Analysis of FDA Proposed Rule to Establish Over the Counter Hearing Aids

Policy Overview, Recommendations, and Practical Implications for Audiology Practices

January 12, 2022

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Panelists

- Kristin Davis, AuD, President, OTC Task Force Member
- Victor Bray, PhD, Immediate Past President, OTC Task Force Co-Chair
- Alicia Spoor, AuD, Advocacy Committee Chair, OTC Task Force Co-Chair
- David Akbari, AuD, OTC Task Force Member
- Bryan Greenaway, AuD, OTC Task Force Member
- Stephanie Czuhajewski, MPH, Executive Director

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Today's Agenda

1. Provide a fact-based analysis of the FDA Proposed Rule to Establish OTC Hearing Aids including potential implications for ADA members, audiology practices, and consumers.
2. Present members with ADA's draft recommendations to the FDA and solicit feedback.
3. Share information with ADA members about actions they can take to prepare for implementation of the final rule and discuss relevant ADA resources and initiatives.

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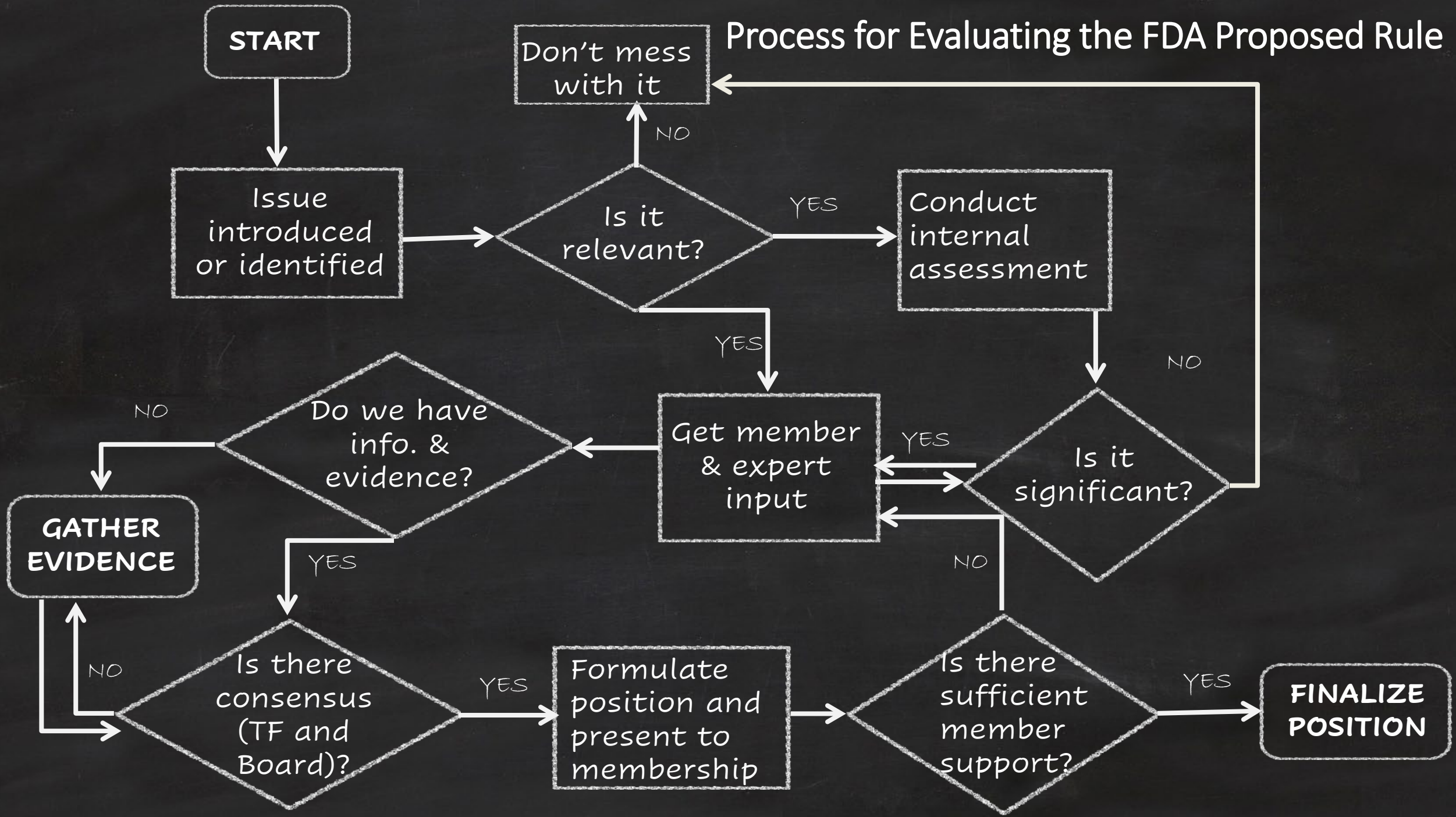
Process for Evaluating the FDA Proposed Rule

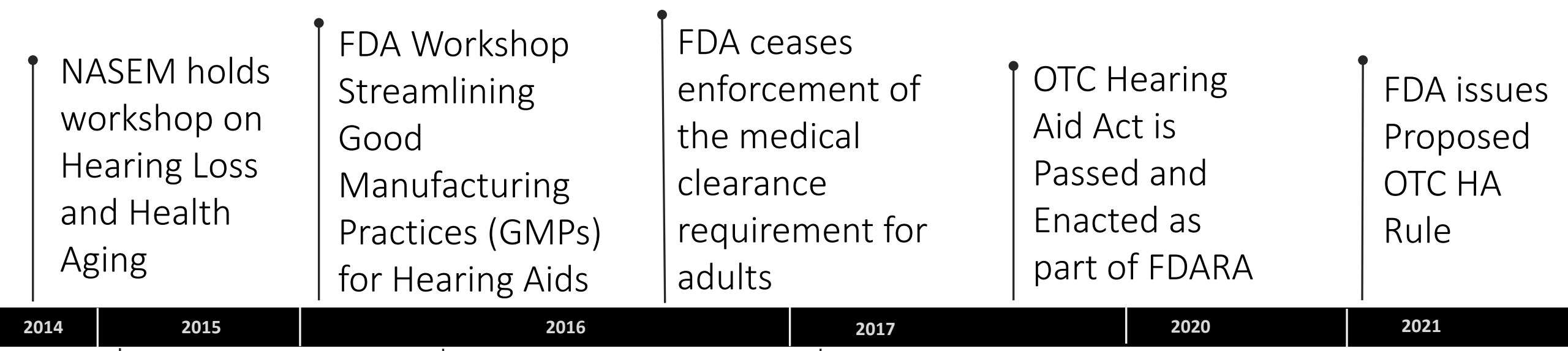


ADA Analysis of Proposed OTC Hearing Aid Rule: Values and Context

The ADA OTC Hearing Aid Working Group agreed that the FDA Proposed Rule would be evaluated in the context of having to support the following values:

- Evidence-based clinical and business practices
- The autonomous practice of audiology
- Consumer choice and patient autonomy
- Increased competition, transparency, and consumer protection
- NASEM recommendations outlined in Accessible and Affordable Hearing Health Care for Adults (2016)

Recent Public Policy Initiatives to Advance OTC Hearing Aids



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Statutory Requirements for OTC Hearing Aid Regulations

FDA Reauthorization Act of 2017 (FDARA)

Food, Drug, and Cosmetic Act (FD&C Act)

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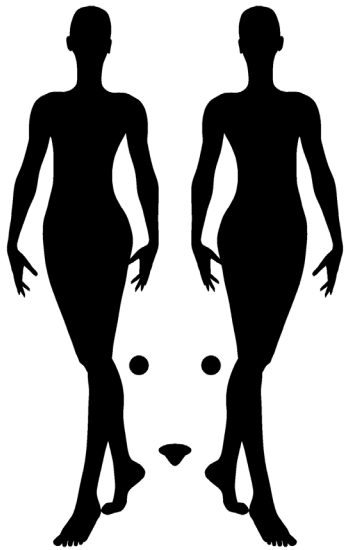
Criteria for OTC Hearing Aids Dictated by Federal Statute

1. Intended Use of OTC Hearing Aids (Who and Under What Conditions)

- By **adults** over the age of 18 years
- To compensate for **perceived mild to moderate** hearing impairment



2. Technical Specifications for OTC Hearing Aids

- *Must* use same fundamental scientific technology as air conduction HAs or wireless air conduction HAs as defined in federal regulations
- *Must* allow user to control and customize the OTC HA to the user's hearing needs through tools, tests, or software
- *May* use wireless technology
- *May* included tests for self-assessment of hearing loss

FDARA Statute Mandates Consumer Access to OTC Hearing Aids and Includes Preemptions

A Clear Mandate

- OTC hearing aids will be available to consumers through in-person transactions, by mail, or online, without the supervision, prescription, or other order, involvement, or intervention of a licensed person.

