January 17, 2022

U.S. Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20857
Submitted Electronically

Re: Docket No. 2021-N-0555, U.S. Food and Drug Administration (FDA) Proposed Rule, Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

Dear Acting Commissioner Woodcock,

The Academy of Doctors of Audiology (ADA) appreciates the opportunity to submit comments regarding Docket No. 2021-N-0555, the U.S. Food and Drug Administration (FDA) Proposed Rule: Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids (Proposed Rule).

ADA is the premiere network and resource for independent audiologists and the leading national authority on audiology private practice. ADA aims to advance evidence-based clinical and business practices in the provision of audiology services, professional autonomy, and patient choice.

Hearing health is a public health issue. The cost of hearing aids and the stigma associated with hearing loss are irrefutable barriers to hearing healthcare for millions of Americans. ADA applauds FDA's efforts to establish regulations for over the counter (OTC) hearing aids to address these critical unmet needs.

ADA acknowledges the financial risks to traditional hearing aid dispensing businesses presented by the Proposed Rule as summarized in the Preliminary Regulatory Impact Analysis (PRIA). ADA also recognizes that audiologists who deliver high-quality hearing and balance services will continue to serve as an essential resource and partner for consumers. In fact, ADA believes that the availability of OTC hearing aids will present new and expanded opportunities for audiologists to help patients optimize their hearing health throughout their lifetime.

For these reasons, ADA has been a longstanding proponent of public policy initiatives that improve access to affordable hearing healthcare services and treatments, including OTC hearing aids.

- ADA issued statements of support for recommendations made by the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Science Engineering and Medicine (NASEM) to allow consumer access to OTC hearing aids in 2015 and 2016 respectively.[1,2]
- ADA delivered public testimony supporting consumer access to OTC hearing aids during the FDA Public Workshop, "Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids," held on April 21, 2016.[3]
- An ADA representative served as an expert panelist to provide testimony to the Federal Trade Commission (FTC) during its 2017 Public Workshop, "Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Healthcare, held on April 18, 2017.[4]
- ADA's written testimony, in support of H.R. 1652/S. 630, The Over-the-Counter Hearing Aid Act, was recognized and praised by the bill's co-sponsors in 2017.[5]

[1] https://hearingreview.com/inside-hearing/industry-news/ada-lends-qualified-support-pcast-recommendations
[2] https://www.audiologypractices.org/headquarters-report-sept-2019
[3] Announcement of FDA Workshop, Streamlining Good Manufacturing Practices. 2016. https://www.fda.gov/news-events/press-announcements/fda-engages-stakeholders-opportunities-improve-hearing-aid-usage-and-innovation
[4] Video and transcript of FTC Workshop: Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Healthcare held on April 18, 2017. https://www.ftc.gov/news-events/audio-video/video/now-hear-competition-innovation-consumer-protection-issues-hearing
[5] Recording and transcript of Energy and Commerce Health Subcommittee hearing held on May 2, 2017. https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/20170502-HE%20Examining%20Improvements%20to%20the%20Regulation%20of%20Medical%20Technologies.pdf

ADA enthusiastically supports the Proposed Rule overall and supports its goal to increase competition, expand product choices, reduce prices, and remove existing channel restrictions encountered by consumers. ADA offers constructive recommendations for FDA consideration.

CATEGORIZATION OF HEARING AIDS

ADA supports the proposed categorization of hearing aids by conduction technology (bone conduction or air conduction) and the proposed subcategorization of air conduction hearing aids as either OTC hearing aids or prescription hearing aids, as determined by their intended use and/or technical, design, and performance specifications.

