# FDA Final Rule Establishing OTC Hearing Aids

## (and Prescription Hearing Aids)

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# Panelists

- David Akbari, Au.D., OTC Committee Member
- Victor Bray, Ph.D., Past President, OTC Committee Co-Chair
- Stephanie Czuhajewski, MPH, CAE, Executive Director
- Kristin Davis, Au.D., President and OTC Committee Member
- Alicia Spoor, Au.D., Advocacy Chair, OTC Committee Co-Chair

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# Agenda

1. Introduction/Background
2. FDA Final Rule Provisions for Establishment of OTC *and* Prescription Hearing Aids
3. Impact, Implications, and Unintended Consequences of Recategorization of Restricted Hearing Aids to Prescription Hearing Aids
4. Must Nots and Must Dos for Your Patients, Your Practice, and Your Profession
5. Q&A


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# Introduction/Background

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# Timeline for Public Policy Initiatives for OTC Hearing Aids

**2014**

- NASEM holds workshop on Hearing Loss and Health Aging

**2015**

- PCAST issues report, recommends OTC hearing aids

**2016**

- FDA Workshop Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids
- NASEM releases landmark report: Hearing Health Care for Adults Priorities for Improving Access and Affordability
- FDA stops enforcing the medical clearance requirement for adults

**2017**

- FTC Workshop Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care

**2020**

- OTC Hearing Aid Act is Passed and Enacted as part of FDARA
- FDA misses statutory deadline to issue proposed OTC HA regulations

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# Recent Public Policy Initiatives to Advance OTC Hearing Aids

**July 2021**

On July 9, 2021, President Biden issues EO urging FDA to issue the Proposed Rule on OTC Hearing Aid within 120 days

**October 2021**

FDA issues proposed OTC Hearing Aid Rule on October 17, 2021

**January 2022**

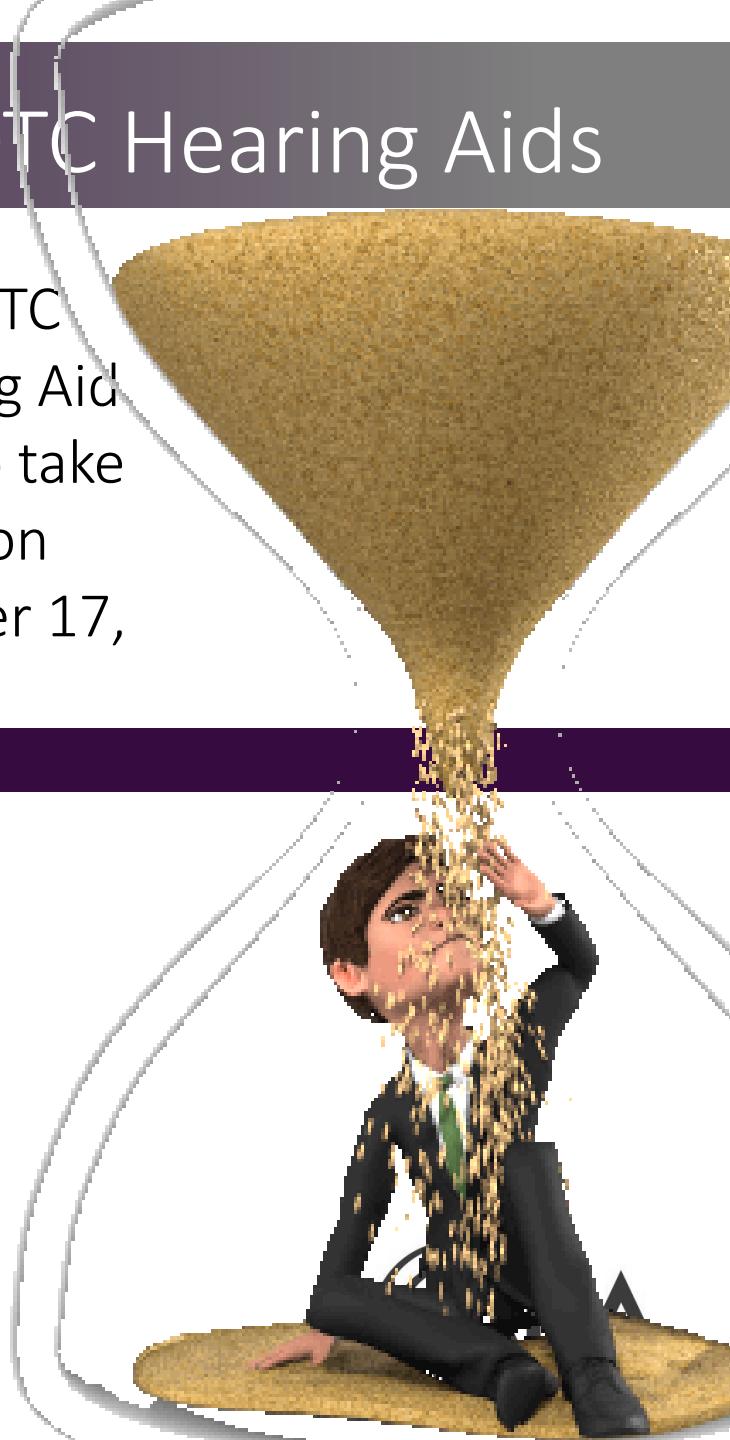
Public Comments on Proposed OTC Hearing Aid Rule due to FDA on January 18, 2022

