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Ahead of the Curve.

October 20-23, 2022

Grapevine/Dallas, Texas

STATE ADVOCACY WORKSHOP

ADA

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Federal Issue or State Issue? A few examples

Federal Issue

- Medicare reimbursement
- FDA regulations
- HIPAA
- False Claims Act
- Surprise Billing Act
- Federal anti-kickback statute
- Federal minimum wage

State Issue

- Scope of Practice
- Licensing requirements
- Hearing aid returns and sales tax
- State surprise billing laws
- State anti-kickback laws
- State minimum wage (cannot be lower than federal minimum but can be higher)

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Statute or Regulation?

Statutes

- Laws written and enacted by the legislative branch of government
  - U.S. Congress
  - State legislature

Regulations

- Laws created by agencies
- Also referred to as rules
  - to supplement laws that were passed by the legislature.
  - Usually authorized by a statute
  - Are subordinate to statutes but have the same legal force as statutes

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Many laws, including state licensing laws involve both statutes and regulations.

Important Questions

- What entity has jurisdiction over the issue?
- What is the process and protocol to address the issue?
- What relationships and resources are necessary to advance the effort?
- What relationships and resources exist to advance the effort?
  - Lobbyist
  - Coalition
  - Time, talent, and treasure
  - Personal relationships
- What obstacles exist (opposition, financial, time, process etc.)?

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FDA Final Rule on OTC and Prescription Hearing Aids

FDA Final Rule Includes Federally-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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New FDA Hearing Aid Definitions

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

- Air-conduction hearing aid
- Intended for use by a person aged 18 years or older to compensate for perceived mild to moderate hearing impairment
- Output up to 117 dB SPL, no gain restrictions
- Allows the user to control the hearing aid and customize it using tools, tests, or software,
- May use wireless technology and may include tests for self-assessment of hearing loss
- Involvement of licensed person not required

*Not an exhaustive list of features

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New FDA Hearing Aid Definitions

Prescription hearing aid

Literally, everything else.

- “A prescription hearing aid is a hearing aid that is not an OTC hearing aid as defined in this section (21 CFR 800.30) or a hearing aid that does not satisfy the requirements in this section.”

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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

A License Can/May Be Required for Fitting OTC HAs

"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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I WAS TOLD TO
CREATE OTC HEARING AIDS
BUT I ADDED PRESCRIPTION TOO

FDA Final Rule on OTC (and Prescription) HAs

- Maintains existing definition and medical device classifications for AC 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*)**

IN WHAT UNIVERSE IS IT A GOOD IDEA TO CREATE A PRESCRIPTION CATEGORY OF HEARING AIDS AND REPEAL LONGSTANDING FEDERAL PREEMPTIONS WITHOUT ENOUGH ADVANCE NOTICE FOR STATES TO UPDATE THEIR LAWS TO CONFORM WITH EVIDENCE-BASED PRACTICES?

IN NO UNIVERSE!

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ADA Expressed Concerns During the Public Comment Period

During the comment period ADA expressed 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. Asked FDA to 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. ADA asked FDA to amend the Proposed Rule to expressly prohibit States from enacting requirements that go beyond requirements for professional licensure as conditions of sale.

