

# FDA proposed rule for over-the-counter (OTC) hearing aids: What the practicing audiologist needs to know

Laura Coco, PhD, AuD, CCC-A





The views expressed do not reflect the official policy or position of the US Veterans' Administration or the US Government.



# OUTLINE

- Background
- Summary of the FDA rule
- What does the research show?
- Implications for clinicians & patients
- How to post a public comment

# Background





Back

YOUR HEALTH

The FDA  
hearing a

October 19, 2021 · 1:55 PM

BILL CHAPPELL US regul  
counter*U.S. health offici  
without a prescri*By MATTHEW PERR  
October 19, 2021, 9:The Food and Drug Administra  
advocates have long called for  
Keith Bedford/Boston Globe via Ge***F.D.A. Moves to Make Some Hearing Aids  
Available Without a Prescription***

The proposed rule could make it easier for Americans with mild to moderate hearing impairments to get the devices.

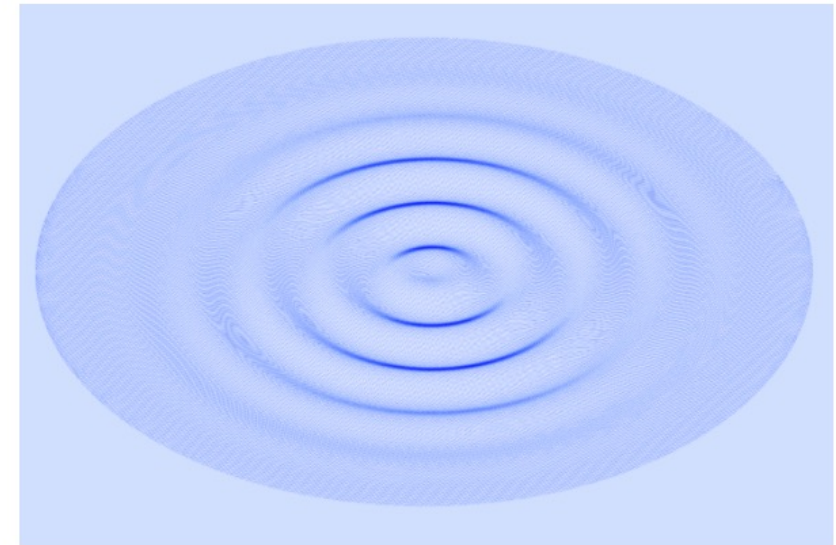


Current regulations, which are more than 40 years old, allow only licensed providers to prescribe and sell the devices, which can cost nearly \$5,000 a pair, and require multiple visits for fitting, testing and adjustments. iStock/Getty Images Plus

THE ON TECH NEWSLETTER

***A Hearing Aid for Everyone***

Over-the-counter hearing aids have the potential to show government and tech companies at their best.



Ruru Kuo



By Shira Ovide

Oct. 20, 2021

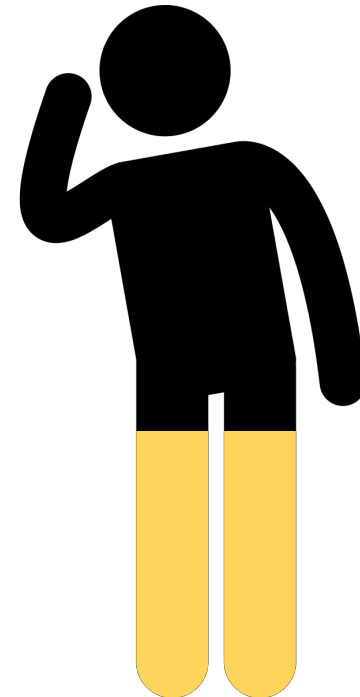
# Background

Approximately 38 million US adults have some degree of hearing loss

Among adults  $\geq 70$  years, **fewer than 1/3 use hearing aids**

Factors influencing uptake:

- Cost



# Background


Original Article

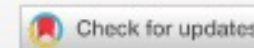
## Hearing aid affordability in the United States

Anna Marie Jilla , Carole E. Johnson & Nick Huntington-Klein

Received 21 Jul 2020, Accepted 08 Sep 2020, Published online: 28 Oct 2020

 Download citation

 <https://doi.org/10.1080/17483107.2020.1822449>



“ an average bundled cost of \$2500 would constitute a **catastrophic expense** for 77% of Americans with functional hearing loss ( $N = 7,872,292$ ) and would add an additional 4% of the population into poverty for the year ( $N = 423,548$ )”

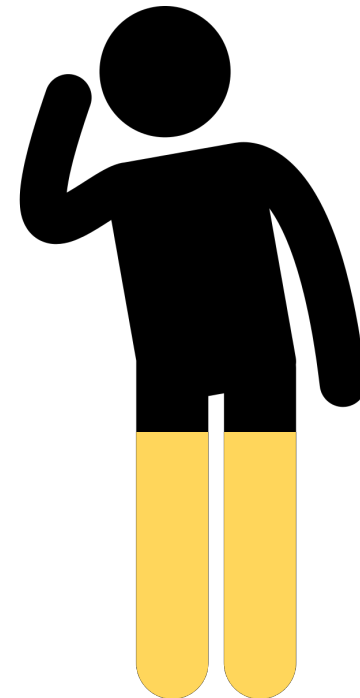
# Background

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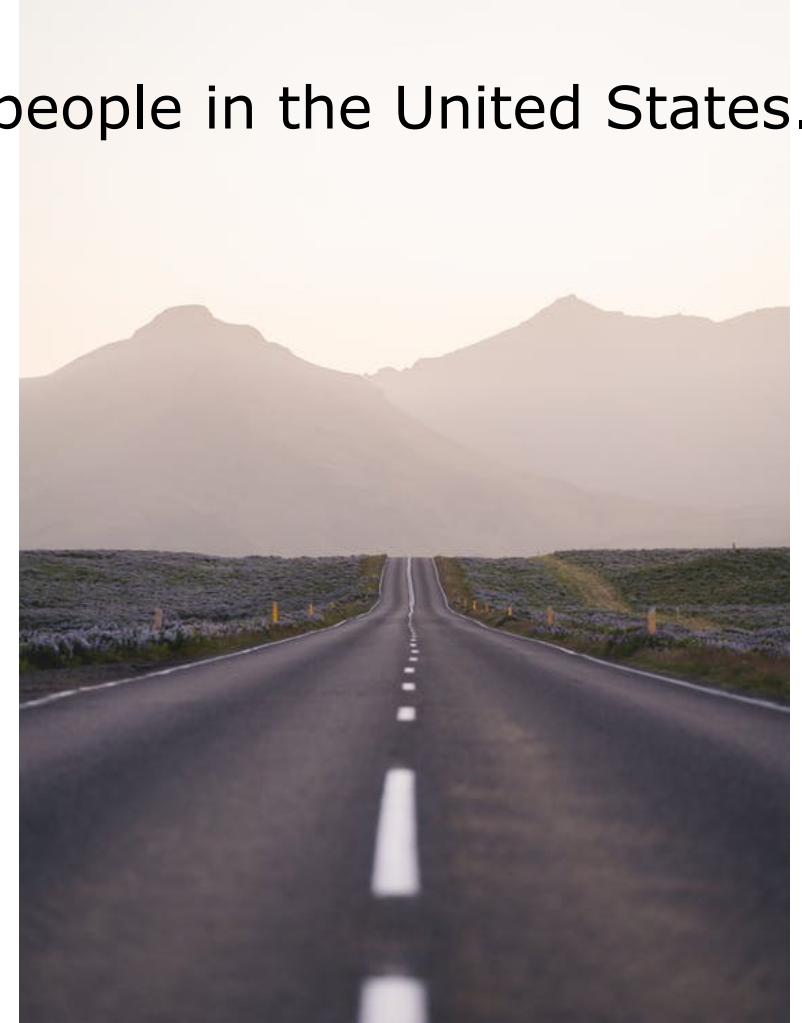
- Cost
- Self-reported hearing disability
- Perceived benefit
- Degree of hearing loss
- Stigma
- Age
- Psychological factors



# Availability of providers

There are an average of 4 audiologists per 100,000 people in the United States.