Express Federal Preemption

- Prohibits State or local governments from establishing or continuing any law, specifically applicable to hearing products that will:
  - *"restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids that is different from, in addition to, or otherwise not identical to, the regulations promulgated under the federal OTC hearing aid regulations"*

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Other FDARA Mandates for OTC Hearing Aid Regulations

- Exempt OTC HAs from current federal HA regulations for professional and patient labeling and conditions for sale
- Include requirements that provide reasonable assurances of the safety and efficacy of OTC HAs
- Establish or adopt output limits appropriate for OTC HAs
- Include requirements for appropriate labeling of OTC HAs (statute also specifies certain criteria for labeling)

- Describe Condition for Sale for OTC HAs as permitted without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.
- Outline effects on state law and preemptions
- Make determination as to whether 510(k) is necessary for OTC hearing aids

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“Reasonable Assurance”: A Legal Standard

FDA regulations offers a legal definition for the “reasonable assurance” of safety and efficacy under 21CFR 860.7 that is based upon valid scientific evidence.

Safety

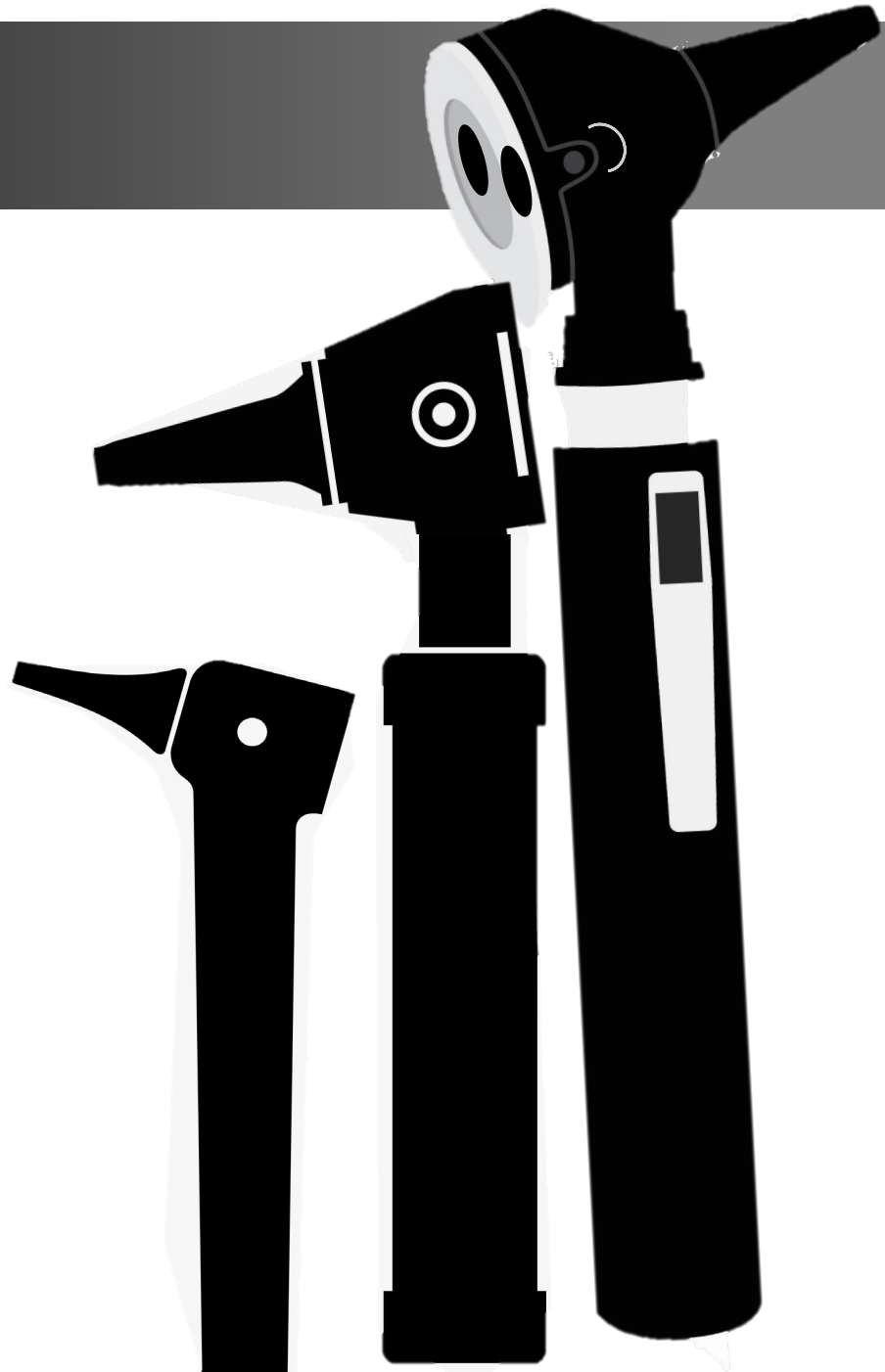
“There is **reasonable assurance** that a device is **safe** when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.”

Efficacy

“There is **reasonable assurance** that a device is **effective** when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.”

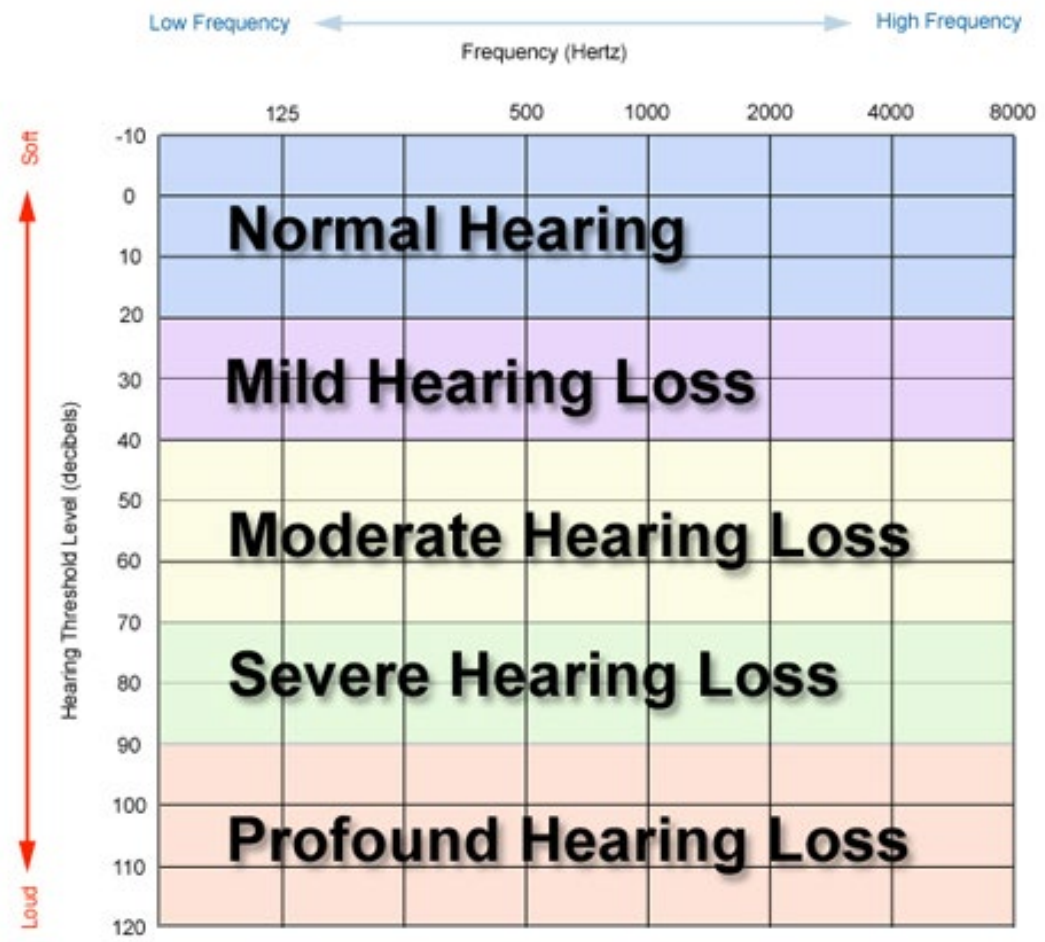
FDA Proposed Rule

- Maintains existing definition and medical device classifications for hearing aids (Class I and Class II) as consistent with FD&C Act
- Repeals conditions for sale for hearing aids under CFR Title 21 801.421, as “restricted” devices
- Creates category of OTC hearing aids, regulatory controls, and conditions for sale, as mandated by FDARA
- Categorizes non-OTC hearing aids as prescription hearing aids and establishes labeling requirements
- Denotes FDARA federal preemptions
- Removes preemption exemption decisions that are moot