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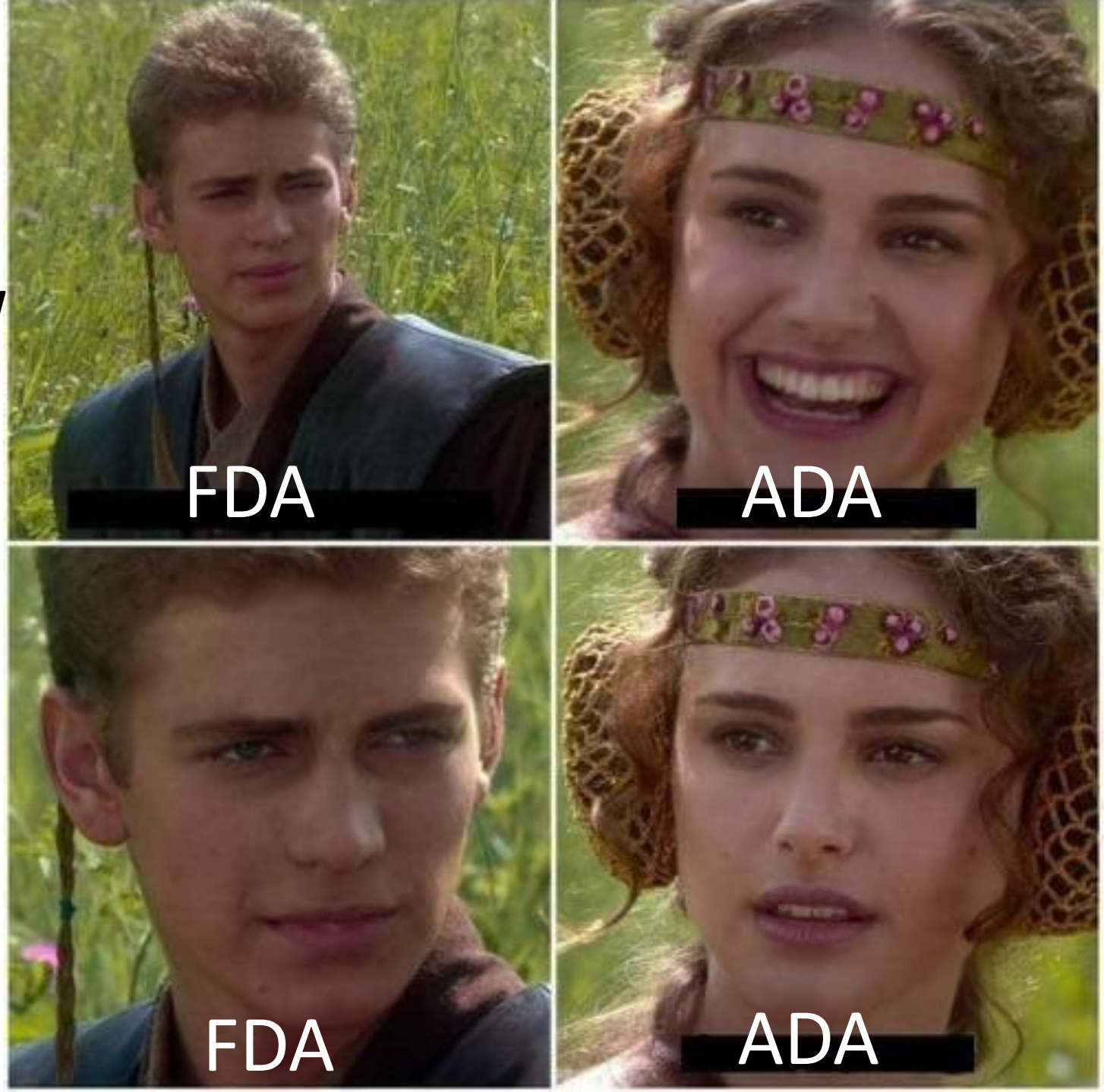
WE ARE EXCEEDING CONGRESS' MANDATE AND CREATING A NEW CATEGORY OF PRESCRIPTION HEARING AIDS



AND ENSURING THAT CONSUMERS CAN GET THEM FROM AN AUDIOLOGIST, RIGHT?

AND ENSURING THAT CONSUMERS CAN GET THEM FROM AN AUDIOLOGIST… RIGHT?

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Prescription HAs Require Licensed Prescriber

"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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ONE DOES NOT SIMPLY
CREATE A PRESCRIPTION
CATEGORY OF HEARING AIDS

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.

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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.
2. States can create new laws that will restrict who, how, when, and where, prescription hearing aids are prescribed and dispensed.
3. Anti-competitive forces may seek to restrict consumer access to audiologists and modern testing and treatment delivery channels.