**August 2022**

FDA issues Final OTC Hearing Aid Rule on August 17, 2022

**October 2022**

Final OTC Hearing Aid Rule to take effect on October 17, 2022



# New FDA Hearing Aid Definitions

***Over-the-counter hearing aid.***

- “An over-the-counter (OTC) hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention, and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment.
- The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs.
- The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements in this section.”

***Prescription hearing aid.***

- “A prescription hearing aid is a hearing aid that is not an OTC hearing aid as defined in this section or a hearing aid that does not satisfy the requirements in this section.”

# OTC Hearing Aids

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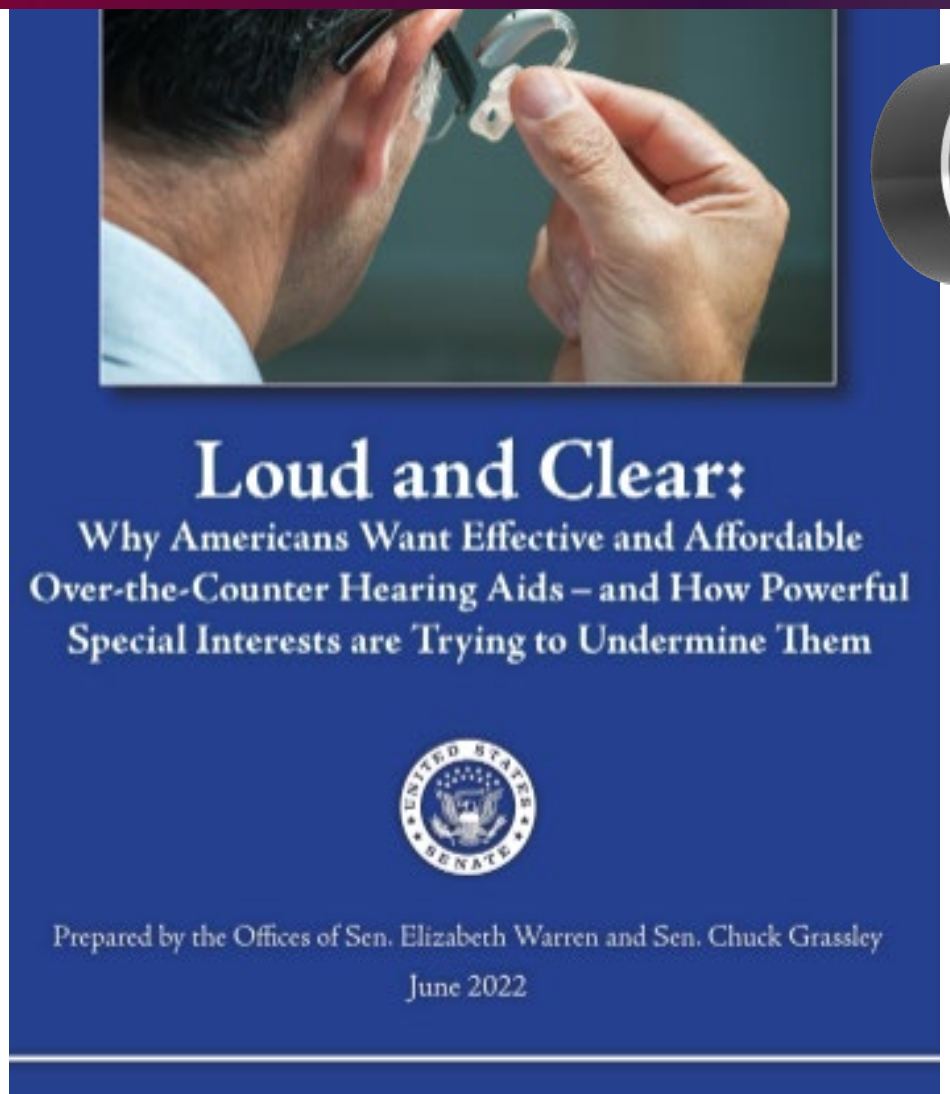
# Level-Setting: ADA Support for OTC Hearing Aids

- ADA aims to advance evidence-based clinical and business practices in the provision of audiology services, professional autonomy, and patient choice.
- ADA believes that 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 believes that audiologists who deliver high-quality hearing and balance services will always serve as an essential resource and partner for consumers.
- 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, to address critical unmet needs.***

# Warren and Grassley Report: Calling Bull$*&% on Industry Efforts to Restrict Output and Gain




# FDA Final Rule Includes FDARA-Mandated 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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# FDA OTC HA Output and Gain Limits

***General output limit:***

- An OTC hearing aid shall not exceed an output limit of 111 dB SPL at any frequency except as ...

