits, the user interface (UI) and user experience (UX) are likely to be key for OTC devices because they are all "self-fitting." The UI and UX of these devices have the potential to affect rates of uptake and continued use. Good UI and UX can avoid what the FDA and others refers to as "leaving the device in the dresser drawer," but the FDA only mentions hearing needs and not usability in considering this phenomenon. Usability enhances and may even be a critical linchpin for achieving effectiveness.

With the introduction of the OTC hearing aid, safety and effectiveness are of paramount importance. According to the FDA's website: "The FDA regulates the sale of medical device products. Before a medical device can be legally sold in the U.S., the person or company that wants to sell the device must seek approval from the FDA. To gain approval, they must present evidence that the device is reasonably safe and effective for a particular use." FDA's Role in Regulating Medical Devices | FDA

The FDA should ensure that manufacturers of OTC hearing aids, due particularly to their self-fitting nature by lay individuals, demonstrate that they have followed human factors or usability engineering processes during device development, focusing especially on the user interface.

HLAA and the undersigned organizations recommend that manufacturers of OTC hearing aids demonstrate safety and effectiveness the way that self-fitting hearing aids are defined under § 874.3305, focusing, in particular, on (iv) usability testing. Manufacturers should be required to submit documentation that the intended population (and, in particular, the populations mentioned above) are able to achieve safe and effective device use without professional intervention.

3. **Add critical labeling information to external and internal packaging, as well as online.**

In the NRPM on OTC Hearing Aids, the FDA invited comment on labeling for outside the package, inside the package and online. HLAA and the undersigned organizations support the FDA's proposed requirements for labeling. We agree that it should be clear outside the package

that these products are intended for adults over 18 years of age and that the "red flag" conditions should be included. In addition, we fully support the FDA's proposal to make this information readily available online to consumers before purchase of these devices. (§800.30 (c) (1) (i) (E) Notice of Weblink and telephone number for information and (c) (2) Labeling, inside the package. NPRM on OTC Hearing Aids pp. 58177-58179).

However, more information is needed for consumers to be able to properly compare and purchase an OTC hearing aid that works for them. Without the guidance of a hearing health professional, it is critical that consumers can access the information they need to judge and compare products in order to select and purchase the most appropriate product for their needs. We have these additional recommendations for labeling:

a. Require that information about needed adjunctive technology (such as a smartphone) is included outside the package, inside the package and online.

It is essential that consumers know whether they will need adjunctive technology (e.g., smartphones or tablets) to set up and/or use their OTC hearing aid. Our industry contacts have told us that many of the devices that are under development for the OTC market have this requirement. Some devices will require the consumer to download an app to a smartphone or tablet in order to select initial settings. Other devices will employ an app to make further adjustments, or selections (e.g., volume adjustments, program selections, or the selection of connectivity features to engage).

Consumers who do not own the appropriate adjunctive technology will not be able to use these devices. Therefore, consumers should be clearly informed prior to purchase whether adjunctive technology is needed, and if additional technology is needed, what specific technology is required. Those without adjunctive technology tend to come from low-income communities, and from the older population, according to the Pew Research Center. For example, while smartphone ownership is close to 100% among Americans with household incomes over $100K, it is only 76% among those with household incomes under $30K. Ownership is nearly 100% among people between ages 18-29 but only 61% among those aged 65 and over.

It seems plausible that consumers new to hearing device use would not anticipate that an OTC hearing aid would require the use of adjunctive technology such as a smartphone or tablet. Clear external labelling about needed adjunctive technology is essential for making an informed purchase.

HLAA and the undersigned organizations recommend that outside the package, inside the package and online include one of these two statements:

> ***You will need additional technology in order to set up and/or use this hearing aid. Use and/or set up of this hearing aid requires: [e.g., the download and use of a software application on a smartphone or tablet.]***
>
> ***You do not need additional technology in order to use this hearing aid.***

b. Require that information about compatibility with wireless device use for telecommunications is included outside the package, inside the package and online.