FDA User Considerations and Assumptions: OTC Hearing Aids

- Adult users
- Users with *perceived* mild-to-moderate hearing loss
- Users with actual variations in type, degree, and configuration of hearing loss
- Users with various levels of hearing aid experience
- Users with various lifestyle needs
- Users with unknown levels of health literacy



FDA Proposed Rule: Categorizes OTC Hearing Aids and Prescription Hearing Aids

Proposed Rule Creates OTC *and* Prescription Categories

OTC Hearing Aid

Air conduction hearing aids will be categorized as OTC hearing aids if the following conditions are met:

- Conformity to technical, performance, labeling, and design requirements
- Intended use
  - Adults, 18 years and older
  - Perceived mild-to-moderate hearing loss

Prescription Hearing Aid

Hearing aids will be categorized as prescription hearing aids if they do not meet the definition of, or the requirements for, OTC hearing aids.

- Prescription hearing aids to be dispensed by licensed dispensers under State authority

ADA Findings: Proposed Categorization of Hearing Aids

ADA Finding: Evidence supports FDA's decision to reclassify all hearing aids from the current "restricted" category as either OTC hearing aids or prescription hearing aids.

ADA Finding: FDA's decision to classify hearing aids by sound conduction technology is reasonable.

ADA Finding: FDA's decision to categorize air conduction hearing aids as either OTC hearing aids or prescription hearing aids based on their intended use and design, technical, performance, and labeling criteria aligns with FDARA and offers opportunities for manufacturers to readily create hearing aids for either or both categories.

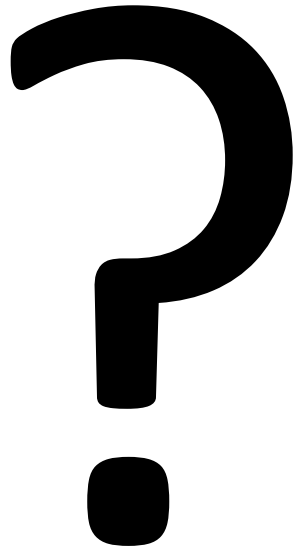
ADA Finding: FDA does not address tinnitus maskers.

ADA Finding: FDA's decision to eliminate hearing aids from devices in the restricted category may result in a change in jurisdiction from FDA to FTC for hearing aid advertising.

ADA Question on Impact of Proposed Categorization of Hearing Aids on FDA Jurisdiction of Advertising

ADA Question to FDA: ADA seeks clarification from the FDA about the impact that the proposed reclassification of hearing aids from "restricted" devices to either OTC hearing to prescription hearing aids will have on FDA's jurisdiction and oversight of hearing aid advertising and marketing.

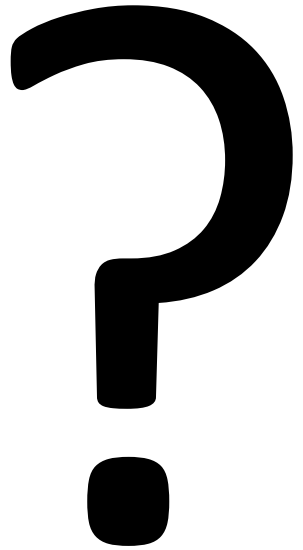
If the Proposed Rule is finalized will the Federal Trade Commission (FTC) play an increased role in oversight of OTC hearing aids and/or prescription hearing aids?



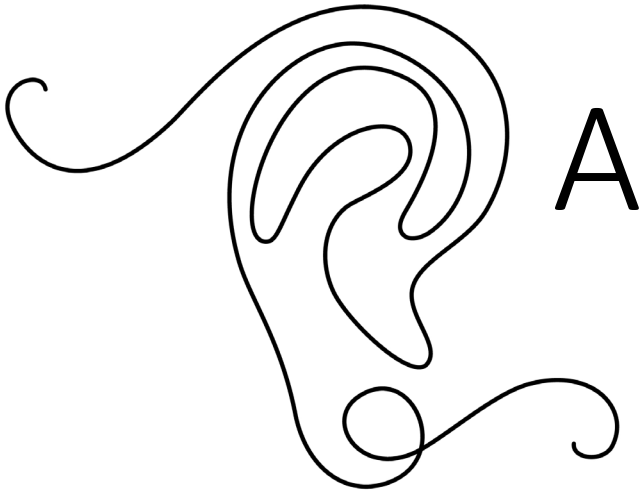
ADA Question on Category for Tinnitus Maskers

ADA Question to FDA: Tinnitus maskers are currently classified as Class II restricted devices under 21 CFR 874.34.

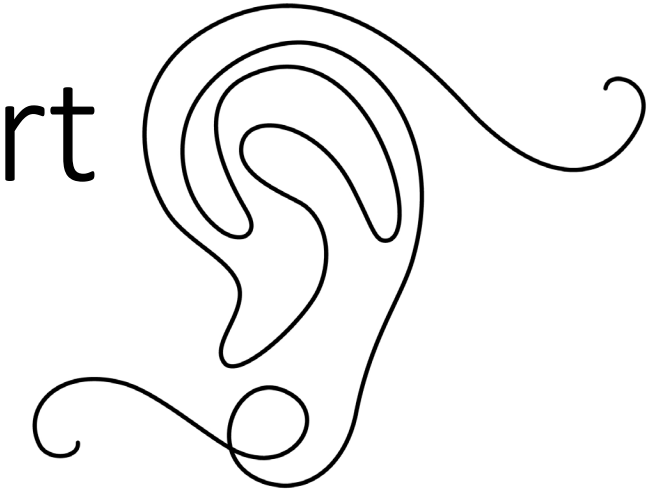
Does FDA intend to leave tinnitus maskers (and/or hearing aids with tinnitus maskers) in the restricted category, or does it intend to move them to the prescription category?



Proposed Rule: Categorization of Hearing Aids



ADA Position: Support with Requests for Clarification



FDA Proposed Rule: Technical, Design, and Performance Specifications for OTC Hearing Aids

FDA Proposed Technical, Design & Performance Specs

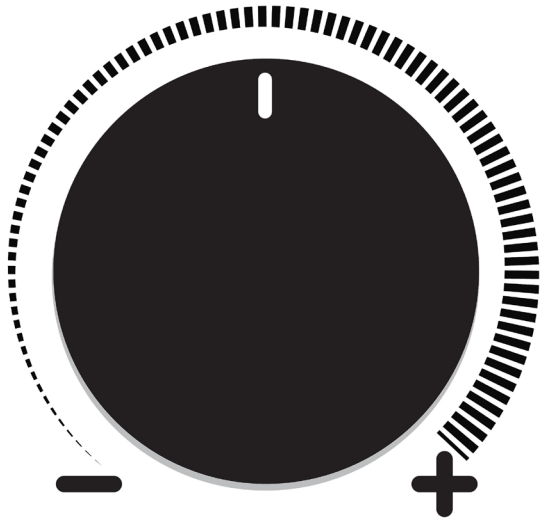
- Maximum Output
  - Maximum OSPL90 output level of 115 dB SPL or a maximum limit of 120 dB for OTC hearing aids that implement input-controlled compression and a user-adjustable device volume control
- No gain limit requirement
- May be legacy, wireless, or self-fitting
- Maintains existing 510(k) requirement for self-fitting

- Electroacoustic Performance
  (Specs defined in ANSI/CTA 2051)
  - Distortion Control
  - Self-generated Noise
  - Latency
  - Bandwidth
  - Smoothness
- Design Requirements
  - Max insertion depth at bony cartilaginous junction
  - Made from atraumatic materials
  - Proper physical fit
  - Tools, tests, or software allow user to customize to their hearing need

ADA Findings and Recommendations: Maximum Output

ADA Finding: Evidence supports FDA's assertion that user-adjustable volume controls and input-controlled compression can mitigate the risk of a maximum output limit up to and including 120 dB SPL.