***Output limit for a device with activated input-controlled compression.***

- An OTC hearing aid that has input-controlled compression activated shall not exceed an output limit of 117 dB SPL at any frequency.
- The output limits that we are finalizing balance safety and effectiveness without unduly sacrificing either.
- Lowering the output limit even further would begin excluding intended users without achieving meaningful improvements in safety for them.

***"We did not propose, and are not finalizing, a separate gain limit":***

- A gain limit reduces the ability to adequately amplify soft sound inputs in some cases, which can lead to decreased device effectiveness and user satisfaction.
- Imposing a gain limit may constrain device design and innovation, which could have an undesirable effect on device benefit for intended users.
- By not requiring a gain limit, the broadest range of intended users will have access to effective devices.

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# FDA OTC HA Electroacoustic Requirements

***Electroacoustic performance limits:***

- An OTC hearing aid shall perform within all the following electroacoustic limits …
- Reference ANSI/CTA-2051:2017 …

****Input/Output distortion control limits:***

- The total harmonic distortion plus noise shall not exceed 5 percent …

***Self-generated noise level limits:***

- Self-generated noise shall not exceed 32 dBA …

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*New performance standards

****Latency:***

- Latency shall not exceed 15 msec …

***Frequency response bandwidth:***

- The lower cutoff frequency shall extend to 250 Hz or below, and the upper cutoff frequency shall extend to 5 kHz or greater …

****Frequency response smoothness:***

- No single peak in the one-third-octave frequency response shall exceed 12 dB relative to the average levels of the one-third-octave bands, two-thirds octave above and below the peak …

# FDA OTC HA Design Requirements

***Insertion depth:***

- The design of an OTC hearing aid shall limit the insertion of the most medial component so that, when inserted, the component is reasonably expected to remain at least 10 millimeters (mm) from the tympanic membrane.

***New: User-adjustable volume control:***

- The OTC hearing aid shall have a user-adjustable volume control.

***Tools, tests, or software:***

- The OTC hearing aid shall, through tools, tests, or software, permit a lay user to control the device and customize it to the user's hearing needs.

***Use of atraumatic materials:***

- The material for the eartip of an OTC hearing aid shall be atraumatic.

***Proper physical fit:***

- The design of an OTC hearing aid shall enable consumers to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear.

***Adequate reprocessing:***

- If the OTC hearing aid is used or rebuilt, it must be adequately reprocessed for the next user prior to sale.

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# FDA OTC HA Conditions for Sale

***Age minimum:***

- Sale to or for a person younger than 18 years of age is prohibited.

***Statement of OTC availability:***

- The principal display panel shall bear the marks “OTC” and “hearing aid” for the device's statement of identity.

***Labeling:***

- Required labeling outside-the-box and inside-the box on age, medical warnings, usage cautions, and seeking professional help.

***Professional requirements:***

- The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids, or an equivalent activity, whether through in-person transactions, by mail, or online, shall not cause, require, or otherwise obligate a person providing such services to obtain specialized licensing, certification, or any other State or local sanction unless such requirement is generally applicable to the sale of any product or to all places of business regardless of whether they sell OTC hearing aids.
- A licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.

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# The FDA Final Rule States:

"Thus, for example, a State may require a license for a hearing aid fitter, because ''fitting'' is not listed among the activities in section 709(b)(4) of FDARA, and we do not interpret any of the listed activities to include fitting. A person could not be a fitter in that State, even for OTC hearing aids, without a license. However, the State could not require a hearing aid fitting prior to a user purchasing an OTC hearing aid because that would restrict or interfere with commercial activity involving OTC hearing aids."

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# Prescription Hearing Aids

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# Shedding Light on the Implications, and Unintended Consequences of FDA Final Rule Provisions Repealing Regulations for Restricted Hearing Aids and Establishing a New Prescription Hearing Aid Category

# FDA Final Rule

- Maintains existing definition and medical device classifications for hearing aids (Class I and Class II) as consistent with FD&C Act
- Creates category of OTC hearing aids, regulatory controls, and conditions for sale (mandated by FDARA)
- Denotes FDARA federal preemptions for OTC hearing aids
- Creates category of prescription hearing aids, regulatory controls, and conditions for sale (***there was no Congressional mandate to do this***)
- Repeals conditions for sale for hearing aids under CFR Title 21 801.421, as “restricted” devices (***there was no Congressional mandate to do this***)
- Removes federal preemptions and 40-year-old exemption decisions for restricted hearing aids (***there was no Congressional mandate to do this***)

Information originally presented on January 12, 2022

# FDA Exceeded Congress' Mandate Under the OTC Hearing Aid Act/FDARA:

1) Eliminating the current restricted category of hearing aids and associated regulations
2) Creating a prescription category of hearing aids


Class I and II Prescription hearing aids did not exist before.