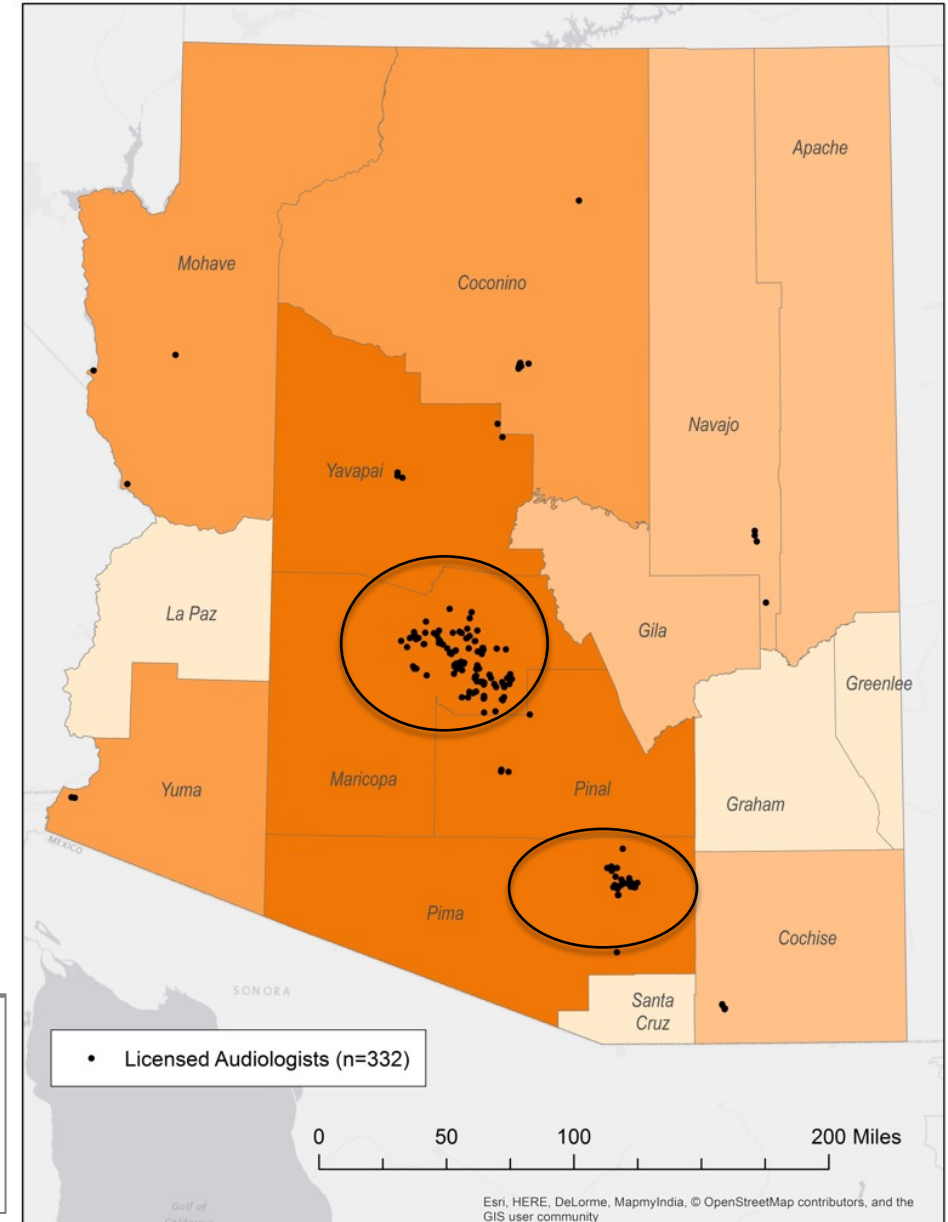
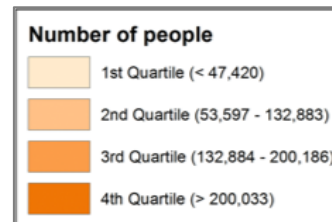
- Fewer audiologists in counties with older populations and lower family incomes (Planey, 2019).
- Patients in rural areas are delayed in use of hearing aid services compared to urban counterparts (Chan et al., 2017).



# Availability of providers

## Arizona Case Study:

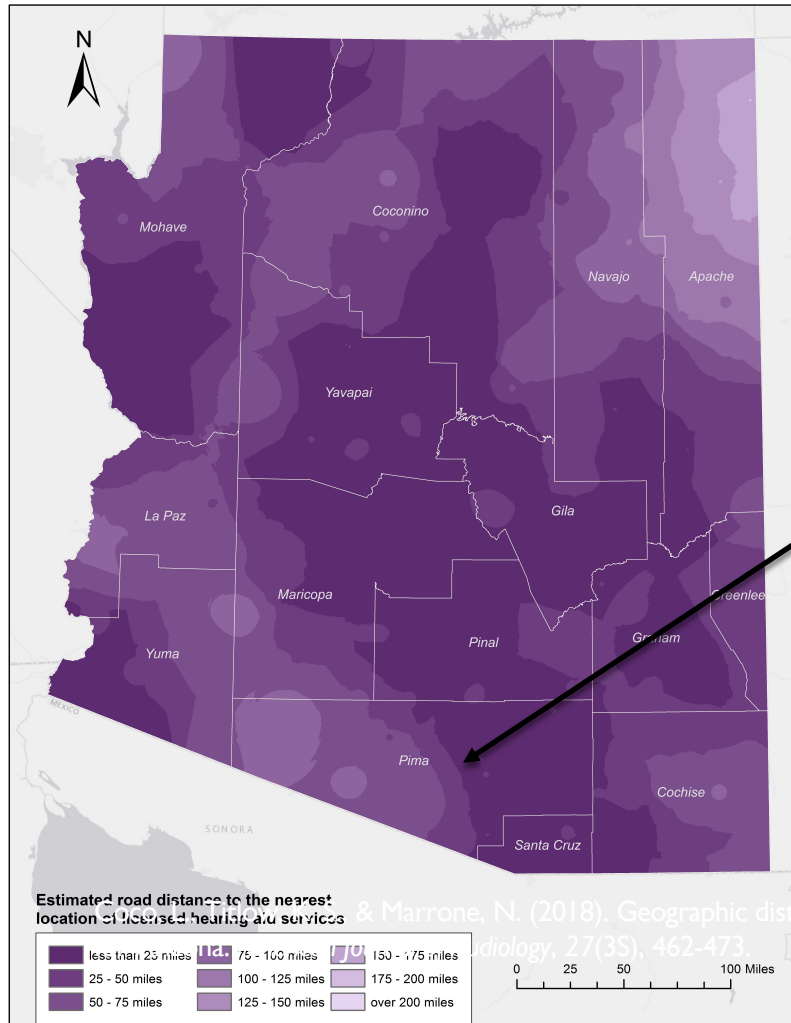
- Fifteen counties in AZ.
- Six non-metro counties in AZ without any audiologists.
- Driving distance to the nearest audiologist could exceed 100mi.





# How far will you travel?

Average estimated road distance to nearest hearing aid services



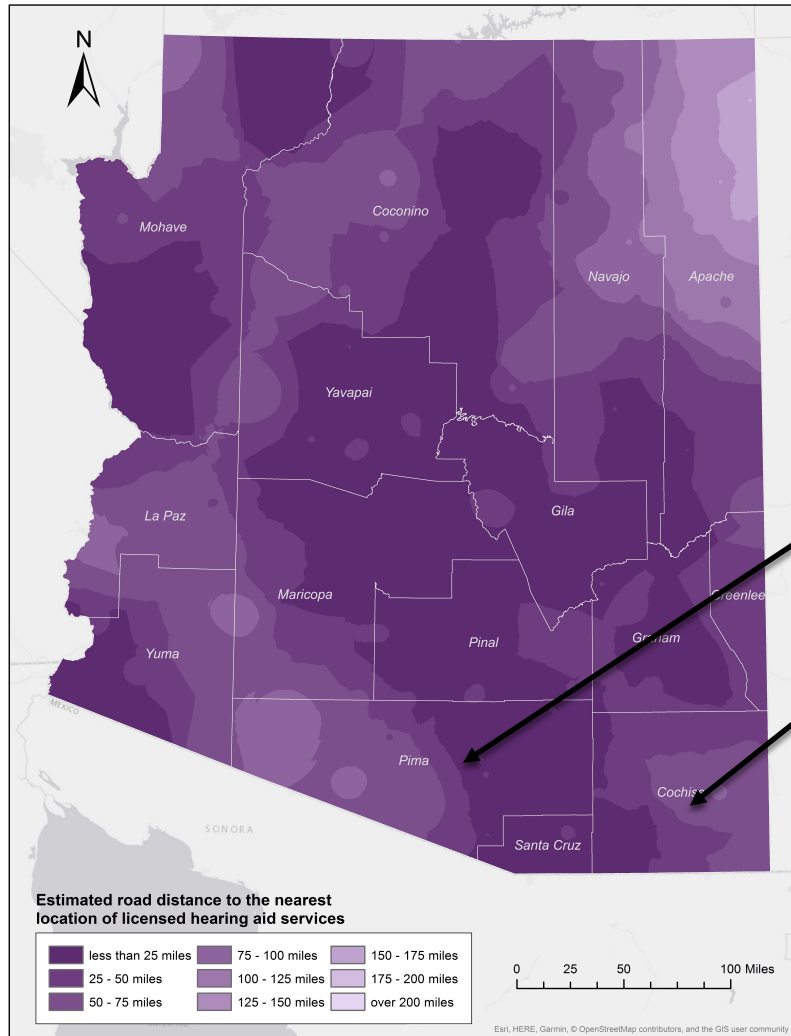
Pima

4.11 miles

Coco, L., Titlow, K. S., & Marrone, N. (2018). Geographic distribution of the hearing aid dispensing workforce: A teleaudiology planning assessment for Arizona. *American Journal of Audiology*, 27(3S), 462-473.