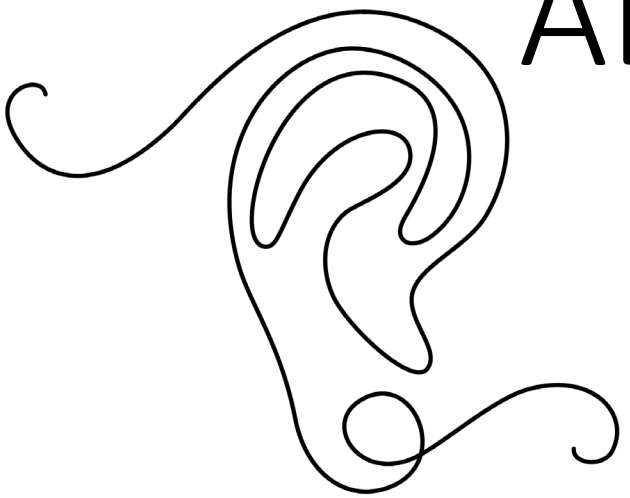
1. **ADA Recommendation:** In order to best achieve a reasonable assurance of safety and efficacy, FDA should reduce the maximum allowable output limit from 115 dB SPL to 110 dB SPL for OTC hearing aids that lack a user-adjustable volume control and input-controlled compression.
2. **ADA Recommendation:** Stronger inside package labeling related to the consequences of high output sound pressure level.



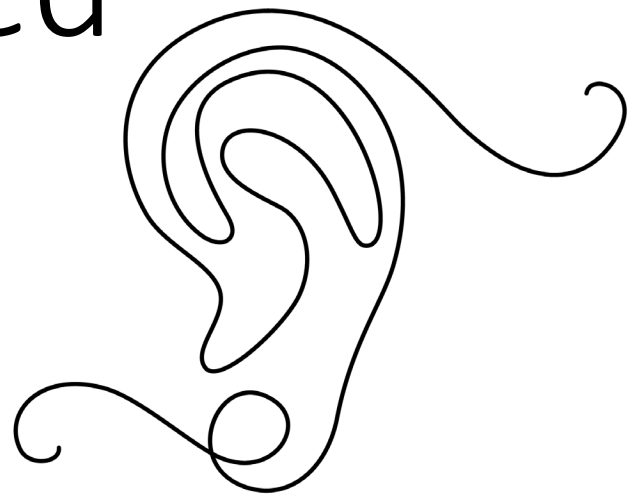
Under the FDA Proposed Rule, all OTC hearing aids will be air conduction hearing aids…

…but not all air conduction hearing aids will be OTC hearing aids

Proposed Rule: Maximum Output Requirements



ADA Position: Qualified Support with Constructive Recommendations



ADA Findings: Technical, Performance & Design Requirements for OTC Hearing Aids

ADA Finding: Evidence supports FDA's decision not to impose a gain limitation for OTC hearing aids.

ADA Finding: Evidence supports FDA's decision to require a 510(k) for self-fitting hearing aids.

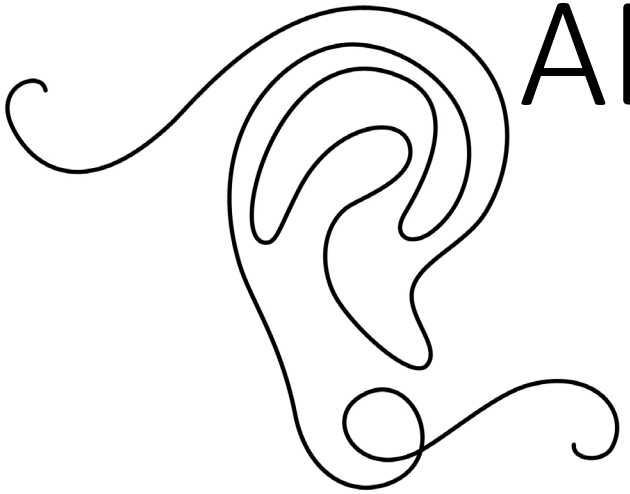
ADA Finding: ANSI/CTA-2051 criteria as appointed by FDA, for the performance of OTC hearing aids, provides reasonable assurance of safety and efficacy and in some cases offers advantages to ANSI/ASA S3.22 criteria; however, there are instances of conflict with ANSI/ASA S3.22, which may create confusion for consumers and providers, and increase the regulatory burden for manufacturers.

ADA Finding: The proposed OTC hearing aid design requirements related to ear tips, physical fit, and the use of atraumatic materials are insufficient.

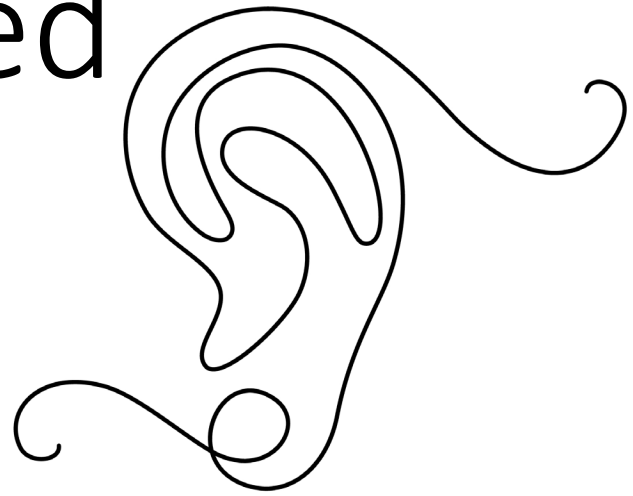
ADA Recommendations: Technical, Performance & Design Requirements for OTC Hearing Aids

1. In situations where conflicts exist between ANSI/CTA 2051 and ANSI/ASA S3.22, FDA should harmonize requirements for OTC hearing aids and prescription hearing aids.
2. FDA should require OTC hearing aid ear tips to be able to be inserted and removed without the use of a special tool.
3. FDA should include a warning regarding the potential for ear tips to be left in the ear canal that direct the consumer to seek otologic or audiologic intervention.
4. FDA should require OTC hearing aids to comply with ISO 10993 standards for cytotoxicity, irritation, and skin sensitization.
5. FDA should require OTC hearing aids to meet IEC 60601 standards for basic safety and essential performance of medical electrical equipment and IEC 62133 standards for basic safety and essential performance of batteries as applicable.

Proposed Rule: Technical, Performance & Design Requirements for OTC Hearing Aids



ADA Position: Qualified Support with Constructive Recommendations



Proposed Rule: Conditions for Sale for Hearing Aids

- Labeling requirements indicating that OTC hearing aids are not for children under 18 years of age.
- Labeling requirements indicating the risk of using OTC hearing aids by those under 18 years of age.
- No requirement that OTC HA sellers verify proof of age.
- No requirement that OTC HA buyers provide proof of age.
- Repeals conditions of sale for all hearing aids under CFR 21 801.421

ADA Findings: Proposed Conditions for Sale for HAs

ADA Finding: Evidence supports FDA's decision to forgo "proof of age" requirements as a condition for sale of OTC hearing aids. Despite widespread availability of direct-to-consumer hearing aids, there is no evidence that such devices have been routinely purchased or used by minors. ADA, therefore, agrees with FDA's assertion that adding proof of age requirements for buyers or sellers of OTC hearing aids will increase the regulatory burden for retailers and reduce consumer access to OTC hearing aids without providing any additional consumer protections.

ADA Finding: Repeal of section 801.421, conditions for sale for hearing aids may create a regulatory vacuum that could be used by State governments to unfairly restrict access to prescription hearing aids for adult consumers.

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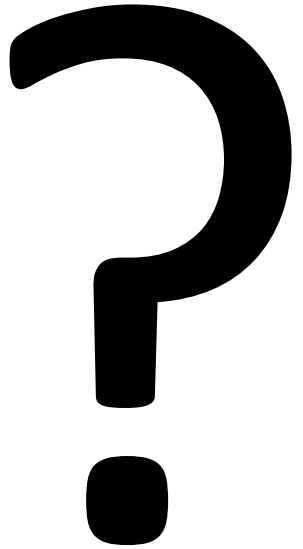
ADA Question Regarding Conditions for Sale of HAs

ADA Question to FDA: FDA leaves ambiguity around the federal preemption related to medical evaluations as a condition of sale for prescription hearing aids.