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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**

- **Ensure Audiologists as prescribers**
- **Avoid medical evaluation (if not already prohibited)**
- **Avoid minimum testing and treatment procedures**
- **Avoid mandatory in-person/face-to-face visits**
- **Avoid prohibitions on sending prescription hearing aids by mail and/or across state lines**
- **Retain fitting license requirements**

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 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)**

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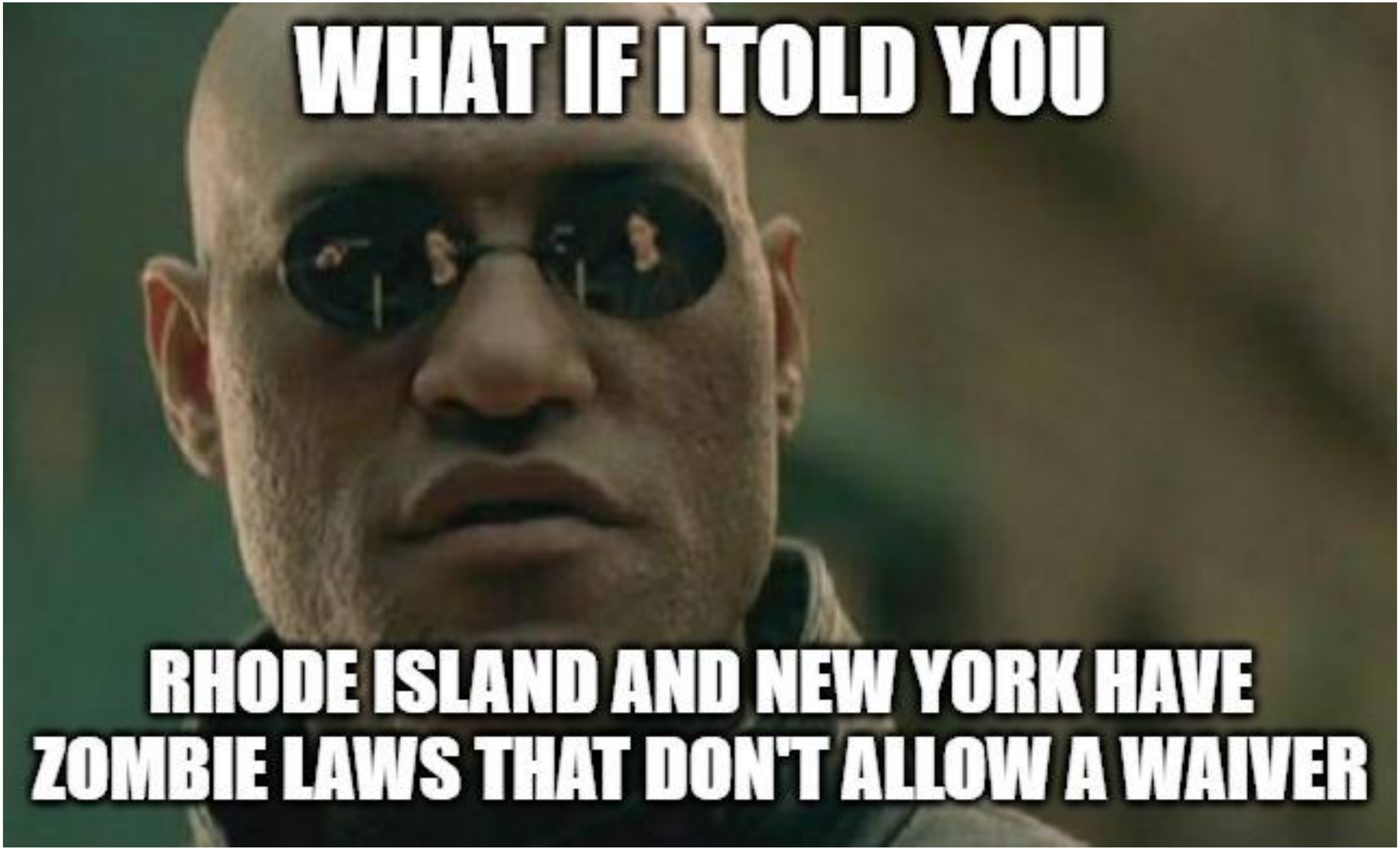
WHAT IF I TOLD YOU
RHODE ISLAND AND NEW YORK HAVE
ZOMBIE LAWS THAT DON'T ALLOW A WAIVER