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# FDA Final Rule: Creating OTC and Prescription Hearing Aid Categories

## OTC Hearing Aid

- Category of hearing aid never existed before
- Defined by technical specifications and intended use
- May be dispensed by licensed or unlicensed person
- Federal preemptions are strong

## Prescription Hearing Aid

- Category of hearing aid never existed before for air conduction HAs
- Defined by technical specifications and intended use
- Must be dispensed by licensed person as governed by State law
- Federal preemptions are limited

# FACT: Air Conduction Prescription Hearing Aids Did Not Exist Before the FDA Final Rule on OTC Hearing Aids

- As ADA Outlined in its landmark paper, State Laws and Hearing Aid Sales (May 2021) air conduction hearing aids have never been categorized as prescription devices.
- As ADA reported in January 2022, during the Town Hall meeting on the FDA Proposed Rule for OTC HAs, implementation of the Final Rule will establish a *new* FDA prescription category of hearing aids.
- Disinformation developed, disseminated, and driven by bad actors, and circulated by the uninformed has created a false paradigm for many audiologists.

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Ironically, the FDA Final Rule establishing OTC hearing aids will make it more difficult for consumers to access traditional (now prescription) hearing aids and for for audiologists to dispense them.

# FDA Final Rule States:

"Prescription hearing aids are prescription devices and as such, they are subject to § 801.109. Under § 801.109(a), a prescription device is a device that is:

(1) either in the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device or in the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device and

(2) is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice."

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# FDA Final Rule States:

"With respect to prescription hearing aids and other State and local requirements for hearing aids not otherwise preempted by FDARA section 709(b)(4), **FDA is removing all of the regulations in part 808 related to hearing aids**; that is, almost all regulations codifying the previous decisions in §§ 808.53 through 808.101, except for the portions of § 808.55 (California) that do not relate solely to hearing aids."

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# TL;DR: Repeal of 801.421 Poses Risk for Access

**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.

Information originally presented on January 12, 2022

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# ADA Concerns: Conditions for Sale Hearing Aids

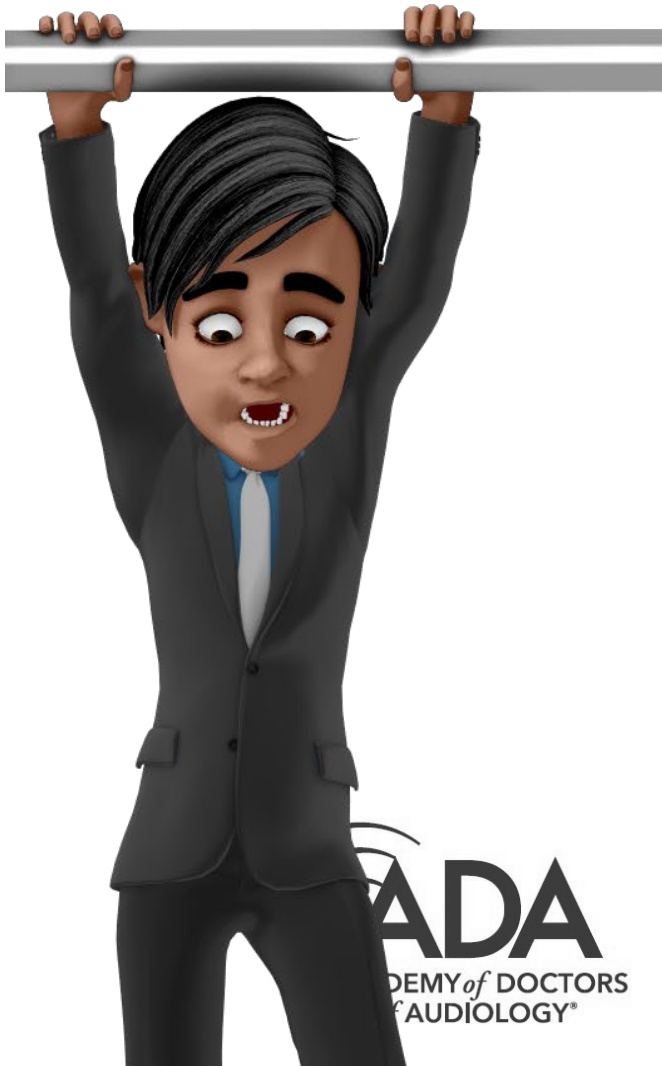
ADA has grave concerns that the repeal of 801.421 may result in the unintended consequence of State-imposed restrictive or anti-competitive conditions for sale for adults purchasing prescription hearing aids.