Does the Proposed Rule provide an express federal preemption that will prohibit State governments from imposing medical evaluation requirements as a condition for sale for adults for both OTC and prescription hearing aids or does the federal preemption only apply conditions of sale for adults purchasing OTC hearing aids?



ADA Question to FDA: *Does FDA intend to impose a medical evaluation requirement as a condition for sale for hearing aids intended for use by children or will FDA intend to leave such regulation oversight to each State?*

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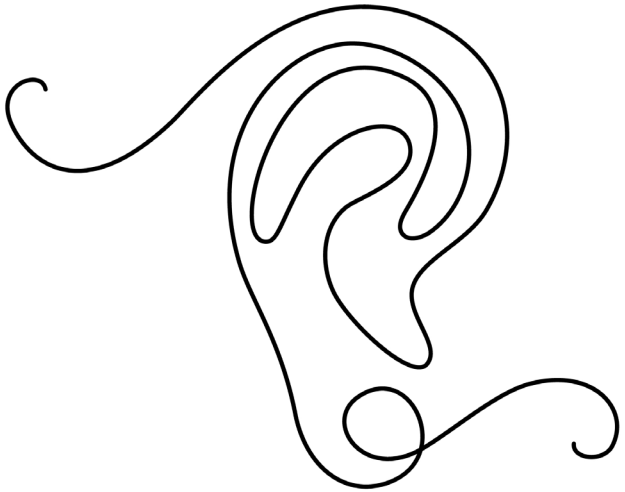
ADA Recommendations: Conditions for Sale Hearing Aids

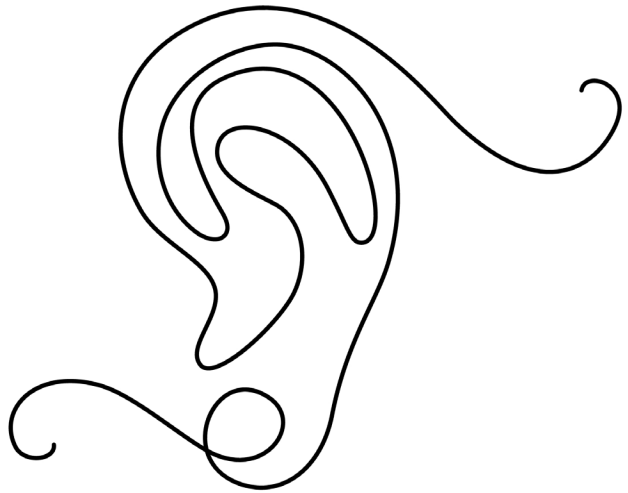
ADA has grave concerns that the repeal of 801.421 may result in the unintended consequence of State-imposed restrictive or anti-competitive conditions for sale for adults purchasing prescription hearing aids.

1. FDA should clarify whether the Proposed Rule will prohibit States from requiring a medical evaluation as a condition of sale for adults seeking to purchase prescription hearing aids.
2. FDA should amend the Proposed Rule to expressly prohibit States from enacting requirements that go beyond requirements for professional licensure as conditions of sale for prescription hearing aids to adults including but not limited to the following:
    a. Medical evaluation (if not already prohibited)
    b. Minimum testing and treatment procedures
    c. Mandatory in-person/face-to-face visits
    d. Prohibitions on sending prescription hearing aids by mail and/or across state lines

Proposed Rule: Conditions for Sale for Hearing Aids



ADA Position: Qualified Support with Constructive Recommendations and Request for Clarification



FDA Proposed Rule: Labeling Requirements for OTC Hearing Aids

Note: New labeling requirements will be **in addition** to applicable labeling requirements in existing regulation under part 801 and 830.

Proposed Rule: Package Labeling for OTC Hearing Aids

- Conspicuous statement that product is for those 18 years of age and older
- Candidacy screening including symptoms of perceived mild-to-moderate hearing loss
- Information on contraindications, conditions, or symptoms of medically treatable hearing loss (red flag conditions) and advisements to consult with a healthcare practitioner

- Return policy (note: returns are not required under Proposed Rule)
- Disclosure about whether hearing aid is new or rebuilt
- Website and phone number to obtain user instructional brochure and other "inside-the-box" information without requiring purchase

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Proposed Rule: Inside-the-Box Labeling for OTC Hearing Aids

- User instructional brochure
- Warnings and cautions against the use of the OTC hearing aids by people under 18 years of age
- Red flag conditions that prompt consultation with physician
- Expectations about what a hearing aid will do
- Warning about hearing aid not being hearing protection
- Warning about sound output
- Illustrations and information about the controls, user adjustments, and battery compartment
- Description of any accessory that accompanies the hearing aid
- Directions for use
- Technical specifications to allow comparison of OTC hearing aid performance
- Description of commonly occurring avoidable events that could adversely affect or damage the OTC hearing aid
- Identification of known physiological side effects associated with use of OTC hearing aid that could warrant consultation with physician
- Information about repair services including address for repairs
- Summary information about clinical or non-clinical studies

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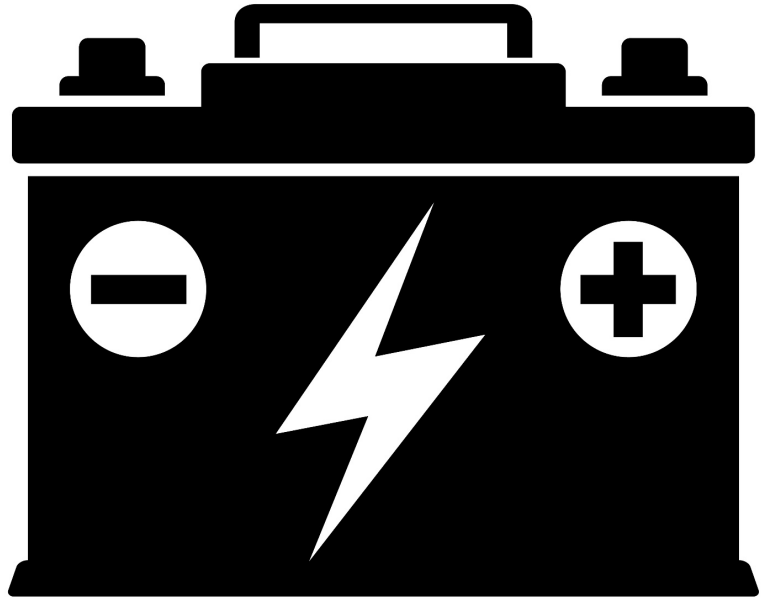
Proposed Rule: Device Labeling for OTC Hearing Aids

- Hearing aid serial number
- Symbols for proper battery insertion orientation, if applicable
- Tag indicating that device has been rebuilt if it has been rebuilt



ADA Findings: Labeling for OTC Hearing Aids

ADA Finding: FDA's proposed labeling requirements for OTC hearing aids are generally supported by evidence.

ADA Finding: FDA's proposed language for self-selection for OTC hearing aid candidacy and for self-determination of red flag conditions sometimes uses language that may be difficult for consumers to understand.

ADA Finding: ADA found no evidence to support extending the look back period for consumers for their personal history related to red flag conditions from 90 days to 6 months.

ADA Finding: The list of red flag conditions proposed by FDA omits conditions that consumers should consider.

ADA Finding: Labeling requirements exclude some important information that consumers may require in order to make an informed decision about the purchase of the OTC hearing aid.

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ADA Recommendations: Labeling for OTC Hearing Aids

1. Require that patient information and warning labels meet federal government plain language guidelines and are printed in a font size that supports readability.
2. Specific recommendations for FDA Red Flag condition warnings:
   - Personal medical history look back period should NOT be extended to six months. It should be based on the red flag condition.
   - Clarify that consultation with a physician should be initiated for conditions and symptoms that have not been resolved/addressed.
   - Add additional red flag conditions to OTC hearing aid labeling.
   - Use Red Flag condition descriptors consistent with a consumer-validated tool such as CEDRA that are easier to understand.