# How far will you travel?

Average estimated road distance to nearest hearing aid services



Pima

4.11 miles

Cochise

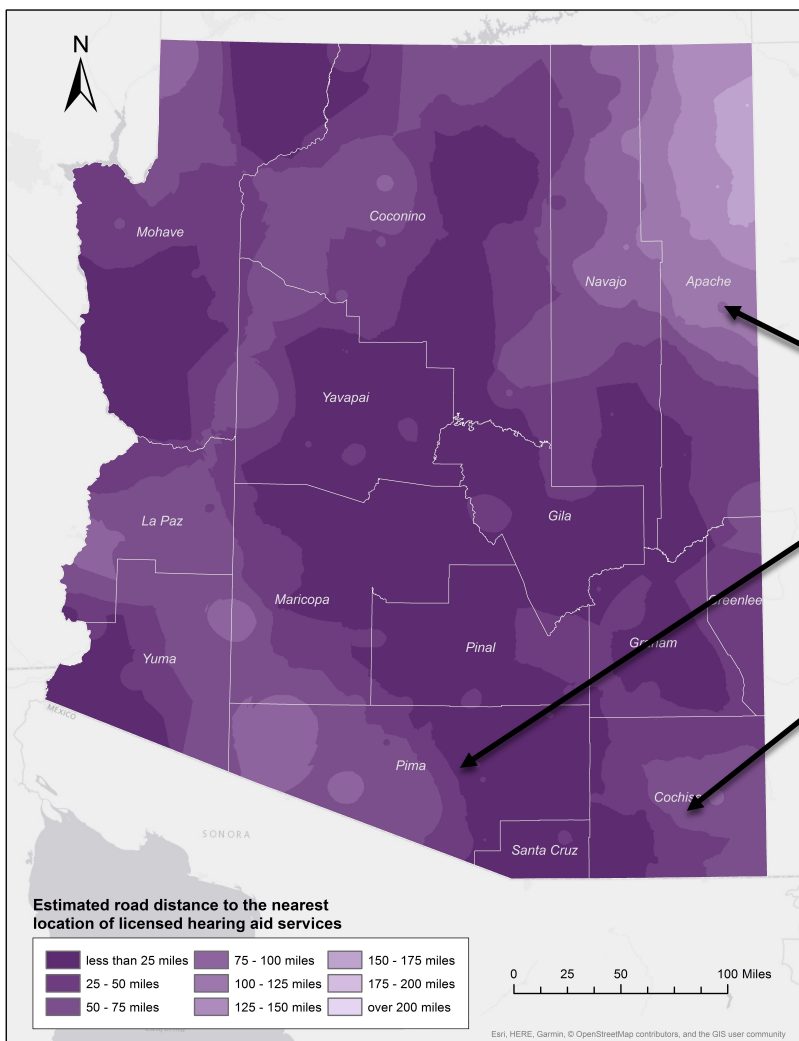
21.6 miles

Coco, L., Titlow, K. S., & Marrone, N. (2018). Geographic distribution of the hearing aid dispensing workforce: A teleaudiology planning assessment for Arizona. *American Journal of Audiology*, 27(3S), 462-473.



# How far will you travel?

Average estimated road distance to nearest hearing aid services



Pima	4.11 miles
Cochise	21.6 miles
Apache	118.9 miles

Coco, L., Titlow, K. S., & Marrone, N. (2018). Geographic distribution of the hearing aid dispensing workforce: A teleaudiology planning assessment for Arizona. *American Journal of Audiology*, 27(3S), 462-473.

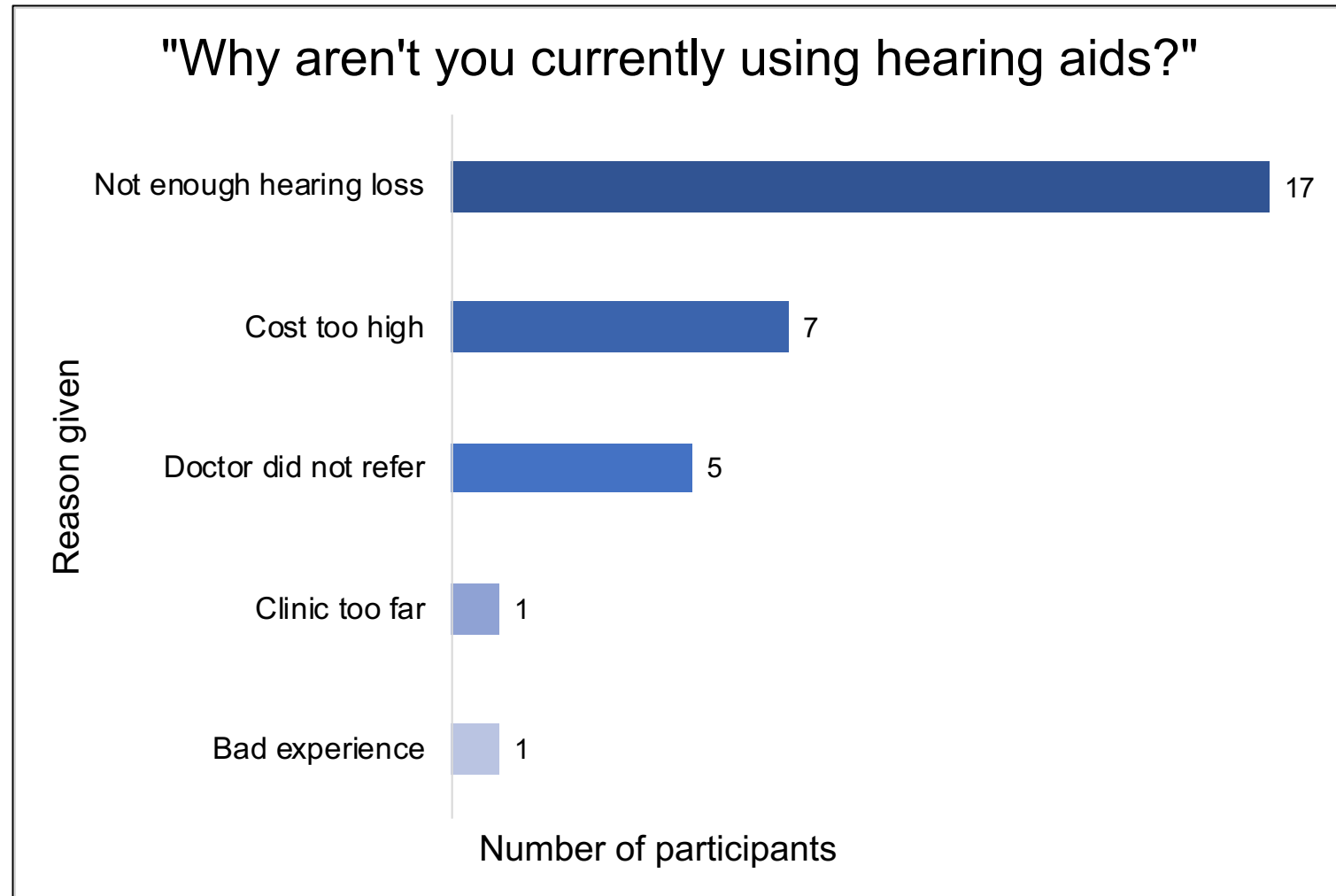
# Conexiones (Connections) results



## CONEXIONES

**Coco, L.,** Piper, R., Navarro, C. & Marrone, N. Community Health Workers as patient-site facilitators in adult hearing aid services via synchronous teleaudiology: Feasibility results from the Conexiones randomized controlled trial. *Ear and Hearing*. (Invited to Resubmit)

# Conexiones (Connections) results



# Background

President's Council of  
Advisors for Science &  
Technology (**PCAST**)  
2015

National Academies of  
Sciences, Engineering,  
and Medicine (**NASEM**)  
2016

EXECUTIVE OFFICE OF THE PRESIDENT  
PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY  
WASHINGTON, D.C. 20502

October 2015

President,

Hearing loss, especially in older Americans, is a substantial national problem. Only a small fraction of older Americans who need assistance with hearing obtain and use hearing aids, in large part because of complex dispensing procedures, social stigma, and performance shortfalls. While the problem is complex, your President's Council of Advisors on Science and Technology (PCAST) believes that a few simple actions by the Federal Government could dramatically enhance the pace of innovation, increase the level of competition in this domain, leading to rapid decrease in cost and improvement in care, and use of assistive hearing devices. We expand on these ideas in this letter report.

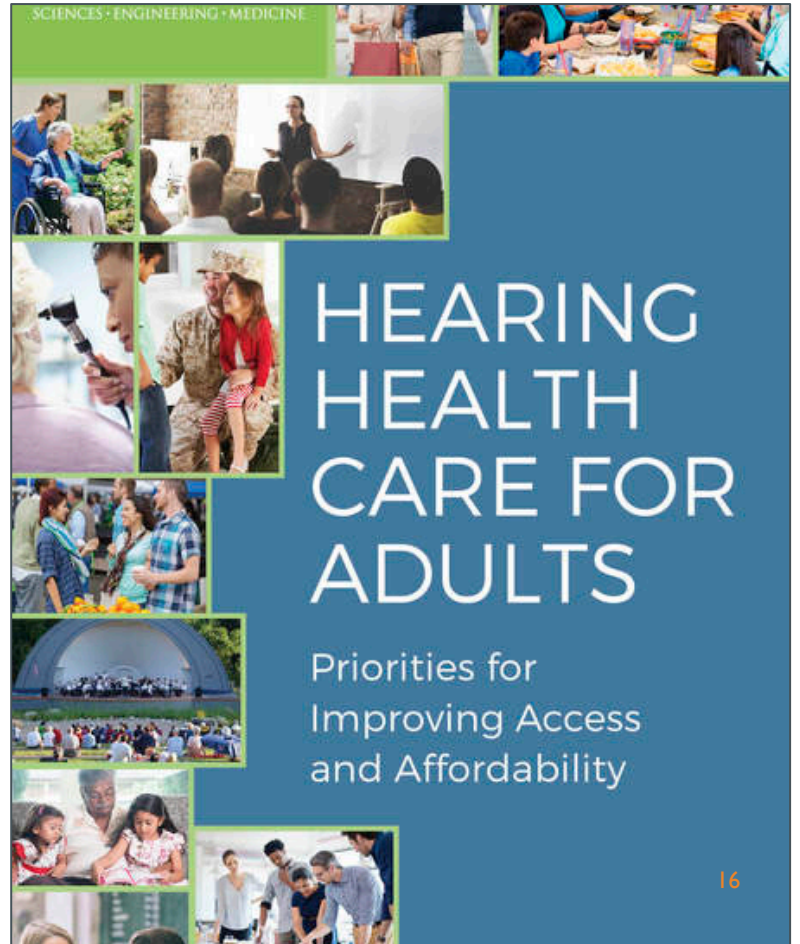
We focus here only on devices to assist the tens of millions of Americans with age-related, moderate to severe hearing loss. PCAST recognizes that many Americans have severe hearing impairment from congenital or illness/injury causes, but we do not address these categories of need.

**I. Age-related hearing loss is a substantial national problem.**

Age-related hearing loss affects many Americans, with older adults particularly at risk—a quarter of Americans aged 50 and 69 years, over half in the range 70-79 years, and almost 80 percent of those older than 80 years have difficulty hearing.<sup>1</sup> The absolute number of those affected, already almost 30 million,<sup>2</sup> is expected to increase as the population ages.