ADA respectfully submits the following recommendations related to hearing aid categorization for consideration:

- **ADA recommends that FDA develop a pathway that will allow air conduction hearing aids to be upgraded from OTC hearing aids to prescription hearing aids through the use of hardware and/or software fitting expansion capabilities, that can be accessed by a licensed dispenser, in consultation with the consumer/patient, to make fitting adjustments, and download updated labeling and packaging requirements as needed.**
- **ADA recommends that FDA provide a pathway and guidance for licensed dispensers to designate an OTC hearing aid for OTC or prescription use, based on whether the hearing aid is intended to be used by an adult or a child.**

The Proposed Rule does not address tinnitus maskers, which are currently categorized as Class II restricted devices under 21 CFR §874.34. Tinnitus maskers are subject to special controls requiring labeling that indicates the need for a diagnosis, professional fitting, and follow up care, and tinnitus maskers are distributed to licensed providers who are familiar with the diagnosis and treatment of tinnitus. *ADA seeks more information from FDA about whether tinnitus maskers (and/or hearing aids with tinnitus maskers) will be categorized as restricted devices or as prescription devices under the final rule.*

It is ADA's understanding that the Federal Trade Commission (FTC) has jurisdiction of advertising and marketing for medical devices apart from "restricted" devices. *As such, ADA seeks additional information about whether the FTC will play an increased role in oversight of the advertising of OTC hearing aids and/or prescription hearing aids when the rule is finalized or whether FDA will retain jurisdiction for those activities.*

TECHNICAL, DESIGN, AND PERFORMANCE SPECIFICATIONS: OUTPUT AND GAIN LIMITS

ADA notes that many of the public comments on the Proposed Rule, submitted to date, urge FDA to reduce the allowable output limit for OTC hearing aids to 110 dB SPL at any frequency, regardless of whether the device is equipped with input-controlled compression and user adjustable volume control, and suggest a high frequency average (HFA) full on gain limit of 25 dB as defined for measurement in a 2cc coupler, with an input level of 50 dB SPL per ANSI S3.22-2014.

These public comments often mirror and reference consensus recommendations that were developed by ADA and other hearing healthcare associations contained in *"Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness, Consensus Paper from Hearing Care Associations,"* (Consensus Paper) published in August 2018.[6]

[6] Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness, Consensus Paper from Hearin gCare Associations, August 14, 2018. https://hearinghealthmatters.org/hearingnewswatch/2018/consensus-otc-hearing-aid-classification/

The FDA Proposed Rule includes the following output limits for an OTC hearing aid (the device maximum acoustic output sound pressure level (SPL) in a 2-cubic centimeter (cm3) coupler when the device input is a 90 dB SPL pure-tone, and the gain/volume control is full on):

(1) General output limit. An OTC hearing aid shall not exceed an output limit of 115 dB SPL at any frequency except as provided in paragraph (d)(2) of this section.

(2) Output limit for a device with input-controlled compression and user adjustable volume control. An OTC hearing aid that includes input-controlled compression and a user adjustable volume control shall not exceed an output limit of 120 dB SPL at any frequency.

The FDA Proposed Rule forgoes a gain limit requirement for OTC hearing aids. FDA provides a rationale as follows:

"We are proposing not to limit the device gain because we believe that the proposed maximum output limit (together with the other proposed requirements) will provide reasonable assurance of safety and effectiveness without limiting the device gain also. Moreover, a gain limit may unduly constrain the design of effective devices. Appropriate gain characteristics can depend on the implementation of the amplification circuit design (e.g., linear amplification versus wide dynamic range compression). Thus, appropriate gain settings for one device may not be appropriate for another device of a different design. We believe that allowing flexibility in the gain settings will help maximize the effectiveness of the particular circuit design a manufacturer implements for a device to address perceived mild to moderate hearing loss. In light of this, and since a maximum output limit would also in effect limit gain, we do not believe a separate, additional gain limit is necessary to provide reasonable assurance of safety and effectiveness."[2]

ADA analyzed FDA's proposed output limits and decision to forgo gain limits for OTC hearing aids, as specified in the Proposed Rule, using the assumptions and evidence cited in the Consensus Paper, as well as new information and evidence. ADA's findings produced evidence-based recommendations that, if adopted, will enhance the Proposed Rule.

ADA respectfully submits the following recommendations for output limits and gain requirements for OTC hearing aids for FDA consideration:

- **ADA urges FDA to implement a general output limit for OTC hearing aids of 110 dB SPL at any frequency.**
- **ADA supports FDA's proposal to allow an output limit for OTC hearing aids equipped with input-controlled compression and user adjustable volume control of 120 dB SPL at any frequency.**
- **ADA supports FDA's proposal to forgo gain limitations for OTC hearing aids.**

These requirements, along with adequate product labeling and directions for use, will provide reasonable assurance of safety *and* efficacy for adult OTC hearing aid users with perceived mild-to-moderate hearing loss.