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

Slide originally presented on January 12, 2022

# FDA Failed to Act to Ensure Continued Access to Traditional (now Prescription) Hearing Aids

1. States that have archaic laws on their books which were previously preempted, may now enforce them
    - Example: Laws in New York and Rhode Island states require that adults obtain a medical clearance to purchase a hearing aid—with no waiver option
2. States can create new laws that will restrict who, how, when, and where, prescription hearing aids are prescribed and dispensed and there is no longer a federal preemption to ensure consumers ready access to these products.
3. There are anti-competitive forces who will seek to restrict consumer access to audiologists and modern testing and treatment delivery channels. This could result in increased costs to consumers and reduced autonomy for audiologists.



# FDA Response to Rhode Island Department of Health

"Comment 121) A comment from the Rhode Island Department of Health noted that Rhode Island General Laws sections 5–49–2.1 and 2.2 contain provisions that would require consumers or purchasers to obtain a certificate of need from a physician who attests that the individual is in need of a hearing aid, and therefore requested that FDA retain § 808.89, which denied Rhode Island's request for exemption from preemption. Doing so, the comment said, would align with FDA's approach of authorizing non-physician licensed hearing professionals to make determinations of need and would also benefit consumers by reducing unnecessary costs and added time to the process of obtaining a hearing aid."

# FDA Response to Rhode Island Department of Health

"(Response) FDA has decided not to retain § 808.89, because the repeal of the conditions for sale in § 801.421 substantively changes the underlying Federal requirements against which the previous denial of exemption from preemption was made. The repeal of § 801.421 means Rhode Island General Laws sections 5–49–2.1 and 2.2 are no longer preempted under section 521(a) of the FD&C Act, because no counterpart Federal requirement exists (see § 808.1(d)). Without that preemption, the previous denial would have no effect even were we to retain the regulation."

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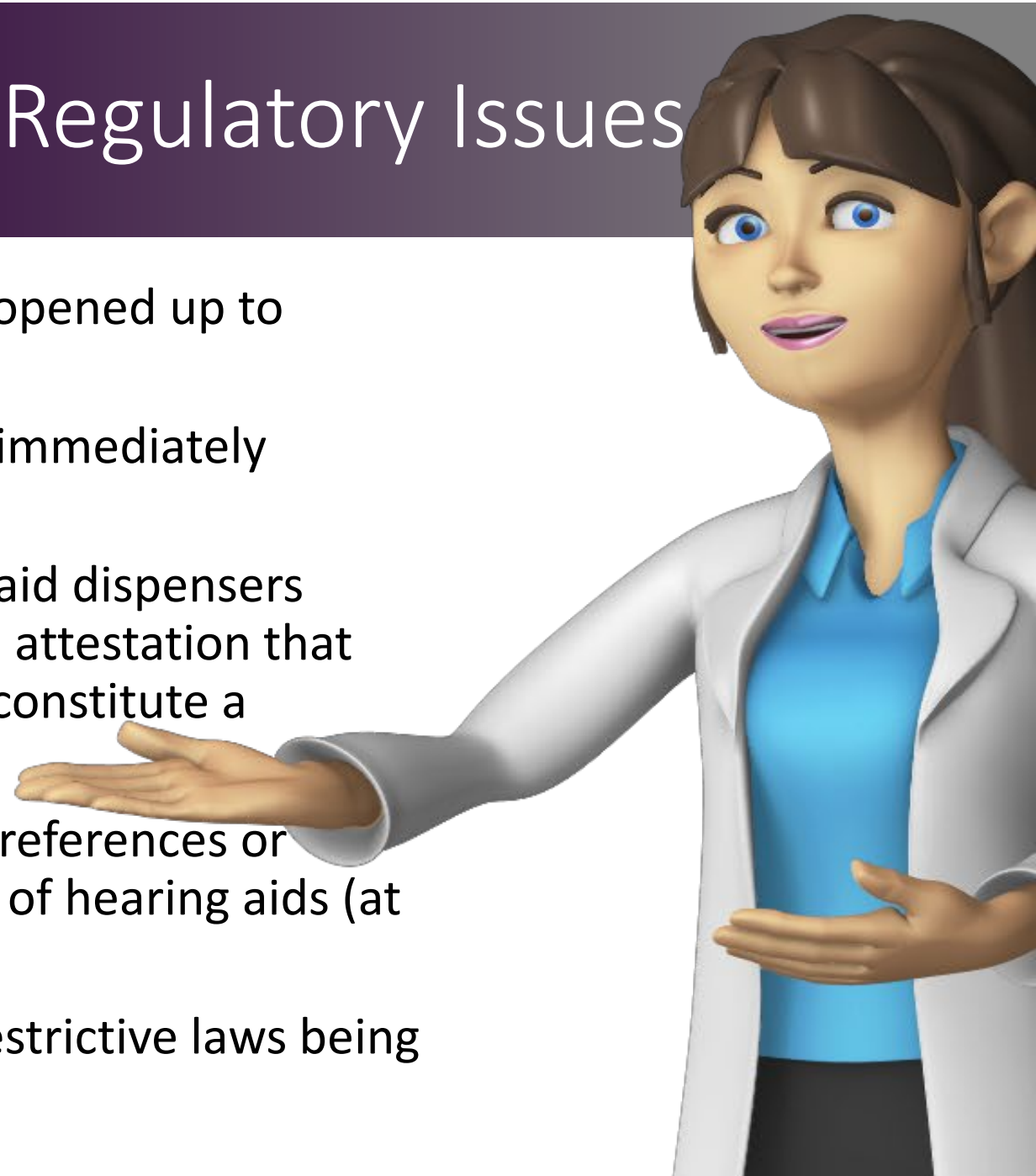
# TL;DR: Federal Rule Creates Unintended State Statutory/Regulatory Barriers to Access