FDA creates prescription hearing aid category

Fails to consider unintended consequences

Successful State and Federal Advocacy Efforts,

- ADA and other organizations wrote a letter to FDA outlining concerns related to ambiguity in prescribing laws and state medical clearance requirements for adults, where a waiver was not allowed.
- FDA met with the coalition and in response to coalition requests, wrote a letter to each and every state clarifying its intention with the final rule and that FDA did not intend to impede or preclude audiologists or hearing aid dispensers from dispensing prescription hearing aids.

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Rhode Island,

The Rhode Island Department of Health issued a guidance document to stay enforcement of physician certificate of need requirements and to preserve the status quo for audiologists and dispensers to order and dispense traditional/prescription hearing aids using the waiver process until the Rhode Island statutes can be considered.

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RHODE ISLAND AUDIOLOGISTS
YOU GET TO KEEP DISPENSING TRADITIONAL HEARING AIDS

North Carolina

- Issued guidance on September 30, 2022

As a result of the FDA final rules on over-the-counter hearing aids (see FDA Regulations for Over-the-Counter Hearing Aid Sales) the Board has been requested to provide guidance to licensees. The final FDA rule creates two classes of hearing aids, over-the-counter (OTC) and prescription, where one previously existed. Though the ruling emphasizes that the sale of OTC hearing aids is not within the purview of the board, the ruling qualifies that OTC hearing aids are only intended for adults with perceived mild-to-moderate hearing loss. As such, it would be unsafe for licensees to recommend over-the-counter hearing aids for children. Licensees are to continue to follow all state statutes under Article 22. Licensure Act for Speech and Language Pathologists and Audiologists and rules under the North Carolina Administrative Chapter 64, surrounding assessment and dispensing of traditional or "prescription" hearing aids for adults and children. https://ncboeslpa.org/announcement/guidance-for-over-the-counter-hearing-aids/

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Ohio

- The Board is in the process of reviewing the impact that the FDA's final regulations will have on its laws and rules governing the sale, fitting, and dispending of hearing aids by audiologists and hearing aid fitters. From our initial review, we do anticipate changes to Ohio Administrative Code sections 4747-1-19 (I) and (J) and 4753-8-03 (C) dealing with the physician clearance/waiver system. Under the final regulations, the FDA repealed the conditions for sale that require a medical clearance and/or medical waiver under section 801.421(a). Therefore, beginning October 17, 2022, an audiologist or hearing aid fitter will no longer be required to obtain a written statement from a prospective user of a hearing aid that their hearing loss has been medically evaluated and may be considered a candidate for a hearing aid. The FDA also repealed the requirement allowing for a written waiver of the medication evaluation signed by the prospective user. Accordingly, until such time that the Board can rescind the medical clearance and medical waiver provisions from OAC sections 4747-1-19 and 4753-8-03, beginning October 17, 2022, the medical clearance and medical waiver requirements will be unenforceable by the Board. https://shp.ohio.gov/

Take Action

- Join your state association, volunteer for advocacy efforts, and donate to your state association
- Contact your state licensing board to find out what they are doing/have done/intend to do.
- If they have not issued guidance, seek a determination from your state licensure Board or regulatory body regarding “prescribing” prescription hearing aids
- Seek the advice and/or a determination from your own legal counsel
- Open and update the audiology and/or hearing aid dispensing statutes and/or regulations if necessary