Hearing loss is statistically associated with higher risks of social isolation; depression; disability; injury; and inability to work, travel, or be physically active.<sup>3,4,5,6,7,8,9</sup> While the National Institutes of Health is planning a large randomized trial to supplement these correlational findings, the magnitude of the problem, the number of correlations, and their clinical plausibility are indicative of the types of problems that could be avoided with improved hearing. Recognizing the importance of good hearing health, President Obama in 2010 has set a national goal to increase the use of hearing aids and other assistive devices.

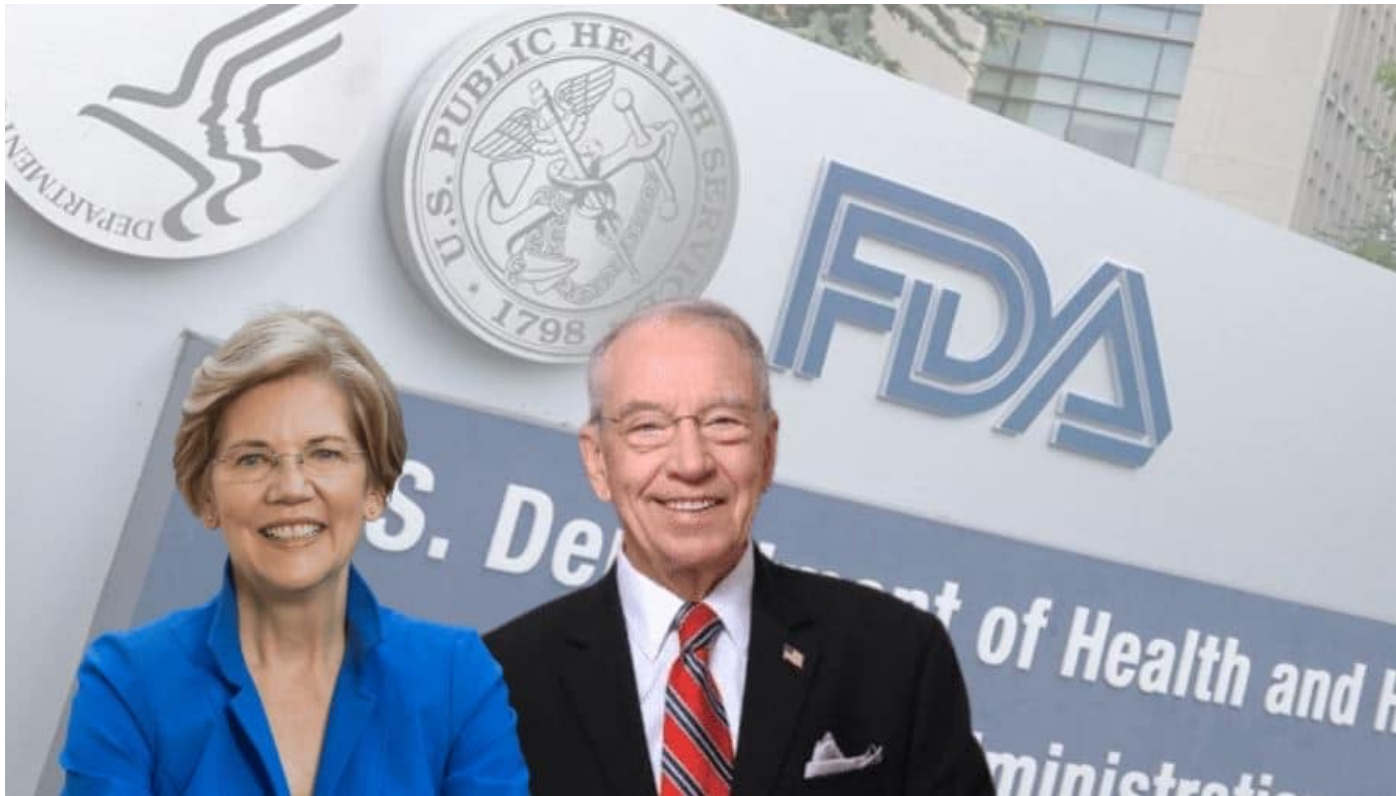
SCIENCE • ENGINEERING • MEDICINE



## HEARING HEALTH CARE FOR ADULTS

Priorities for  
Improving Access  
and Affordability

# Background



# Background



This document is scheduled to be published in the Federal Register on 10/20/2021 and available online at [federalregister.gov/d/2021-22473](https://www.federalregister.gov/d/2021-22473), and on [govinfo.gov](https://www.govinfo.gov)

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 800, 801, 808, and 874

[Docket No. FDA-2021-N-0555]

RIN 0910-AI21

Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.



# Summary of the FDA Proposed Rule on OTC Hearing Aids



# Summary of FDA Proposed Rule

## Executive Summary

### *Purpose of the Proposed Rule*

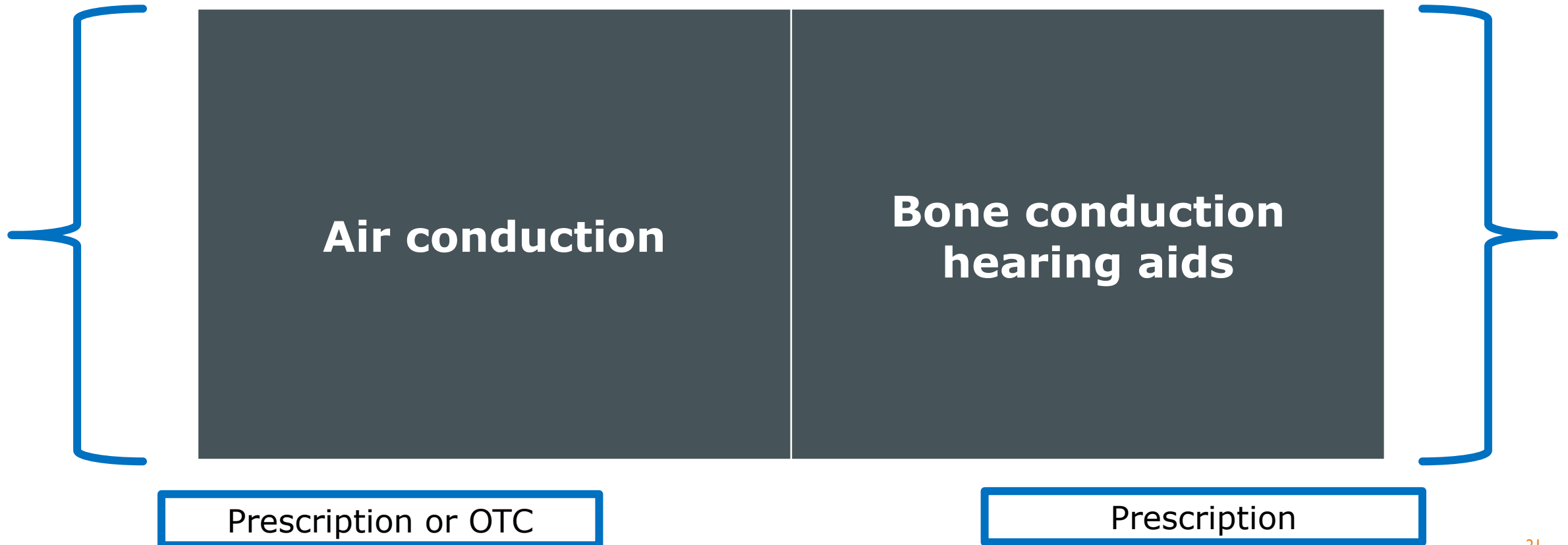
Hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life. Despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek intervention. Several barriers likely impede the use of hearing aids in hearing-impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (perceived hearing benefit relative to price). FDA is proposing rules to address some of these concerns.

Moreover, the FDA Reauthorization Act of 2017 (FDARA) directs FDA to establish a category of OTC hearing aids through rulemaking, and FDARA sets forth various requirements for OTC hearing aids, including preemption provisions. In addition to protecting and promoting the public health, we have developed these proposed rules to establish the OTC category and implement the requirements of FDARA.

- Hearing aid classification changes
- Category for OTC Hearing Aids
- Prescription hearing aid labeling