ADA Recommendations: Labeling for OTC Hearing Aids

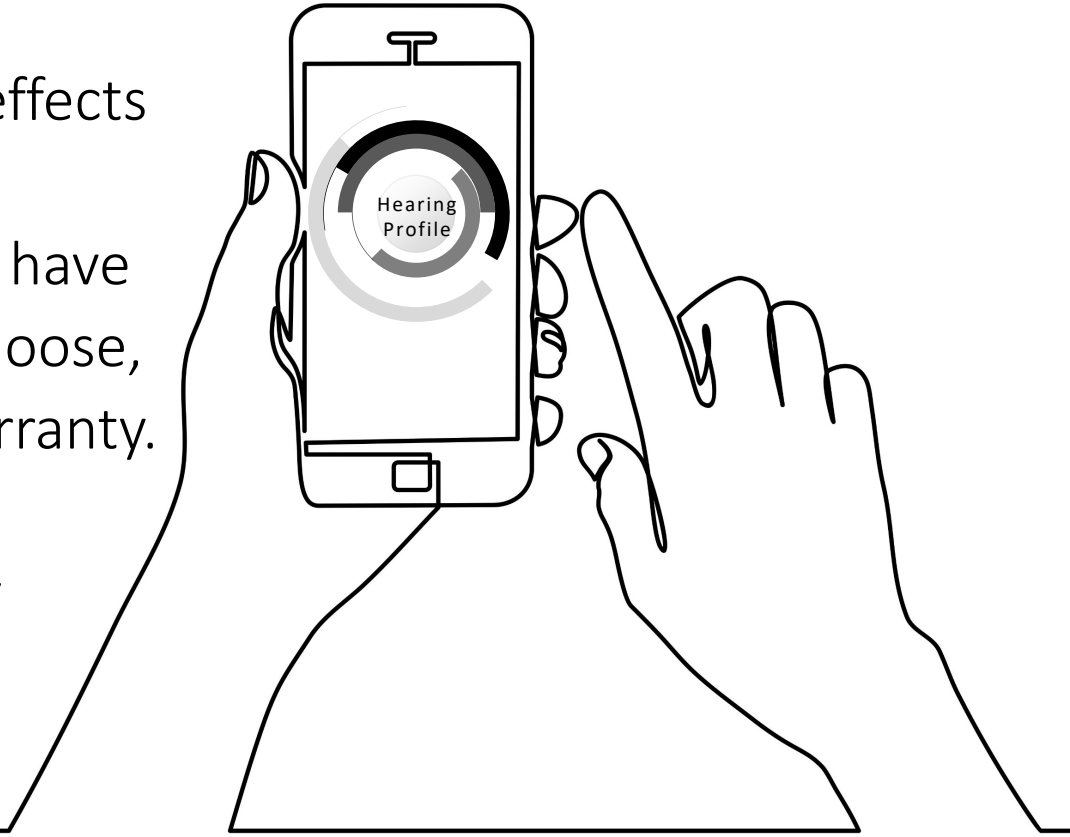
3. All labeling should specify licensed audiologist, physician, or hearing instrument specialist as indicated and appropriate, rather than the generic “hearing healthcare professional”.
4. Any information intended to be duplicated on the outside and inside labeling should be presented in a consistent format using identical terminology.
5. Align the OTC hearing aid self-screening candidacy statements with a validated screening tool such as the short version of the Hearing Handicap Inventory for Adults/the Elderly (HHIA-S/HHIE-S).

ADA Recommendations: Package (Outside) Labeling

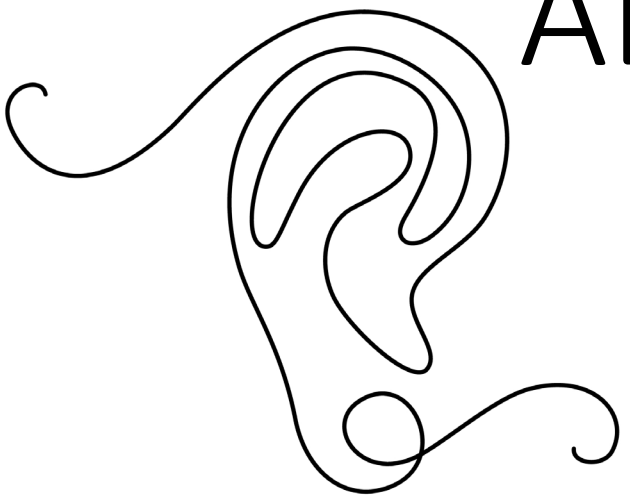
1. Require label to indicate the type of battery required and whether or not batteries are included.
2. Require use of a QR code in addition to a website address to make it easier for consumers to access information.
3. Require label to include the fitting range for the device across frequencies (500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz), so that consumer can use an audiogram to self-determine if the OTC hearing aid is likely to be appropriate for their hearing loss.
4. Require label to indicate whether the hearing aid has a telecoil
5. Require label to indicate whether the hearing aid is Bluetooth compatible, and if so, with what operating system(s).

ADA Recommendations: Inside-the-Box Labeling

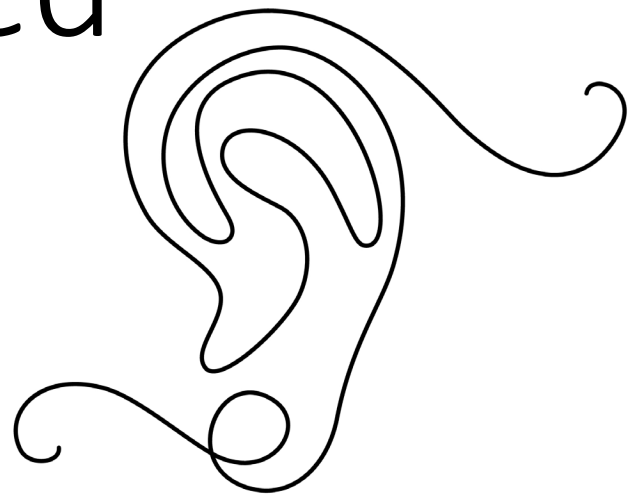
1. Require labeling to include stronger warnings related to the consequences of high output sound pressure level
2. Add “pain” to the label list of physiological side effects and adverse events in addition to “irritation”.
3. Require labeling to indicate that consumers may have their OTC hearing aid repaired anywhere they choose, without penalty to voiding the manufacturer warranty.
4. Require labeling to include information and specifications for accessories that are commonly replaced