Currently, mobile wireless service providers and device manufacturers are required to offer a specific number of handsets that are compatible with or do not cause interference with hearing aids and cochlear implants. Packages containing hearing aid compatible wireless handsets must be explicitly labeled and must include detailed information about the handset rating system in the package or product manual under rules promulgated by the Federal Communications Commission (FCC). (CFR Title 47 Chapter I, Subchapter B, Part 20, § 20.19, eCFR: 47 CFR 20.19 -- Hearing aid-compatible mobile handsets.)

However, the mobile device is only half of the equation. Hearing aids must be able to interface with wireless handsets to be usable by the consumer. For years, a rating system similar to the wireless handset rating system has been in effect for hearing aids, but those ratings have not been available to consumers.

We believe it is important to be transparent about the status of a hearing aid's RF (Radio Frequency) immunity for wireless device compatibility for both OTC hearing aids and prescription hearing aids. RF immunity should be tested and reported in accordance with ANSI C63.19-2019–in both microphone (M) and, if present, telecoil (T) coupling modes. The information should be readily apparent to the consumer by having this information outside the package, inside the package and online.

HLAA and the undersigned organizations recommend the FDA include the following language to inform the consumer whether or not a hearing aid is compatible with a wireless device for telecommunications.

> ***This device has been tested for and is compatible with wireless phone use for telephone calls.***
>
> ***This device has not been tested for compatibility with wireless phone use for telephone calls.***
>
> ***This device is not compatible with wireless phone use for telephone calls.***

c. Require that information about connectivity to other devices is included outside the package, inside the package and online.

Hearing aids work best for individuals when the sound source is within approximately six feet of the microphones on their hearing aids. If the consumer wearing the hearing aids is farther away from the sound source or the environment is noisy, reverberant or otherwise interferes with the desired sound, the effectiveness of the hearing aid may be compromised, reducing the ability of the consumer to fully access the information needed. Assistive listening devices and systems and systems with direct wired and wireless connectivity have worked to mitigate these problems.

Difficult listening situations may be less problematic for people with mild to moderate hearing loss than for individuals with more severe hearing loss. However, it is also the case that degree of hearing loss alone is not fully indicative of the degree to which someone with hearing loss will struggle in difficult listening situations. What we do know definitely is assistive listening systems are effective in mitigating problems with speech understanding, communication performance and satisfaction, and listening effort that occur in difficult listening situations. For consumers who need an over-the-counter device or a prescription hearing aid with connectivity features beyond simple microphone coupling to the ambient acoustic environment, we believe it is in the best interests of the consumer to be fully informed regarding a hearing aid's ability to connect to other devices and the modes of connectivity offered.

HLAA and the undersigned organizations recommend the FDA require labeling that provides information about connectivity options for both over-the-counter and prescription hearing aids for all modes of wireless connectivity supported by the device (e.g., telecoil, Bluetooth, etc.).

The following is example language. The exact language used would depend on the type of technology available for connectivity. By simply stating all modes of connectivity supported by the device, future technology developments in the area of audio connectivity can easily be accommodated.

This device is Bluetooth enabled for audio connectivity.

This device contains a telecoil for audio connectivity.

d. Require that information is provided in sufficiently large font outside the package and inside the package to be accessible to all members of the target population.

As noted previously, mild-to-moderate hearing loss occurs disproportionately in older adults: approximately 50% of those with mild to moderate hearing loss are age 65 and over.[6] Older Americans are more likely to have low vision, and so may struggle to read small print text. A recent analysis of the Behavioral Risk Factor Survey found that 38% of Americans aged 50 and older have difficulty reading print in a newspaper, magazine, recipe, menu, or numbers on the telephone.[7]

Larger font size helps those with low vision read better. While sources suggest no smaller than 12-point sans serif font we do not recommend a particular standard. Rather we note that if the packaging information appears in a tiny font, the information will simply not be accessible to or useful for many consumers.