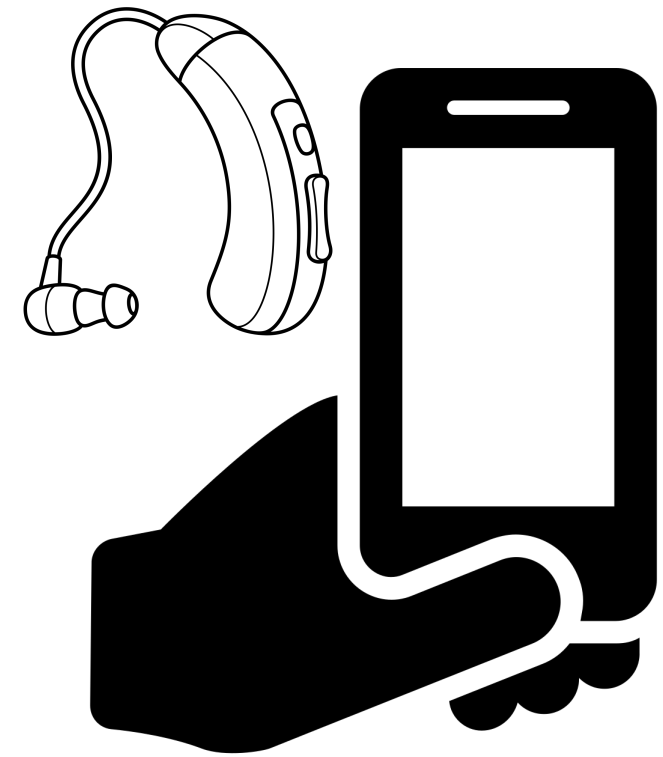


# Proposed hearing aid classification



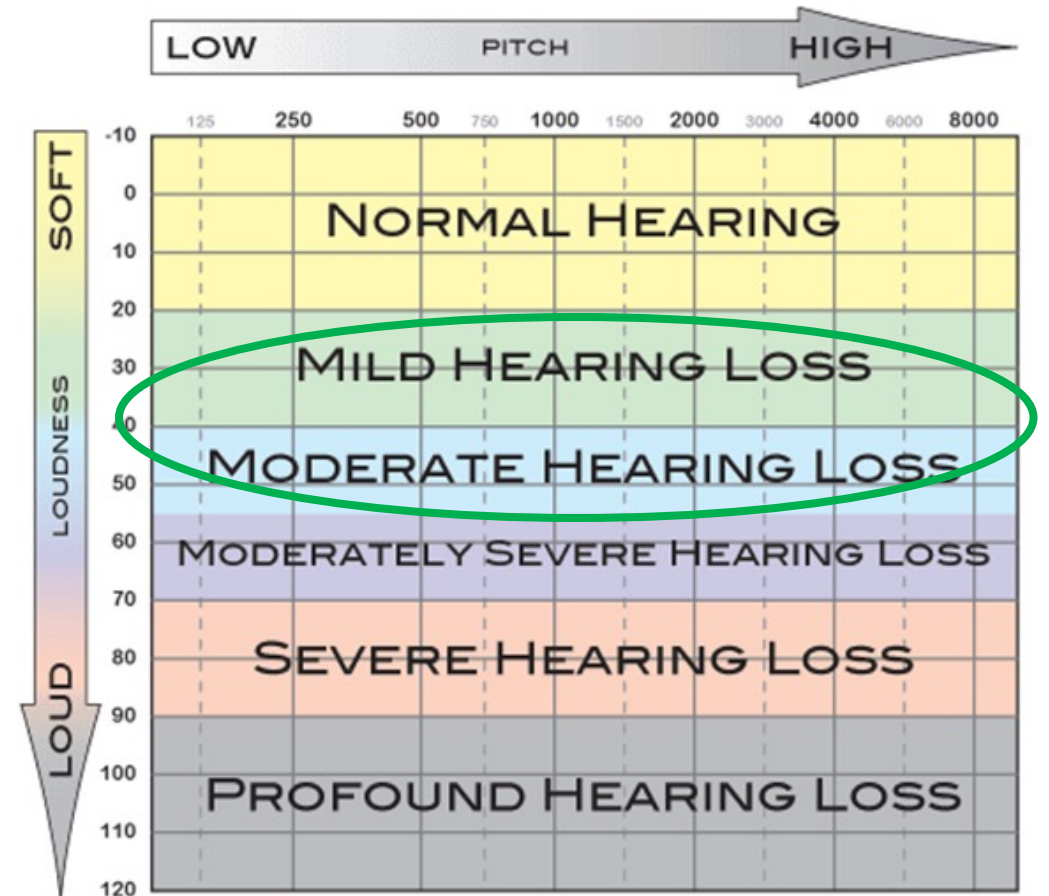
# Definition of OTC hearing aids

1. Uses the same technology as air conduction HAs
2. "...through tools, tests, or software, allow the user to control the hearing aid and customize it to the user's hearing needs"
3. Available without involvement of a licensed person



# Definition of OTC hearing aids

- Adults  $\geq 18$  years (no ID check).
- Perceived mild to moderate HL.
- No “Red Flag” conditions.



# Definition of OTC hearing aids

## Personal Sound Amplification Products (PSAPs)

### 4. Hearing Products not Regulated as Hearing Aids

FDA does not consider personal sound amplification products (PSAPs) to be “devices” within the meaning of section 201(h) of the FD&C Act (21 U.S.C. 321(h)) when they are not intended to aid a person with, or compensate for, impaired hearing and do not otherwise meet the

# Definition of OTC hearing aids

## Personal Sound Amplification Products (PSAPs)

### The BEAN™ is perfect for someone who:

- May not be ready to wear a hearing aid full-time
- Wants a small amount of enhancement, especially for conversation or speech
- Needs help hearing the TV or following conversations
- Wants to hear better when a speaker is farther away than in face-to-face communication. For example: worship service, a theatre play, a lecture.



### The BEAN | Quiet Sound Amplifier

★★★★☆ 4 reviews

Starting at \$28/mo with [affirm](#). Prequalify now

#### Quick Overview

The BEAN™ is Etymotic's personal sound amplifier, also known as a Quiet Sound Amplifier. This is a product like no other in the market. Think of it as your over-the-counter conversation and speech hearing improvement device!

**\$199.99 – \$299.99**

Color: Platinum

PLATINUM



# Definition of OTC hearing aids

## Personal Sound Amplification Products (PSAPs)

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## Self-fitting hearing aids

*Defining hearing aids.* FDARA authorizes controls for devices that, among other characteristics, use the same fundamental scientific technology as air-conduction hearing aids under §§ 874.3300 or 874.3305. Section 520(q)(1)(A)(i) of the FD&C Act does not specifically refer to § 874.3325 because, at the time of FDARA’s enactment, FDA had not classified that device type. However, we consider self-fitting hearing aids currently classified under § 874.3325 to be eligible for regulation as OTC hearing aids.



# OTC Hearing Aid “Controls”

1. Labeling requirements
2. Electroacoustic requirements
3. Additional specifications
4. Conditions for sale

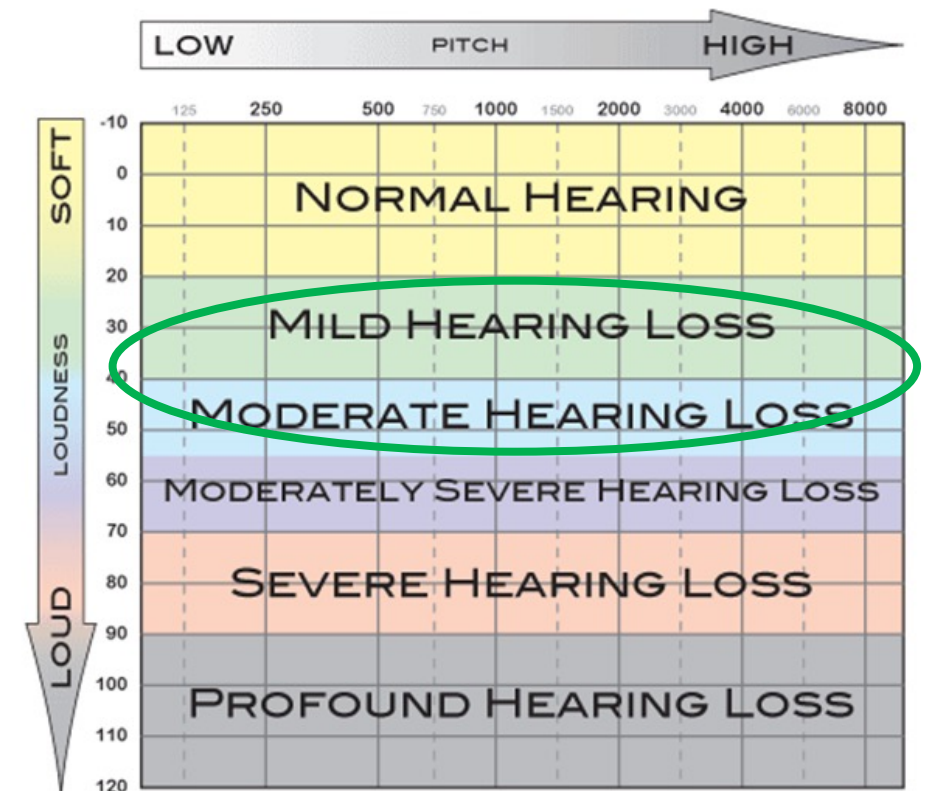


# Labeling requirements

## “Perceived mild to moderate hearing loss”

**This hearing aid is designed and intended for perceived mild to moderate hearing loss in adults. If you experience any of the following, you may have this kind of hearing loss:**

- Difficulty hearing or understanding conversations, especially in groups or noisy places, or when you can't see who is talking
- Difficulty hearing while using a telephone
- Fatigue due to greater listening effort
- Needing to turn up the volume of television, radio, or music louder than normal or loud enough for others to complain





# Labeling requirements

## “Red flag conditions”

### **WARNING: Conditions that Require Medical Care**

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

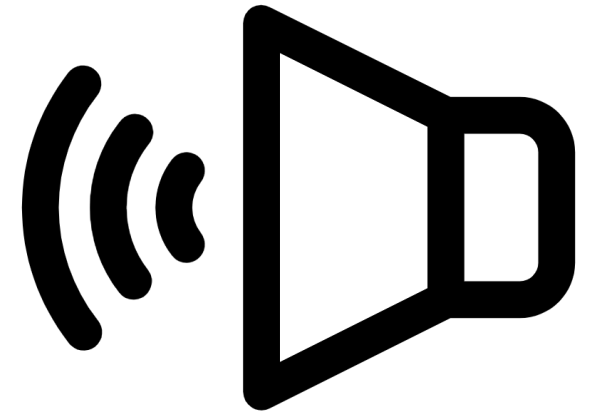
- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

# Electroacoustic requirements

## ***Maximum OSPL90 output level:***

115 dB SPL or

120 dB SPL if the device has input-controlled compression and volume control



# Additional Specifications

***Atraumatic materials***

***Proper physical fit***

***A lay user may control***



# Conditions for sale

- Available over-the-counter
- Without a licensed person.
- Mail, online, or in-person.