The FDA's re-categorization of non-OTC air conduction hearing aids as federally regulated prescription devices has resulted in statutory and regulatory ambiguity at the state level, which is further complicated by the removal of federal preemptions on the condition of sale for hearing aids, which have been in place and relied upon for more than 40 years.

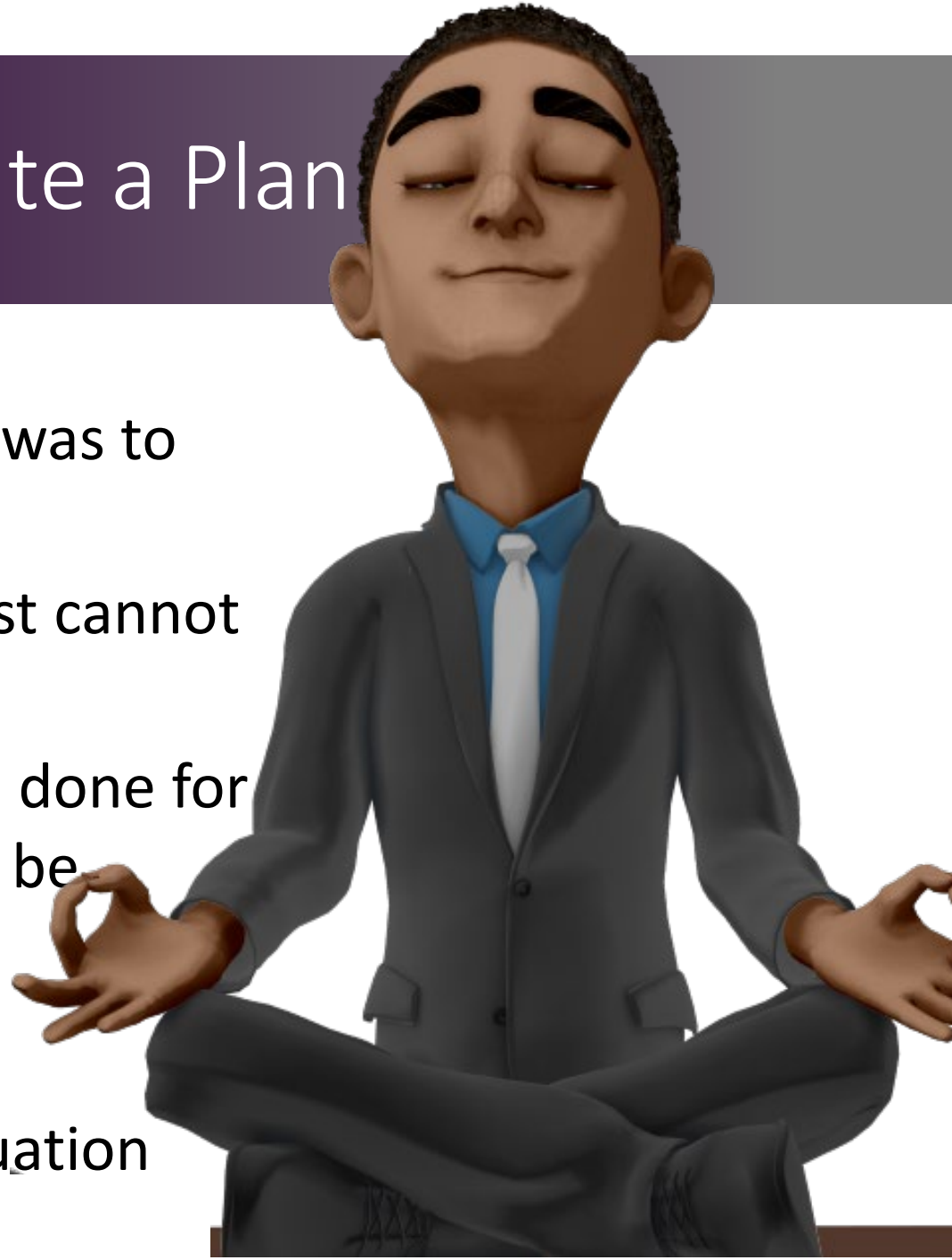
# Urgent State Statutory and Regulatory Issues