4. Require a free (full refund) 45-day trial period, prohibiting any undisclosed fees.

The FDA proposes requiring manufacturers either disclose their return policy or if, none, state that they do not accept returns. We applaud the FDA's awareness that OTC hearing aids may not meet consumer's needs, and the consequent risk that devices will become a "dresser drawer" accessory. However, if the preemption rules of this NRPM on OTC hearing aids become final, it

[6] Pew Research Center. April 7, 2021. Mobile fact sheet. https://www.pewresearch.org/internet/fact-sheet/mobile/

[7] McGwin G, Khoury R, Cross J, Owsley C. Vision impairment and eye care utilization among Americans 50 and older. Current Eye Research. 2010 Jun 1;35(6):451-8.

appears that over-the-counter hearing aids will not be subject to those state laws that mandate free return periods as there are currently for conventional hearing aids in some states. If over-the-counter hearing aids are not covered by state law, this will place the consumer who purchases an OTC hearing aid at an unfair disadvantage relative to the consumer who can afford a prescription device.

Because of this and other issues outlined below we recommend the FDA require a trial period of at least 45 days with the ability to return a device. Further, the terms and conditions of returns and any associated fees should be reasonable, transparent and made available to the consumer to read before purchase. Likewise, a written warranty of what the manufacturer offers in terms of repair and replacement of a faulty product should be made available to the consumer to read before purchase.

A trial period of at least 45 days is needed because hearing aids typically require an adjustment period. Multiple sources, both manufacturers and hearing health professions, advise consumers that it takes some time to adjust to hearing using a hearing aid[8]. Depending on the individual, it can take months to feel comfortable listening through a hearing aid.

In addition, some consumers may need to readjust to simply hearing more than they are used to hearing. We believe it is in the best interests of consumers to allow time to adjust to listening using over-the-counter hearing aids.

Returns are important because many consumers of OTC hearing aids will be unfamiliar with hearing aids and may need to try multiple devices. Market analysis shows that the typical OTC hearing aid buyer will be hearing aid naïve.[9] Hearing aid naïve consumers may not know they may need to try a series of devices to find one that works for them. While experienced hearing aid users are likely to be familiar with this phenomenon, consumers without prior experience with hearing aids may not have entertained this possibility, especially those with low health literacy.

Returns are also important because some consumers may be unable to use their OTC device independently. By law, OTC hearing aids give the user control of the aids without the involvement of a hearing health care professional. This places OTC aids in sharp contrast to prescription hearing aids, where selection, fit, education and ongoing support is provided by a hearing health care professional such as an audiologist or hearing aid dispenser. Evidence suggests that some consumers may struggle with their self-fitting hearing aids.

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[8] https://www.consumerreports.org/hearing-aids/how-to-get-used-to-hearing-aids/; https://www.webmd.com/healthy-aging/new-hearing-aid#1; https://www.healthyhearing.com/report/51911-How-to-help-a-loved-one-get-accustomed-to-new-hearing-aids;

[9] Powers TA, Rogin CM. MarkeTrak 10: Hearing aids in an era of disruption and DTC/OTC devices. *Hearing Review*. 2019;26(8):12-20.

Dr. Elizabeth Convery, an expert in self-fitting hearing aids, says that "people with hearing difficulties and poor cognitive function, lower self-efficacy for hearing aid use, or a more externally oriented locus of control (a belief that life events are influenced by chance luck, or other people, as opposed to one's self) may be unsuccessful with OTC hearing aids."[10]

We do not yet fully know how readily useable OTC hearing aids will be. Given that independently self-fitting hearing aids may not be achievable for some, it is important to allow consumers to return OTC hearing aids if they find they cannot use them within 45 days of purchase.

HLAA and the undersigned also recommend that the FDA prohibit any fees that have not been fully and clearly disclosed to the consumer before purchase of the OTC hearing aid. Any expenses, such as shipping and handling charges, should be prominently displayed at a minimum inside the package and online before purchase.

HLAA and the undersigned organizations recommend the FDA require a trial period of at least 45 days for return of over-the-counter hearing aids. We also recommend that any fees that are not disclosed to the consumer before purchase are prohibited.

HLAA and the undersigned thank the FDA for this opportunity to provide comments on this proposed rule. We stand ready to work with the FDA to ensure that consumers have the education and information they need to ensure they have access to and benefit from the full range of options to achieve the hearing technology that is best for them.

Respectfully submitted,
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[10] Convery E. Meeting the challenges of OTC: Who are self-fitting hearing aids really for? Hearing Review. 2020. https://hearingreview.com/hearing-products/hearing-aids/ot`c/meeting-the-challenges-of-otc-who-are-self-fitting-hearing-aids-really-for

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