# Prescription Hearing Aids

- No medical evaluation
- New labeling rules

The proposed rule would necessitate the relabeling of all current hearing aids (approximately 840) according to either the proposed OTC or prescription hearing aid labeling requirements. While we lack specific data regarding what portion of hearing aids will be relabeled as prescription devices and what portion will be relabeled as OTC hearing aids, for this analysis, we assume that 10 percent will be relabeled as prescription medical devices (about 1 product per manufacturer) and 90 percent as OTC hearing aids (about 7 products per manufacturer). The labeling cost model used in the PRIA suggests an annual estimated third-party disclosure burden of about 19 hours per product.



# Research on self-fitting hearing aids and Personal Sound Amplifiers (PSAPs)



## Study #1

### RESEARCH ARTICLE

# Factors Associated With Successful Setup of a Self-Fitting Hearing Aid and the Need for Personalized Support

Convery, Elizabeth<sup>1,2,3</sup>; Keidser, Gitte<sup>1,2,3</sup>; Hickson, Louise<sup>1,3</sup>; Meyer, Carly<sup>1,3</sup>

Author Information ☺

Ear and Hearing: July/August 2019 - Volume 40 - Issue 4 - p 794-804

doi: 10.1097/AUD.0000000000000663

EDITOR'S CHOICE



#### Hearing Aid – HD100 Companion

\$449.00 - \$830.00

- 45 Day Money Back Guarantee!
- Free [Customizer App](#) for Android & iPhone
- Presets on the device also provide easy, no smartphone needed adjustment
- Rechargeable battery – Up to 15 hours per charge / no button cell batteries
- Integrated Bluetooth so you can take calls directly or stream music to a device
- Directional microphones for optimum performance in noisy conditions
- Environmental profile settings for best sound in different locations
- Flexible fitting for comfort
- Standard 1-year manufacturer's warranty included
- **Note:** Like all hearing aids, SWS products can fail when exposed to excessive moisture such as high humidity and sweating. Because moisture damage is considered normal wear, it is NOT covered by the manufacturer's warranty. To prolong the life of your devices, we suggest you remove them in high-moisture situations and consider investing in a [hearing aid dehumidifier](#) to regularly help dry them out.

Get the Customizer App here:



## Study #1

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Convery, Elizabeth<sup>1,2,3</sup>; Keidser, Gitte<sup>1,2,3</sup>; Hickson, Louise<sup>1,3</sup>; Meyer, Carly<sup>1,3</sup>

[Author Information](#) 😊

Ear and Hearing: July/August 2019 - Volume 40 - Issue 4 - p 794-804

doi: 10.1097/AUD.0000000000000663

EDITOR'S CHOICE

## MAIN OUTCOME:

68% self-fit successfully  
32% were unsuccessful

## Associated with successful self-fit:

- Previous hearing aid experience
- Mobile device ownership



## Study #1

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[Author Information](#) 😊

Ear and Hearing: [July/August 2019](#) - Volume 40 - Issue 4 - p 794-804  
doi: 10.1097/AUD.0000000000000663

EDITOR'S CHOICE

**Among successful fitters:**  
63% sought help  
37% did so independently

**Associated with seeking help:**

- External locus of control

## Study #2

AJA

Research Article

# **The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial**

Larry E. Humes,<sup>a</sup> Sara E. Rogers,<sup>a</sup> Tera M. Quigley,<sup>a</sup> Anna K. Main,<sup>a</sup>  
Dana L. Kinney,<sup>a</sup> and Christine Herring<sup>a</sup>

**Audiology Best Practices**

**Consumer Decides (OTC)**

**Placebo**

## Study #2



Resound Alera  
mini-BTE

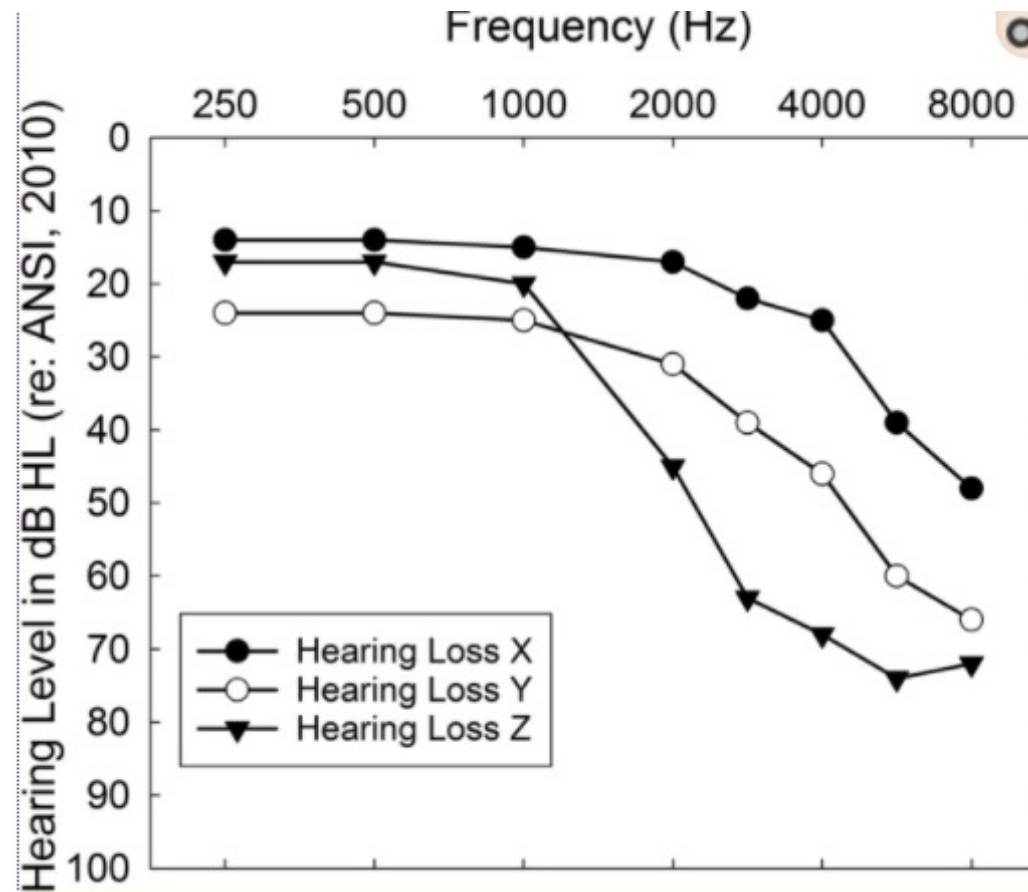
Standard: U.S. \$3,600  
Reduced: U.S. \$600

**Audiology Best Practices** = Program, verify, fine-tune, orientation session

**Consumer Decides (OTC)** = User selects between pre-set programs; instructional video

**Placebo** = Same as Audiology Best Practices, but hearing aid had no gain

## Study #2



Consumer Decides (OTC) group pre-set programming

## Study #2

AJA

Research Article

### The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial

Larry E. Humes,<sup>a</sup> Sara E. Rogers,<sup>a</sup> Tera M. Quigley,<sup>a</sup> Anna K. Main,<sup>a</sup>  
Dana L. Kinney,<sup>a</sup> and Christine Herring<sup>a</sup>



#### Main outcome – Subjective HA Benefit

- No significant price x group interactions

#### Device-related satisfaction

- Best Practices group *better than* OTC and Placebo group

**Audiology Best Practices vs Consumer Decides (OTC) vs Placebo**


Standard: U.S. \$3,600 vs Reduced: U.S. \$600

## Study #3

Original Article

# Validation of a Self-Fitting Method for Over-the-Counter Hearing Aids

Andrew T. Sabin<sup>1</sup> , Dianne J. Van Tasell<sup>1</sup>, Bill Rabinowitz<sup>1</sup>, and Sumitrajit Dhar<sup>2</sup>

Trends in Hearing  
Volume 24: 1–19  
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DOI: 10.1177/2331216519900589  
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Self fit group,  $n = 38$

Audiology Best Practices Group,  $n = 37$

### Prototype Hearing Aid

The Bose prototype hearing aid (Figure 2) used in this experiment functioned like a wireless binaural air-conduction hearing aid. It incorporated microphones on each of the earbuds and a flexible neckband housing rechargeable batteries and electronic components. The earbuds are designed to seal comfortably against the entrance to the ear canal. Signal processing parameters were selected wirelessly via Bluetooth using an

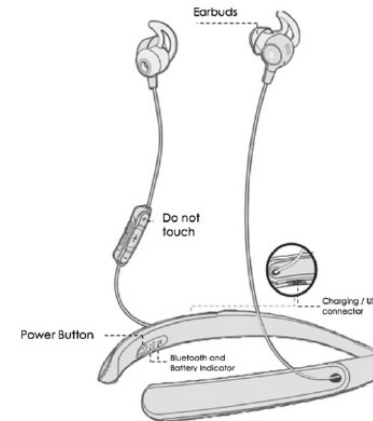


Figure 2. Bose prototype hearing aid. All participants wore this device throughout the experiment.

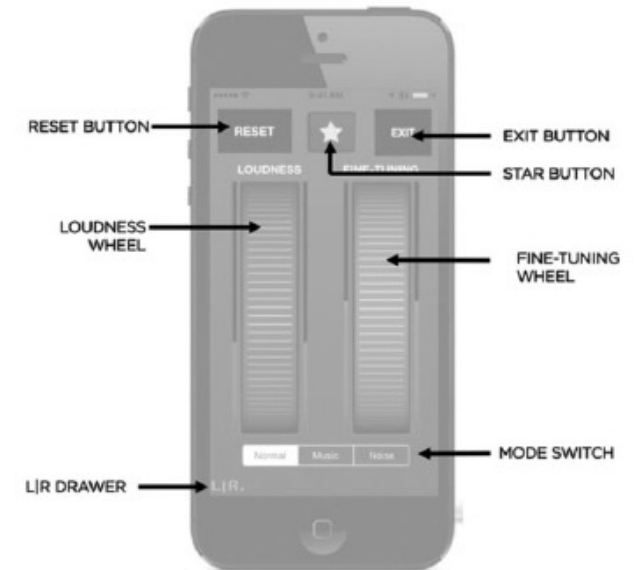


Figure 3. The mobile app home screen for the Self group.