- Number of states where laws will need to be opened up to comply with the federal mandates (50).
- Number of states where archaic laws may be immediately triggered (at least 2)
- Number of states currently requiring hearing aid dispensers and/or audiologists to provide consumer with attestation that activities related to dispensing/fitting do not constitute a prescription or medical advice (at least 20)
- Number of states where there are conflicting references or ambiguity about audiologists as “prescribers” of hearing aids (at least 40)
- Number of states that have a threat of new restrictive laws being put forward by bad actors (50)



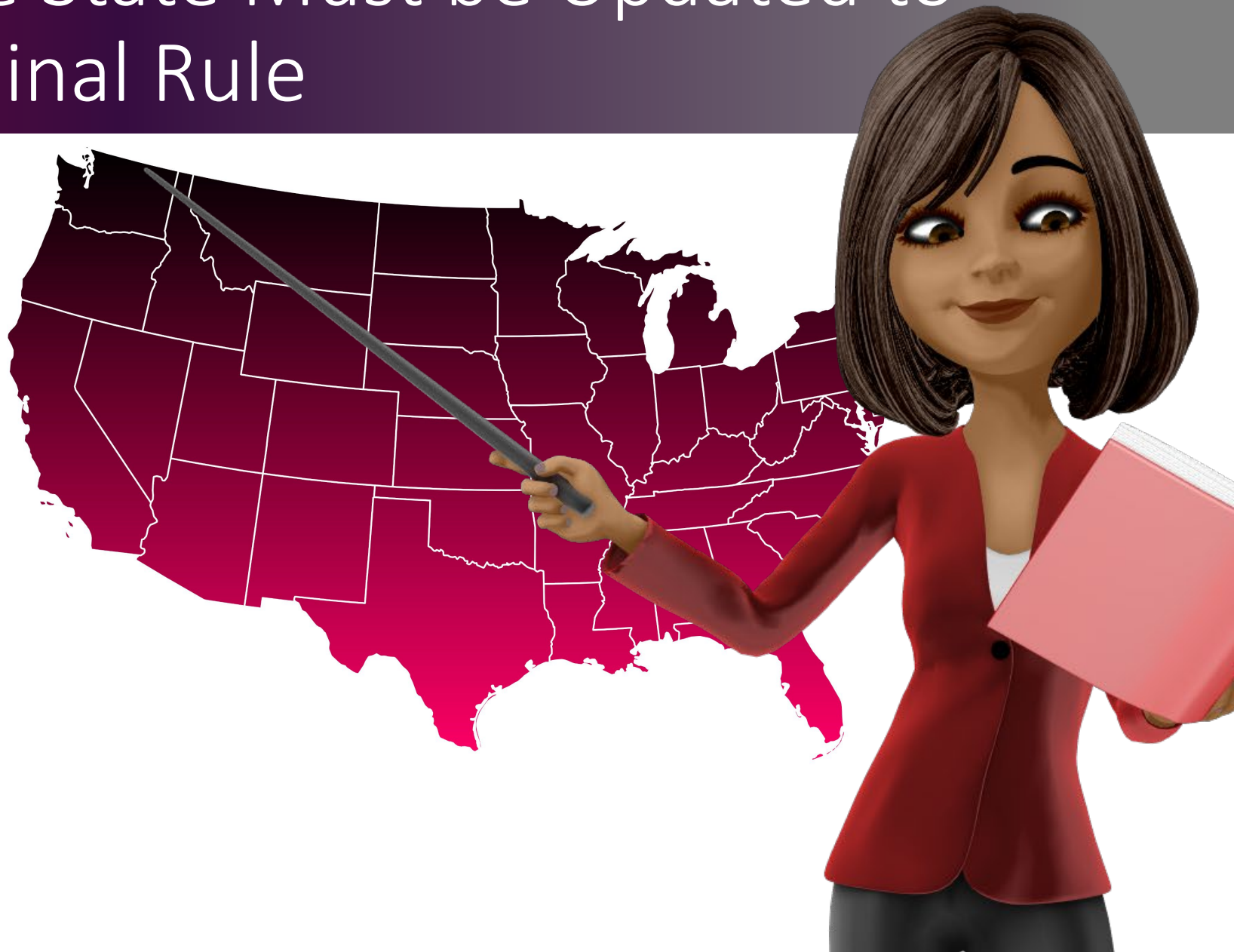
# Take a Deep Breath and Formulate a Plan

- Reason: Congress' intent with the OTC HA Act was to increase access and decrease cost
- Time: All State laws must be updated, and most cannot be until 2023
- Inertia: No reason to think that what has been done for 45 years, should not be assumed to be able to be done going forward.
- FDA weighed in (in 2016) with guidance on air conduction hearing aids and the medical evaluation



# Laws in Every Single State Must be Updated to Conform with the Final Rule

- Statutes *and* Regulations
- Updated definitions (OTC hearing aid, prescription hearing aid, dispenser, licensed dispenser, etc.)
- Licensure laws
- Scope of practice and/or conditions for sale for hearing aids