ADA Recommendations: Labeling for OTC Hearing Aids

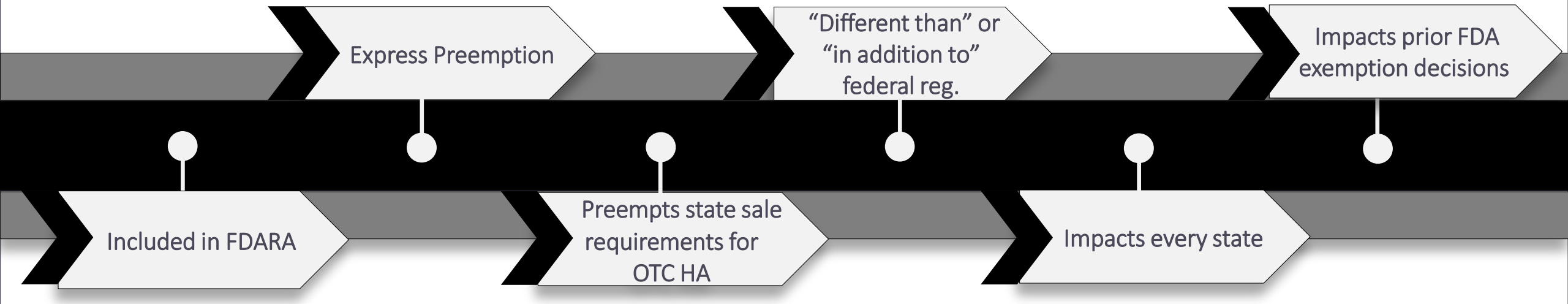


ADA Position: Qualified Support with Constructive Recommendations



FDA Proposed Rule: Federal Preemptions for Sale for OTC Hearing Aids

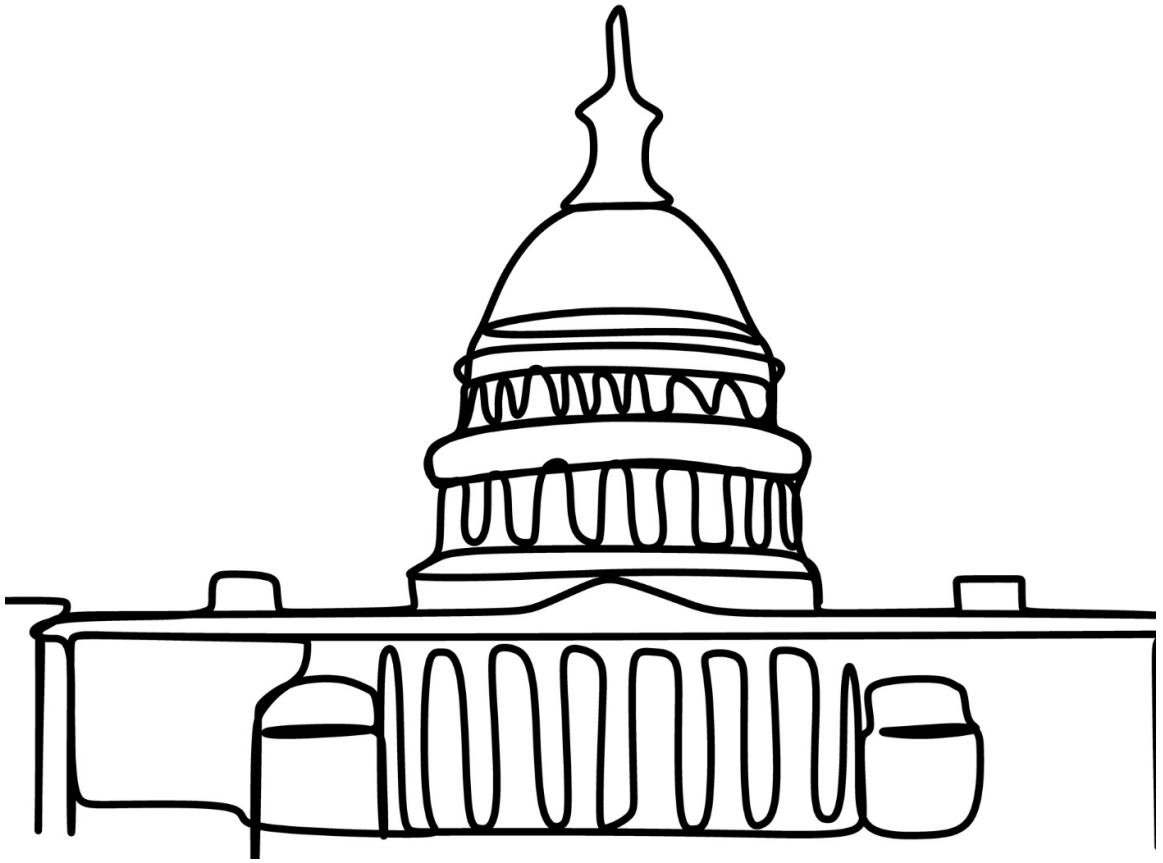
Federal Preemption of State Law



Congress intended FDA OTC hearing aid regulations to supersede state laws.

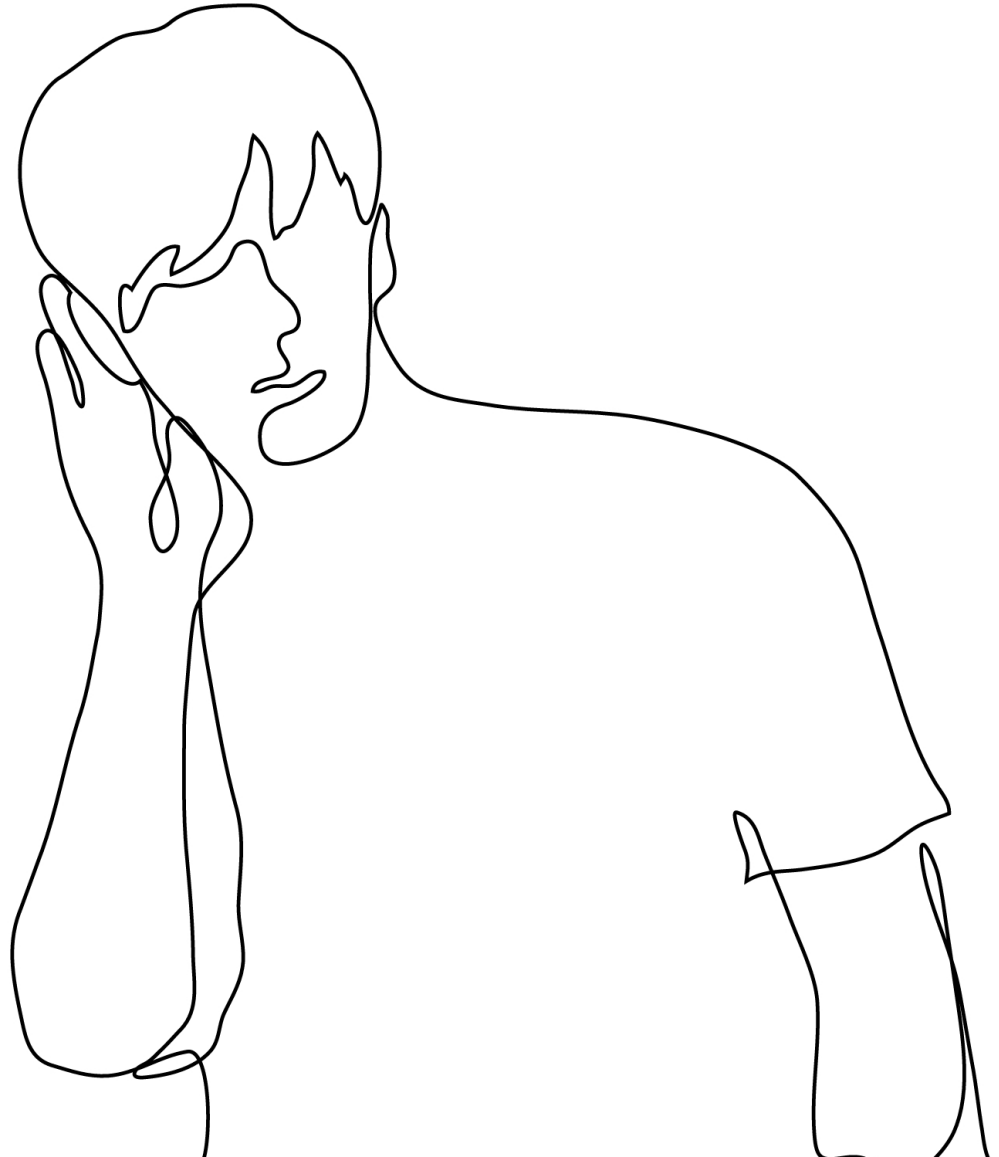
Proposed Rule: Federal Preemption OTC Hearing Aids

- Codify preemption provisions included under FDARA.
- Reevaluates preemption provisions contained under FD&C in the context of FDARA.
- States cannot impose regulations on OTC hearing aids that are different from, in addition to, or otherwise not identical to the OTC Hearing Aid Controls if they will restrict or interfere with commercial activity involving OTC hearing aids.
- Cannot require sellers of OTC hearing aids to be licensed or certified or require buyer to see a licensed professional.



Proposed Rule: Federal Preemption OTC Hearing Aids

- Federal laws do not *necessarily* preempt State requirements regulating professional services such as speech pathology, audiology, or fitting.
- Requirements that apply to any business (and not specific to OTC hearing aids) generally are not preempted.
- Regulation of professional services beyond commercial activities that require licensure (diagnostic services, fitting, counseling etc.) are not preempted and can be enforced by the State.



ADA Findings: Federal Preemption OTC Hearing Aids

ADA Finding: Most of the preemptions addressed in the Proposed Rule are statutorily mandated and cannot be changed by FDA.

ADA Finding: FDA does not intend to require a specific return period or policy for OTC hearing aids. FDA does not prohibit States from establishing return policies, so long as those policies apply to "any product" and does not conflict with the final rule. It is unclear whether State OTC hearing aid return policies would be preempted if they are different from State prescription hearing aid return policies.

ADA Finding: It is expected that every State will need to update, add, or repeal laws in order to comply with the final FDA regulations.

ADA Finding: If the Proposed Rule is enacted previous federal preemptions and preemption decisions will be moot.

ADA Finding: The repeal of certain FDA regulations as indicated in the Proposed Rule may result in attempts by States to impose restrictive, anticompetitive laws unless there are federal preemptions that prohibit such action.

ADA Recommendations: Federal Preemption OTC Hearing Aids

1. In addition to recommendations contained in earlier sections, 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.
2. ADA is gravely concerned that States may seek to create disparate policies between OTC hearing aids and prescription hearing aids to the advantage of one hearing aid type or the other. FDA should specifically prohibit State governments from imposing or enforcing hearing aid return requirements that are not identical for OTC hearing aids and prescription hearing aids.