## Study #3

Original Article

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Andrew T. Sabin<sup>1</sup> , Dianne J. Van Tasell<sup>1</sup>, Bill Rabinowitz<sup>1</sup>, and Sumitrajit Dhar<sup>2</sup>

Trends in Hearing  
Volume 24: 1–19  
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## Field Use

Once the audiologist felt that the participant understood the instructions, they asked the participant to perform a practice “Star Button Press.” These practice events were repeated until the audiologist believed the user could conduct them on their own. These Star Button Press events provided the in-the-field data during the weeks of field use.

## Prototype Hearing Aid

The Bose prototype hearing aid (Figure 2) used in this experiment functioned like a wireless binaural air-conduction hearing aid. It incorporated microphones on each of the earbuds and a flexible neckband housing rechargeable batteries and electronic components. The earbuds are designed to seal comfortably against the entrance to the ear canal. Signal processing parameters were selected wirelessly via Bluetooth using an

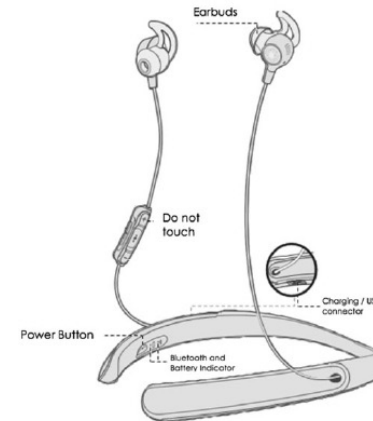


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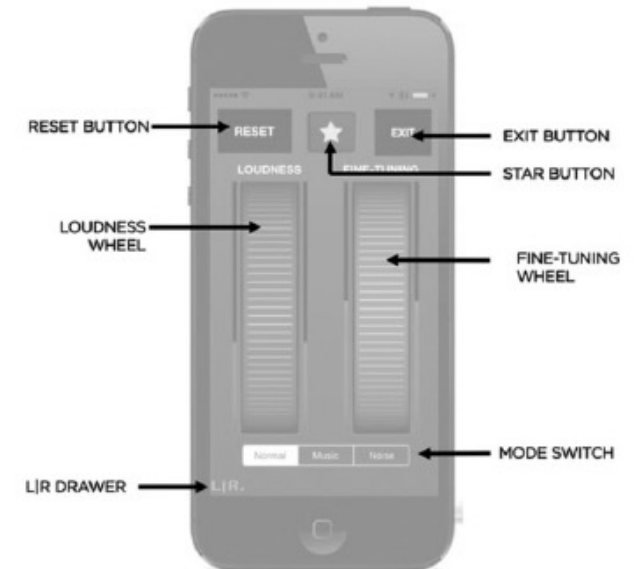


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## Study #3

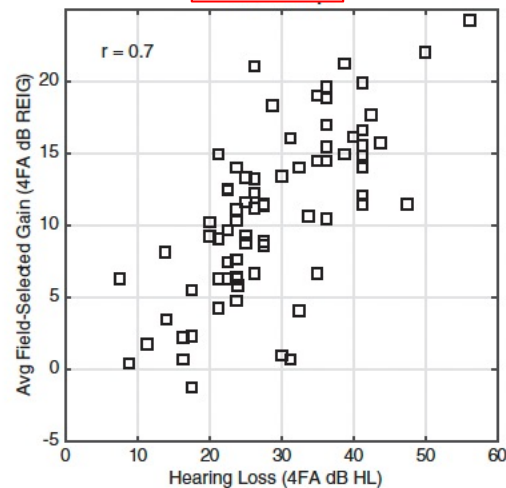
Original Article

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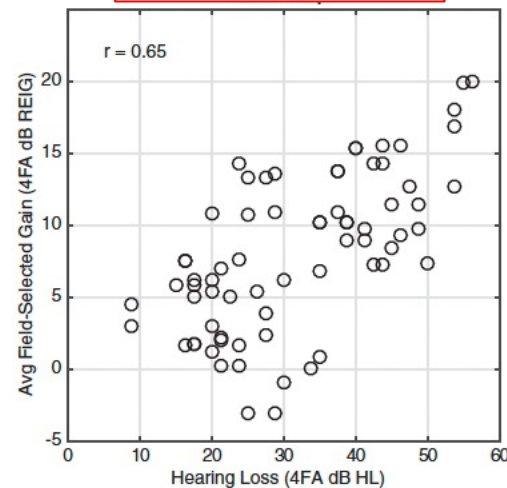
Andrew T. Sabin<sup>1</sup> , Dianne J. Van Tasell<sup>1</sup>, Bill Rabinowitz<sup>1</sup>, and Sumitrajit Dhar<sup>2</sup>

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#### ABP



#### Self-fitting



Relationship between hearing loss and field-selected gains

#### Self-fitters:

Overall gain correlated w/ their HL (**left**)

Small but significant preference for own settings

## Study #4

Randomized Controlled Trial

> JAMA. 2017 Jul 4;318(1):89-90. doi: 10.1001/jama.2017.6905.

### Personal Sound Amplification Products vs a Conventional Hearing Aid for Speech Understanding in Noise

Nicholas S Reed <sup>1</sup>, Joshua Betz <sup>2</sup>, Nicole Kendig <sup>3</sup>, Margaret Korczak <sup>3</sup>, Frank R Lin <sup>1</sup>

Affiliations + expand

PMID: 28672306 PMCID: PMC5817472 DOI: 10.1001/jama.2017.6905

[Free PMC article](#)

**Participants:** 42 adults ages 60 to 85 years with mild-to-moderate hearing loss

## Study #4

Unaided hearing
Oticon Nera 2 hearing aid
Sound World Solutions CS50+
Soundhawk
Etymotic BEAN
Tweak Focus
MSA 30X

Randomized Controlled Trial > JAMA. 2017 Jul 4;318(1):89-90. doi: 10.1001/jama.2017.6905.

**Personal Sound Amplification Products vs a Conventional Hearing Aid for Speech Understanding in Noise**

Nicholas S Reed <sup>1</sup>, Joshua Betz <sup>2</sup>, Nicole Kendig <sup>3</sup>, Margaret Korczak <sup>3</sup>, Frank R Lin <sup>1</sup>

Affiliations + expand

PMID: 28672306 PMCID: PMC5817472 DOI: 10.1001/jama.2017.6905

[Free PMC article](#)

## Study #4

	Cost
Unaided hearing	NA
Oticon Nera 2 hearing aid	1,910.00
Sound World Solutions CS50+	349.99
Soundhawk	349.99
Etymotic BEAN	299.99
Tweak Focus	269.99
MSA 30X	29.99

Randomized Controlled Trial > JAMA. 2017 Jul 4;318(1):89-90. doi: 10.1001/jama.2017.6905.

### Personal Sound Amplification Products vs a Conventional Hearing Aid for Speech Understanding in Noise

Nicholas S Reed <sup>1</sup>, Joshua Betz <sup>2</sup>, Nicole Kendig <sup>3</sup>, Margaret Korczak <sup>3</sup>, Frank R Lin <sup>1</sup>

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	Cost	Mean accuracy, % (95% CI)	Change from unaided hearing, % (95% CI)
Unaided hearing	NA	76.5 (72.7 to 80.3)	NA
Oticon Nera 2 hearing aid			
Sound World Solutions CS50+			
Soundhawk			
Etymotic BEAN			
Tweak Focus			
MSA 30X			

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Sound World Solutions CS50+	349.99	87.4 (83.5 to 91.4)	11.0 (8.8 to 13.1)
Soundhawk	349.99	86.7 (82.7 to 90.6)	10.2 (8.0 to 12.3)
Etymotic BEAN	299.99	84.1 (80.2 to 88.1)	7.7 (5.5 to 9.8)
Tweak Focus	269.99	81.4 (77.4 to 85.3)	4.9 (2.8 to 7.0)
MSA 30X			



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Tweak Focus	269.99	81.4 (77.4 to 85.3)	4.9 (2.8 to 7.0)
MSA 30X	29.99	65.3 (60.1 to 70.4)	−11.2 (−15.2 to −7.3)



What are implications for people with hearing loss?

# Potential advantages of OTC hearing aids

Lower prices

More availability closer to home

Reduced stigma

Psychological ownership, empowerment

Independence

Personalized settings



# Areas for consideration

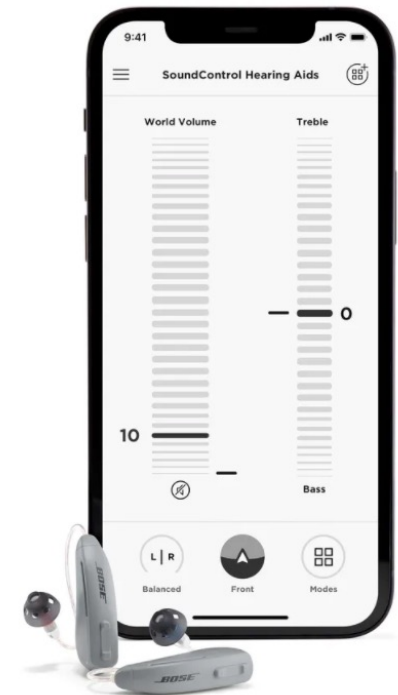
Price still may not be accessible for some

Difficulty navigating self-fitting

Need for post-fitting counseling, rehab, support

Audiologically inappropriate fittings possible

Conditions requiring medical care may not be attended to



Volume and bass / treble adjustment in the Bose Hear app. | Image: Bose

# Potential scenarios

**Scenario #1:** Someone who never used HAs before tries OTC HAs.

They are disappointed and frustrated, stop using them, and vow to never use HAs again.