# Must Nots and Must Dos for Your Patients, Your Practice, and Your Profession

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# Do Not Do This

- Rely on Facebook groups, self-proclaimed audiology pundits, and/or vendors as your sources for accurate information
- Panic
- Leave the important advocacy work that must be done to others

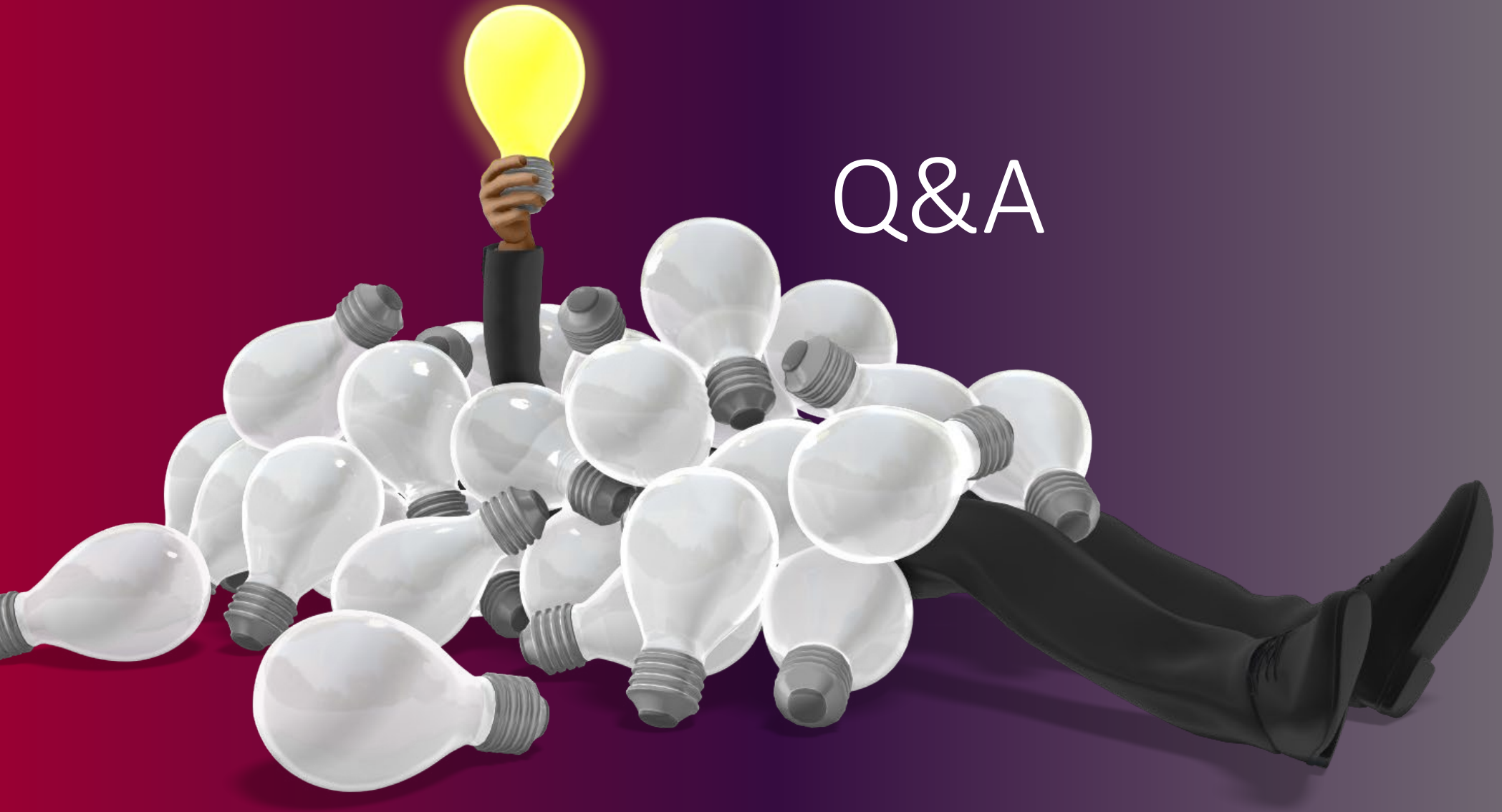
# Do This

- Read the Final Rule for yourself
- Understand the facts about the FDA Final Rule on the Establishment of OTC Hearing Aids
- Donate to the Eric N. Hagberg Advocacy Fund
- Attend the ADA State Advocacy Workshop at AuDacity
- Act on ADA Advocacy Alerts
- Join your state association, volunteer for advocacy efforts, and donate to your state association
- Seek the advice of your legal counsel for questions that you have about your individual practice

# What is ADA Doing?

- ADA has formulated a federal and state advocacy and legal strategy
- ADA is working with coalitions and partners where feasibl
- ADA is developing the tools and resources that audiologists need for effective advocacy
- ADA is crafting advocacy initiatives to protect private practices and the profession of audiology
- ADA is seeking audiologists to lead initiatives in every state

# Q&A



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