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(INCLUDING ADA)
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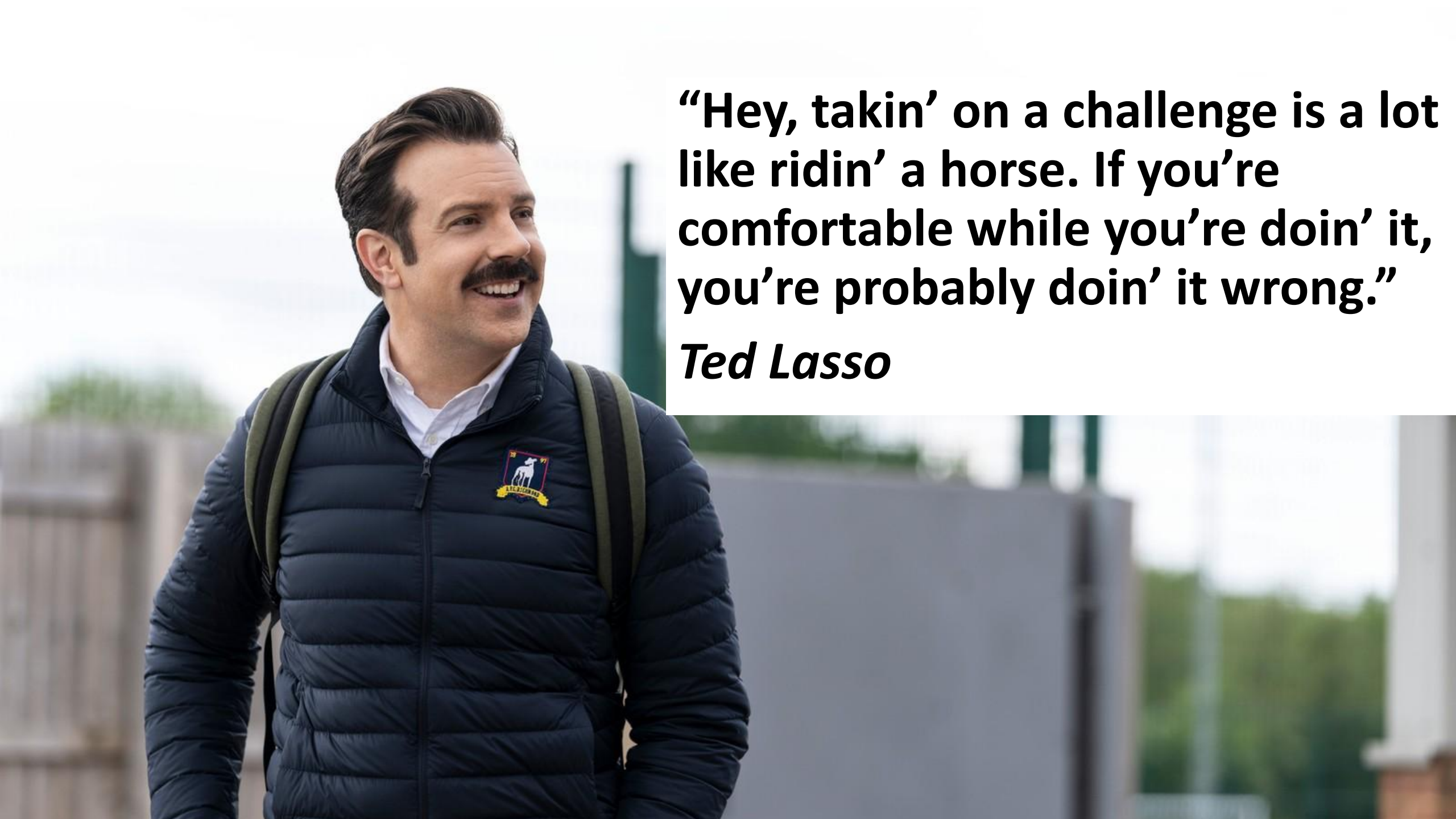

“Hey, takin’ on a challenge is a lot like ridin’ a horse. If you’re comfortable while you’re doin’ it, you’re probably doin’ it wrong.”

Ted Lasso


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