OTC hearing aids are intended for use by adults with *perceived* mild-to-moderate hearing loss. *Perceived mild-to-moderate hearing loss is subjective.* Studies show that adults' perceived hearing loss does not consistently align to the audiologic measurements of their hearing. Studies show that older adults, in particular, often perceive their hearing to be better than subsequent audiometric test results indicate.[7,8]

[7] Humes LE. An Approach to Self-Assessed Auditory Wellness in Older Adults. Ear Hear. 2021 Jul-Aug 01;42(4):745-761. doi: 10.1097/AUD.0000000000001001. PMID: 33720061; PMCID: PMC8221726.

[8] Curti SA, Taylor EN, Su D, Spankovich C. Prevalence of and Characteristics Associated With Self-reported Good Hearing in a Population With Elevated Audiometric Thresholds. *JAMA Otolaryngol Head Neck Surg.* 2019;145(7):626–633. doi:10.1001/jamaoto.2019.1020

There is no uniformly recognized scale representing the boundaries for mild-to-moderate hearing loss, measured with audiometry—therefore, its definition is also subjective. The American Speech-Language-Hearing-Association (ASHA) hearing loss scale, used to develop Consensus Paper recommendations, defines mild-to-moderate hearing loss from 26 dB to 55 dB. Other reputable hearing loss scales define mild hearing loss beginning at 15 dB and define moderate hearing loss up to 70 dB. As there is no uniform standard for the audiometric range of mild-to-moderate hearing loss, the broadest evidence-based range should be assumed when developing performance requirements for OTC hearing aids. [9,10,11]

On reflection, recommendations for output and gain limits for OTC hearing aids should not be based on a set of assumptions that unfairly narrows candidacy to first-time users with sensorineural hearing loss not exceeding 55 dB HL and requiring binaural hearing aid usage, per the Consensus Paper. Therefore, performance requirements for OTC hearing aids must be developed to meet perceived mild-to-moderate hearing loss, including the needs of experienced users as well as those with a monaural device use and/or mixed, and/or conductive loss who do not meet one the red flag warnings or who have been examined and cleared to use OTC hearing aids. [12,13]

To appropriately balance the benefits and risks of OTC hearing aids to most consumers with perceived mild-to-moderate hearing loss, ADA believes that a reasonable assurance of safety and efficacy can be best achieved by reducing *general* maximum output limits for OTC hearing aids to 110 dB SPL, which aligns with Consensus Paper recommendation. However, the intended use for OTC hearing aids, as mandated by the FDA Reauthorization Act of 2017 (FDARA), and resulting practical design and performance implications, necessitate allowance of a maximum output limit up to 120 dB SPL for OTC hearing aids, when configured with input-controlled compression and user adjustable volume control.

The benefits of input-controlled compression combined with a user adjustable volume control are discussed in both the Consensus paper and the FDA Proposed Rule. The Consensus Paper recommends input-controlled compression for all devices and incorporation of this recommendation by FDA would assist persons with mild hearing losses in adjusting the device output to less than 110 dB SPL as needed. If the FDA does not require input-controlled compression and user adjustable volume control on all devices, ADA recommends that the FDA require that at least one of the mandatory tools, tests, or software incorporate a method for the device user to reduce device output SPL to intensities below their individual loudness discomfort level(s).

ADA is concerned that a low-gain limitation (e.g., 25 dB HFA FOG) would not meet the amplification needs of many intended OTC HA device users. ADA agrees with FDA's assessment that a mandatory gain limit is unnecessary for the reasonable assurance of safety and efficacy of OTC hearing aids, and that the inclusion of a gain limit may limit competition and stifle innovation.