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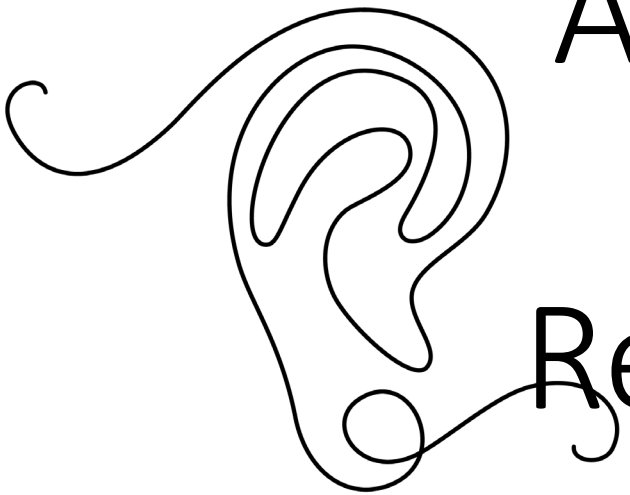
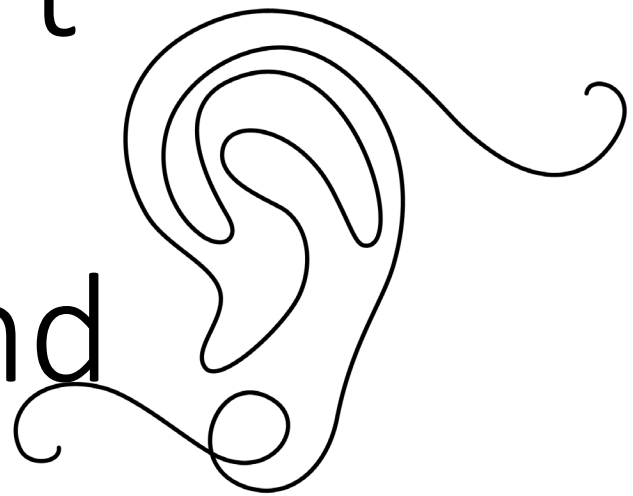
Proposed Rule: Federal Preemptions



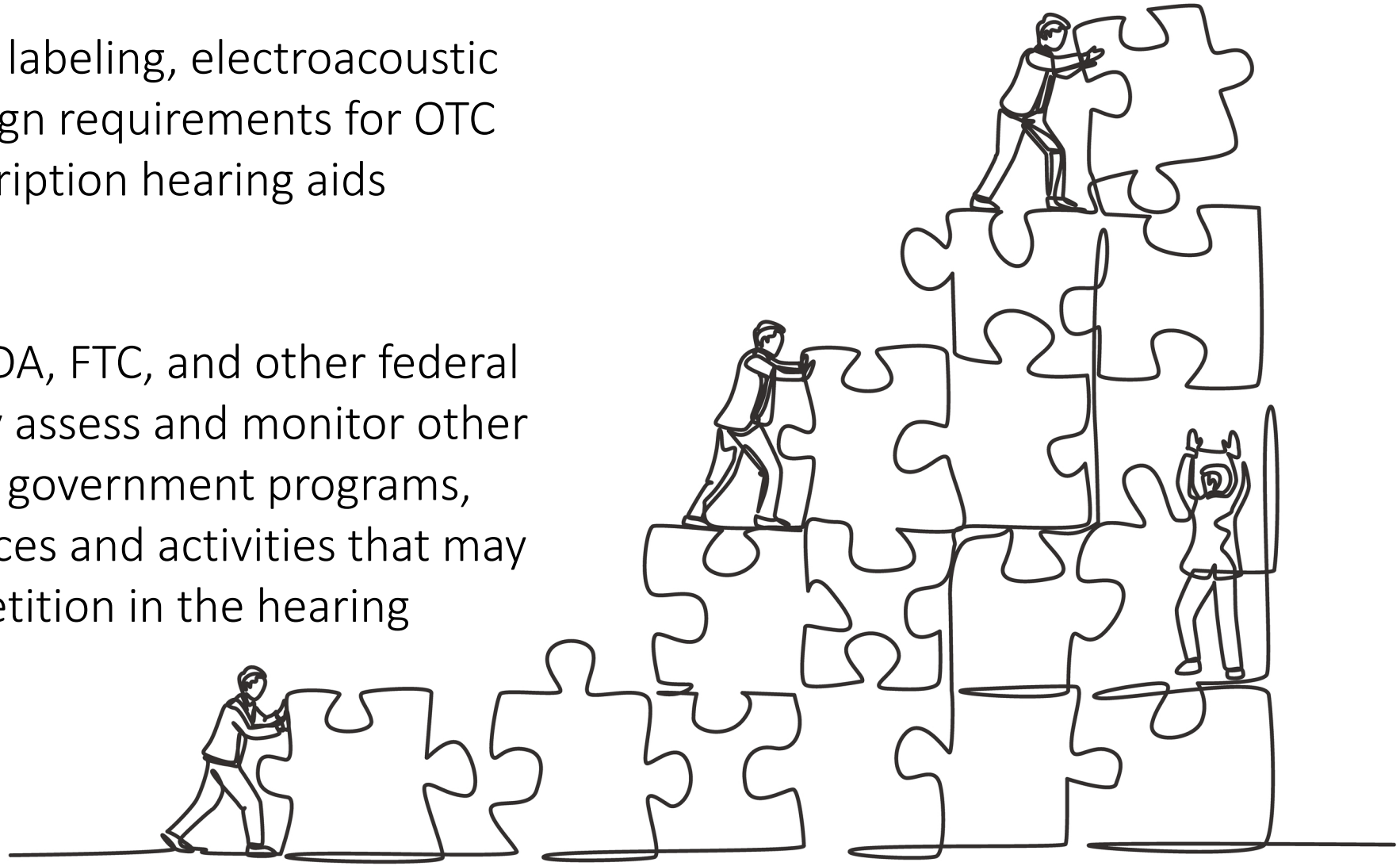
ADA Position: Support with Constructive Recommendations and Clarifications



Additional ADA Recommendations and Requests

1. FDA should harmonize labeling, electroacoustic performance, and design requirements for OTC hearing aids and prescription hearing aids wherever feasible

2. ADA encourages the FDA, FTC, and other federal agencies to proactively assess and monitor other federal and State laws, government programs, and commercial practices and activities that may serve to restrict competition in the hearing industry.



Additional ADA Recommendations and Requests

ADA anticipates that many licensed audiologists will sell OTC hearing aids and prescription hearing aids in their clinics, and many audiologists will also serve patients who have purchased OTC products elsewhere and need assistance in their effective use.

3. FDA should permit air conduction hearing aids to be upgraded from OTC to prescription hearing aids through the use of hardware and/or software expansion capabilities that will allow a licensed dispenser, in consultation with the consumer/patient, to expand the hearing aid output level and download new labeling and packaging requirements.

4. ADA seeks clarification on whether the FDA regulations will permit licensed dispensers to determine which label (OTC or prescription) should be used for a hearing aid product, based on whether it is intended for an adult consumer (thus an OTC hearing aid) or a minor (thus a prescription hearing aid) and/or whether licensed dispensers are prohibited from dispensing hearing aid products “off label”.

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Additional ADA Recommendations and Requests

5. FDA should prohibit manufacturers 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.
6. FDA should mandate unrestricted access to hearing aid software and controls for OTC hearing aids for consumers and dispensers. Further, manufacturers of OTC hearing aids should be required to make available for sale without restriction to the public and/or dispenser accessories and components that commonly require replacement
7. Manufacturers of prescription hearing aids should be required to provide access to prescription hearing aid software and controls to licensed dispensers and make available for sale to licensed dispensers without restriction, accessories and components that commonly require replacement.
8. Software can be a hearing aid. FDA should ensure that the Proposed Rule accounts for innovations like the Jacoti Hearing App, which can turn headphone hardware into a hearing aid.

Opportunities for Action

- Send your comments to FDA by January 18th
- Join your state association and become involved in advocacy efforts in your state
  - State licensure laws
  - Hearing aid sales laws and conditions for sale
  - Truth in advertising laws
- Prepare your yourself and your practice for upcoming opportunities

Questions?

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Insights on Output and Gain Recommendations

- NAL-NL2 Prescription Formula
- ANSI/CTA 2051 is a vetted standard for hearing aids as medical devices
- Research on the output and gain of traditional hearing aid receivers
- FDA's and Congress' stated assumptions and intentions
- Most importantly, because patients' perception about their hearing loss *is* reality