OTHER TECHNICAL, DESIGN, AND PERFORMANCE SPECIFICATIONS

ADA agrees with FDA's assessment that hearing aid technical data on performance characteristics gathered as specified by ANSI/ASA S3.22 are inadequate to insure minimum acceptable OTC hearing aid performance levels, and that such data cannot be readily interpreted by the intended OTC hearing aid user without involvement of a licensed professional. ADA supports Proposed Rule requirements that OTC hearing aids meet or exceed the specified performance characteristic distortion control limits, self-generated noise

[9] Degree of Hearing Loss Scale. American Speech-Language-Hearing Association. https://www.asha.org/public/hearing/degree-of-hearing-loss/
[10] U.S. Food and Drug Administration (FDA). Hearing Loss, Everything You Need to Know. https://www.fda.gov/media/83390/download
[11] Boystown Hospital. Degrees of Hearing Loss.https://www.boystownhospital.org/knowledge-center/degrees-hearing-loss
[12] Keidser, G., Dillon, H., Flax, M., Ching, T., & Brewer, S. (2011). The NAL-NL2 Prescription Procedure. *Audiology research*, *1*(1), e24. https://doi.org/10.4081/audiores.2011.e24
[13] Bisgaard, N., Vlaming, M. S., & Dahlquist, M. (2010). Standard audiograms for the IEC 60118-15 measurement procedure. *Trends in amplification*, *14*(2), 113–120. https://doi.org/10.1177/1084713810379609

limits, latency limit, frequency response bandwidth, and frequency response smoothness limits as specified in ANSI/CTA-2051.[14,15]

ANSI/ASA S3.22 specifies tolerances in electroacoustic measurements for conformity to published device specifications and ANSI/CTA-2051 is different and includes specifications for acceptable electroacoustic performance. ADA notes that certain ANSI/CTA-2051 specifications (e.g., distortion control limits and frequency response bandwidth) use different methodologies than ANSI/ASA S3.22. ADA is concerned that this may create additional, regulatory burdens for hearing aid manufacturers.

ADA supports FDA's decision to exempt most OTC hearing aids from the premarket approval process. ADA also supports a continued requirement for premarket approval for self-fitting air conduction hearing aids until a sufficient number of products has been evaluated. However, ADA is concerned that this requirement may discourage manufacturers from offering self-fitting hearing aids.

ADA respectfully submits the following technical, design, and performance recommendations for FDA consideration:

- **ADA recommends, in situations where conflicts exist between ANSI performance standards, that FDA require harmonization of the test methods and performance requirements for OTC and prescription hearing aids under a single standard that will best meet reasonable assurance for safety and efficacy.**
- **ADA recommends adding a requirement that ear tips must be able to be inserted and removed without the use of a special tool.**
- **ADA recommends that FDA specify that the design requirements for OTC hearing aids must comply with ISO 10993 standards as it relates to cytotoxicity, irritation, and skin sensitization.**
- **Recognizing that device malfunction or battery malfunction may lead to traumatic injury, ADA recommends that FDA require OTC hearing aids IEC 60601 standards for basic safety and essential performance of medical electrical equipment, practical requirements for basic safety and essential performance of hearing instruments, and IEC 62133 standards for basic safety and essential performance of rechargeable cells and lithium ion, or nickel if applicable.**
- **ADA encourages FDA to reevaluate the necessity for premarket approval regularly and to remove the requirement as soon as it is safe to do so.**

CONDITIONS FOR SALE OF OTC HEARING AND PRESCRIPTION HEARING AIDS

ADA supports the conditions for sale for OTC hearing aids contained in the Proposed Rule and agrees that the use of labeling indicating warnings and prohibitions on the use of OTC hearing aids by persons under 18 years-of age will provide sufficient controls. ADA finds no evidence to support the need for a "proof of age" or "validation of age" requirement for buyer or seller and agrees with FDA that such a requirement may unduly restrict access to OTC hearing aids.

ADA commends FDA's proposal to repeal *21 CFR §801.421, hearing aids; conditions for sale*. However, ADA is gravely concerned that this action will create an unintended regulatory vacuum that may result in unwarranted State-imposed regulations that undermine FDA's intention. ADA fears that without an express federal preemption, State governments may seek to impose medical examination requirements and other anticompetitive, restrictive, and unnecessary conditions for sale for adults seeking prescription hearing aids.

[14] Ravn, G., & Preves, D. (2015). Hearing Aid-Related Standards and Test Systems. *Seminars in hearing*, *36*(1), 29–48. https://doi.org/10.1055/s-0034-1396925
[15] ANSI/CTA 2051 Personal Sound Amplification Performance Criteria. Consumer Technology Association. January 2017. Technology & Standards Department www.cta.tech

ADA seeks clarification regarding the impact of the repeal of 21 CFR §801.421 on the sale of prescription hearing aids to children. ADA recognizes that hearing loss in children often necessitates medical intervention, and ADA supports State requirements for medical and/or audiologic evaluation prior to the sale of hearing aids to persons under 18 years-of-age.

ADA notes that Section G.2.f. of the Proposed Rule, Example 6 states, *"…a requirement that a seller maintain a statement of medical examination in connection with the sale of a hearing product would be preempted under FDARA because such a condition of sale would restrict or interfere with commercial activity involving an OTC hearing aid."* The passage is ambiguous about whether medical evaluation requirements are preempted for prescription hearing aids purchased by adults or under the final rule, or whether the federal preemption will only apply to the sale of OTC hearing aids.

ADA anticipates that many licensed audiologists will sell both OTC hearing aids and prescription hearing aids in their clinics. Most licensed audiologists will likewise serve patients who have purchased OTC hearing aids elsewhere and proactively seek professional help for their safe and effective use. The Proposed Rule is unclear about whether States may impose requirements or liabilities for audiologists who provide assistance with the fitting or servicing OTC hearing aids for consumers that are different from, in addition to, or otherwise not identical to those imposed on unlicensed dispensers selling or servicing OTC hearing aids.

ADA respectfully submits the following questions and recommendations to FDA related to the Conditions for Sale of OTC hearing aids and prescription hearing aids:

- **Does the repeal of 21 CFR §801.421 effectively leave regulations for the conditions for sale of prescription hearing aids to adults and children to State governments?**
- **Will States be able to impose liabilities, restrictions, or requirements on licensed dispensers who sell or service OTC hearing aids that are different from, in addition to, or otherwise not identical to those imposed on unlicensed dispensers?**
- **ADA recommends that FDA include an express federal preemption that prohibits States from imposing medical evaluation requirements for adults as a condition of sale for prescription hearing aids.**
- **ADA recommends FDA include an express federal preemption that prohibits States from enacting requirements that go beyond professional licensure as conditions of sale for prescription hearing aids to adults, including but not limited to the following:**
    - **Minimum testing and treatment procedures**
    - **Mandatory in-person/face-to-face visits**
    - **Prohibitions on sending/dispensing prescription hearing aid by mail and/or across state lines**
- **ADA seeks additional clarification from FDA regarding whether States may legally impose any increased requirements or whether there are additional implied responsibilities that may be imposed upon a licensed hearing aid dispenser compared with an unlicensed hearing aid dispenser as it relates to commercial activities and sales of OTC hearing aids.**

LABELING REQUIREMENTS

ADA is pleased that the Proposed Rule provides consumers with opportunities to review all OTC hearing aid labeling before purchase. ADA generally supports FDA's approach to labeling requirements for OTC hearing aids and prescription hearing aids.

Hearing aid labeling should be plainly worded and easy to read. Warning language should be strong and specific, and directions for use must be clear. It will be important for key performance and design information to be disclosed to consumers using consistent language so that consumers can compare products. ADA has identified several areas where the Proposed Rule labeling provisions may be insufficient.

ADA offers the following recommendations for labeling enhancements for OTC hearing aids and prescription hearing aids:

Label Type	Issue	Description
General	Health Literacy	Require patient information and warning labels to meet federal government plain language guidelines.
General	Health Literacy	Require labeling to be in a font size that is easy to read.
General	Health Literacy	Present information that will be duplicated in multiple locations, including consumer warnings and directions, in a consistent format using identical terminology.
General	Differentiate Professions to Avoid Confusion	Require labeling to specify licensed audiologist, physician, or hearing instrument specialist as indicated and appropriate, rather than the using the generic "hearing healthcare professional". The general term "hearing healthcare professional" is confusing to consumers, the intended device users, and fails to distinguish among the three professions and their respective roles in providing hearing healthcare.
Red Flag Condition Warning	Consumer History Requirements	ADA finds no evidence to support universally extending consumer history/personal history lookback requirements from 90 days to 6 months. Create condition-specific consumer history requirements that are determined, based on evidence. For example, evidence may support shortening the lookback period for certain conditions (sudden hearing loss, for example), while other conditions may indeed warrant a lookback period longer than 90 days.
Red Flag Condition Warning	Consumer History Requirements	Update the red flag condition warning with a qualifier that consultation with a physician should be initiated for conditions and symptoms that have not subsided or been previously treated.
Red Flag Condition Warning	Red Flag Conditions	Updated proposed red flag conditions as supported by evidence. Potential examples of conditions to add include the following: • Unresolved recurring headache and/or fever • Head trauma • Facial numbness/tingling
Red Flag Condition Warning	Red Flag Descriptor/Health Literacy	Evaluate red flag condition label descriptors against consumer-validated screening tools such as the Consumer Ear Disease Risk Assessment (CEDRA) to self-referral rates for red flag conditions.[16]
Consumer Warning	Ear Tips/Insertion Depth	Require an additional warning label instructing consumer that if they remove their hearing aids and the ear tips are no longer attached, that the consumer should not attempt to remove the ear tip from their ear canal and should instead seek immediate audiologic or otologic intervention.
Consumer Notice	Efficacy of OTC Hearing Aids: Perceived	In addition to consumer warnings about safety risks related to the use of OTC hearing aids, OTC hearing

[16] Klyn NAM, Kleindienst Robler S, Bogle J, Alfakir R, Nielsen DW, Griffith JW, Carlson DL, Lundy L, Dhar S, Zapala DA. CEDRA: A Tool to Help Consumers Assess Risk for Ear Disease. Ear Hear. 2019 Nov-Dec;40(6):1261-1266. doi: 10.1097/AUD.0000000000000731. PMID: 30946136; PMCID: PMC6774904.

	Improvement of Hearing Ability	aid labeling should also inform consumers that hearing aids are not an effective treatment for every hearing condition. The label should direct consumers to seek a diagnostic hearing examination if there is no perceived improvement in their ability to hear and understand speech through the use of the OTC hearing aid.
Package (Outside)	Candidacy Criteria/Health Literacy	Align OTC candidacy screening statements with a validated screening tool such as the short version of the Hearing Handicap Inventory for Adults/the Elderly (HHIA-S/HHIE-S) to improve successful self-screening for candidacy for OTC hearing aids.[17]
Package (Outside)	Battery Specifications	Label should indicate the type of battery required and whether batteries are included.
Package (Outside)	QR Code	Include a QR Code, in addition to a website address to make it easier for consumers to access information.
Package (Outside)	Fitting Range Information	Require consumer information to include the fitting range for the device across frequencies (minimally 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz), so if the consumer has an audiogram, they can self-determine if a specific OTC hearing aid is appropriate for their hearing loss.
Package (Outside)	Telecoil	Require label to indicate whether the hearing aid has a telecoil on the outside label.
Package (Outside)	Bluetooth Compatibility	Require label to indicate whether the hearing aid is Bluetooth compatible, and if so, with what operating system(s) and device(s).
Inside the Box	Consumer Warning	Strengthen inside package labeling related to warnings about the consequences of high output sound pressure level (including pain, discomfort, and additional hearing loss), and to include specific recommendations for patient action to address uncomfortable sound level (adjust VC or other control), and recommendations for patient to seek professional help if comfortable sound levels cannot be achieved.
Inside the Box	Adverse Effects	Add “pain” to the list of physiological side effects and adverse events in addition to “irritation”.
Inside the Box	Right to Repair	Under “Repair Information”, require label to indicate that consumers may obtain hearing aid repair services anywhere they choose without penalty to any manufacturer warranty.
Inside the Box		Under “Replacement Information”, require information and specifications for accessories that are commonly replaced including ear tips, domes, wax guards, filters, microphones, covers, speakers, slim tubes, receivers, retention lines, anchors, rechargeable batteries, and other common parts.

[17] Feltner CW, Wallace I, Kistler C, Coker-Schwimmer M, Jonas DE, Middleton JC. *Screening for Hearing Loss in Older Adults: An Evidence Review for the U.S. Preventive Services Task Force*. Evidence Synthesis No. 200. Agency for Healthcare Research and Quality; 2021. AHRQ Publication No. 20-05269-EF-1.

CONSUMER PROTECTIONS

ADA notes that FDA does not intend to require a specific return period or policy for OTC hearing aids, nor does it intend to prohibit States from establishing return policies, under the Proposed Rule, so long as those return policies apply to "any product" and do not conflict with the final rule.

ADA is concerned that bad actors may lobby States in an effort to create disparate policies between OTC hearing aids and prescription hearing aids to the advantage of one hearing aid type or the other. Hearing aid return policies warrant additional scrutiny by FDA under the Proposed Rule.

In addition to fair and transparent hearing aid sales return policies, ADA is concerned that the final rule should protect consumers by ensure that they can take their OTC hearing aids or prescription hearing aids to the vendor of their choosing for repair. The Proposed Rule does not address the importance of ongoing consumer access to parts and accessories for hearing aids that they purchase.

ADA opposes to the sale of OTC hearing aids or prescription hearing aids that use "locked" software or other deceptive means to force consumers to obtain services, including post-sale follow-up services, from a specific provider or retail chain.

ADA respectfully submits the following recommendations to FDA related to consumer protections:

- **ADA strongly recommends that FDA specifically prohibit State hearing aid return requirements that are not identical for OTC hearing aids and prescription hearing aids.**
- **ADA recommends that FDA include a provision that prohibits manufacturers and dispensers of OTC and prescription hearing aids from using "locked" software or other features that require consumers to use manufacturer-owned or contracted provider/locations for repair services.**
- **ADA recommends that FDA require manufacturers and retailers to provide unrestricted access to OTC hearing aid software and controls for consumers and providers and make available for sale hearing aid accessories and components that commonly require replacement, including but not limited to the following: ear tips, domes, wax guards, filters, microphones, covers, speakers, slim tubes, receivers, retention lines, anchors, rechargeable batteries, and other common parts.**
- **ADA also recommends that FDA require manufacturers and retailers of prescription hearing aids to provide unrestricted access to OTC hearing aid software and controls for licensed providers, and make available for sale hearing aid accessories and components that commonly require replacement, including but not limited to the following: ear tips, domes, wax guards, filters, microphones, covers, speakers, slim tubes, receivers, retention lines, anchors, rechargeable batteries, and other common parts.**
- **Once the rule is finalized, ADA encourages FDA and/or FTC to strongly enforce truth in advertising laws for hearing aids and personal sound amplification products (PSAPs), as well as intended use marketing violations by companies selling PSAPs and implying that they should be used to treat hearing loss.**

CONCLUSION

The successful adoption of OTC and prescription hearing aids, relies on competition, transparency, safety, and efficacy. The FDA Proposed Rule serves as an excellent foundation and ADA appreciates the opportunity to provide constructive comments to support FDA efforts.

As the final OTC hearing aid regulations are promulgated, ADA encourages FDA to carefully scrutinize recommendations that create barriers for entry into the market and/or that seek to narrow the market for OTC hearing aids by limiting their availability, efficacy, or utility. ADA encourages FDA to proactively seek

opportunities to harmonize technical, performance, and design requirements for OTC hearing aids and to adopt the least burdensome approach that provides reasonable assurance of safety and efficacy.

Over-reaching State licensure acts, telehealth limitations, supplier-imposed tying requirements, and channel restrictions will discourage competition will undermine consumer access. ADA encourages the FDA, FTC, and other federal agencies to actively remove regulations and prohibit commercial practices and activities that are anticompetitive or unduly restrict competition in the hearing industry. Consumers will also be well-served if agencies dedicate regulatory efforts towards improving transparency and competition through the enactment and enforcement of right to repair and truth in advertising laws.

ADA appreciates FDA's thoughtful approach to regulate OTC hearing aids as outlined in the Proposed Rule, which incorporates FDARA requirements and successfully balances diverse, complex, and often opposing stakeholder views to design a practical regulatory framework that can expand consumer access to affordable, high-quality hearing health care as Congress intended.

Please contact Stephanie Czuhajewski at sczuhajewski@audiologist.org if you need any additional information or resources, or if ADA can assist you in any way.

Sincerely,

Kristin Davis, Au.D.

Kristin Davis, Au.D.
President
Academy of Doctors of Audiology