# Potential scenarios

**Scenario #2:** Someone who never used HAs tries OTC HAs.

They are delighted, wear them consistently, and experience benefits in their daily life.





# OTC HAs and the practicing Audiologist



# OTCs and the practicing Audiologist

Potential for expanding existing practices:

- New clients

- New devices

- New services or increased focus on:

  - Rehabilitation

  - Motivational counseling

  - Instructional counseling

  - Listening and communication help

  - Device usage

# Types of services offered to help OTC users

- Diagnostic audiological assessment
- Quality check of devices
- Device customization
- Device training
- Hearing loss self-management skills training
- Services focusing on emotional, psychosocial, & functional impacts of HL

**Audiology's Third Pillar: Comprehensive Follow-Up Care and Counseling for Those Who Choose to Self-Direct Their Care**

By Brian Taylor

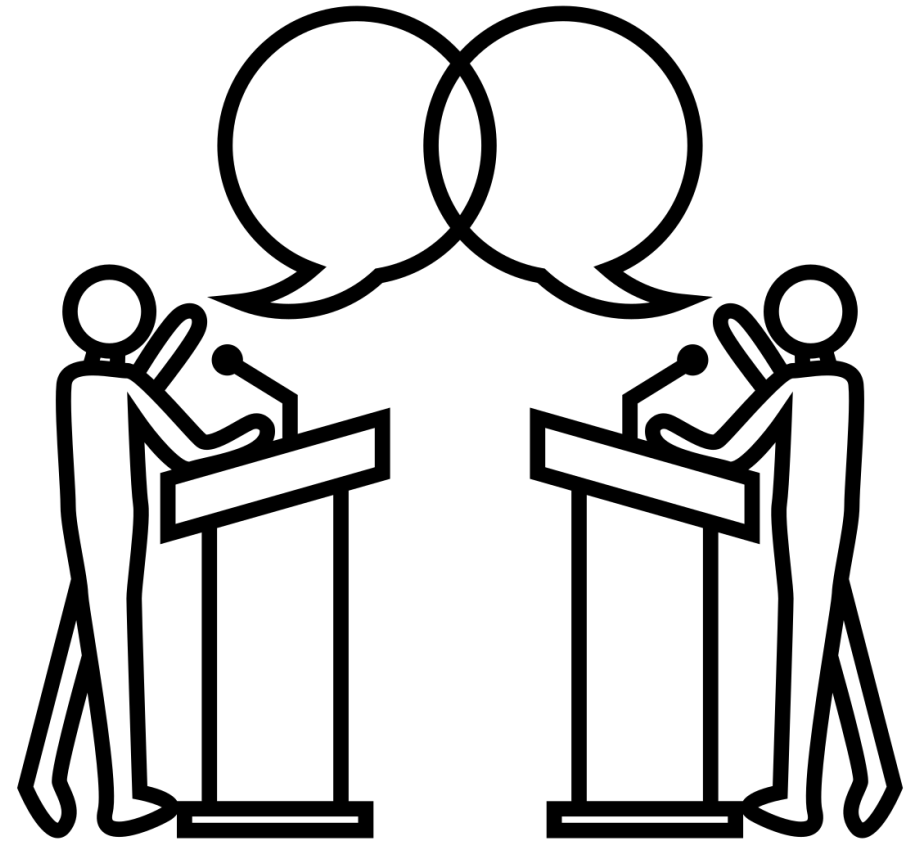
# VA Audiology

- Are OTC HAs an appropriate option for Veterans?
- Will some Veterans prefer OTC?
- May help lower costs
- May help increase reach
- May encourage use by increasing empowerment, independence



# Contentious issues

- Output limits
- Consumers with medical issues
- Candidacy



# OTC candidacy

## The Pure-Tone Average as a Universal Metric—Knowing Your Hearing

Frank R Lin <sup>1 2</sup>, Nicholas S Reed <sup>1 2</sup>

Affiliations + expand

PMID: 33355634 DOI: [10.1001/jamaoto.2020.4862](https://doi.org/10.1001/jamaoto.2020.4862)

## Unpacking the OTC Hearing Aid Act: How About the 12% with Normal Hearing and Self-Rated Hearing Difficulties?

Weinstein, Barbara E. PhD

[Author Information](#) ✓

- Volume 74 - Issue 5 - p 22,23  
3694.a3

## A Questionnaire Survey of Current Rehabilitation Practices for Adults With Normal Hearing Sensitivity Who Experience Auditory Difficulties

Tess K. Koerner, Melissa A. Papesh and Frederick J. Gallun

[https://doi.org/10.1044/2020\\_AJA-20-00027](https://doi.org/10.1044/2020_AJA-20-00027)



# How to comment on the FDA Proposed Rule

# How to post a public comment

**Go to the Federal Register** at [Federalregister.gov](https://www.federalregister.gov)  
Search for the Over-the-Counter Hearing Aids proposed rule  
Click on the green button “submit a formal comment”



The screenshot displays the Federal Register website interface. At the top, the National Archives logo is on the left, followed by the text "FEDERAL REGISTER" and "The Daily Journal of the United States Government". To the right is the Seal of the National Archives and Records Administration. Below this is a blue bar with the text "PR Proposed Rule". The main heading is "Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids". Below the heading, it says "A Proposed Rule by the Food and Drug Administration on 10/20/2021". At the bottom left, a grey box states "This document has a comment period that ends in 5 days. (01/18/2022)". At the bottom right, a green button labeled "SUBMIT A FORMAL COMMENT" is circled in red. Below the button, it says "Read the 833 public comments" with a question mark icon.



# How to post a public comment

## **Direct link:**

<https://www.federalregister.gov/documents/2021/10/20/2021-22473/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids>



## Bose SoundControl™ Hearing Aids

★★★★★ 4.2 (153)

\$849.00

Price per pair. Limit two pairs per customer.

Call **800-761-2673** for any additional questions

Agent availability: Mon to Fri 9-9 ET. Saturday 9-7 ET

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TAKE THE HEARING SCREENER

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SELF-FIT DESIGN



CLINICALLY PROVEN SELF-TUNING



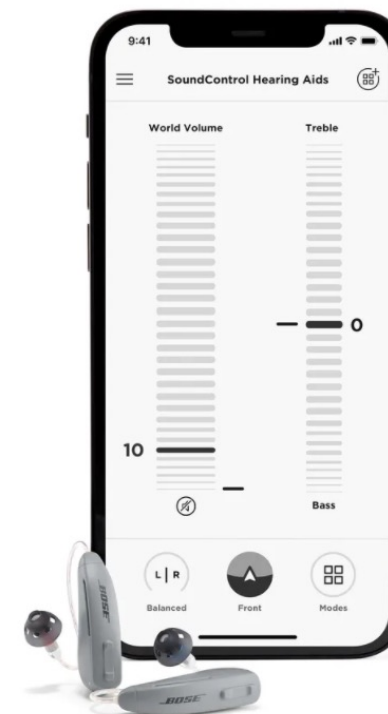
90-DAY RISK-FREE TRIAL



HIGH-QUALITY AUDIO



REPLACEABLE BATTERIES



## Support, when and where you need it

Fitting and tuning Bose SoundControl™ Hearing Aids is simple, but of course, there is some adjustment needed to get used to a hearing aid. That's why we offer comprehensive, complimentary [product support](#), from first-time setup to everyday use. Our Hear Product Experts are here to help you every step of the way. We also have a protection plan to cover your device.

### COMPLIMENTARY SERVICES

**Virtual setup session** with Hear Product Experts is offered to everyone

**Help and guidance** are available through in-app tips and support videos

**Need support or have a question before you buy?** Help is available via chat or phone by clicking the button below

CONTACT OUR HEAR PRODUCT EXPERTS



## Apple Studying Potential of AirPods as Health Device

Earbuds could be offered as hearing aids and include an in-ear thermometer and posture warnings



Apple's AirPods dominate the global Bluetooth headset market, generating an estimated \$12.8 billion in revenue in 2020.

PHOTO: KENNY WASSUS/THE WALL STREET JOURNAL

## Eargo 5



**\$2,450**

EARGO 6

## HEAR LIFE TO THE FULLEST

With Sound Adjust and improved noise  
reduction

**\$2,950**

Finance for as low as \$94/month

[Learn more](#)



## Eargo 5

## Traditional Hearing Aids



Nearly invisible & rechargeable



Fully remote telecare model ?



Access to lifetime support ?



Estimated delivery time

3-5 days

Up to 2 weeks



Average price per pair

\$2,450

\$4700+





The image shows a product page for the 'Hearing Aid - HD75'. On the left is a large image of the hearing aid device, which is black and has a thin tube. Below it are four smaller images showing different views of the device. To the right of the main image, the title 'Hearing Aid - HD75' is displayed in a bold, dark font. Below the title, the price range '\$280.00 - \$595.00' is shown in a blue font. A list of features follows, starting with a bullet point for a '45 Day Money Back Guarantee!'. Other features include a free 'Customizer App' for Android and iPhone, presets for easy adjustment, a 312 non-rechargeable battery with up to 3.5 days of use, integrated Bluetooth for app use only, directional microphones for noisy conditions, environmental profile settings, a flexible tube for different ear lengths, and a standard 1-year manufacturer's warranty. A 'Note' at the bottom of the list states that the device can fail when exposed to excessive moisture and is not covered by the warranty in such cases, suggesting the use of a 'hearing aid dehumidifier'. Below the list, the text 'Get the HD75 App here:' is followed by two app store logos: 'Available on the App Store' and 'Get it on Google play'.

**Hearing Aid - HD75**

**\$280.00 - \$595.00**

- **45 Day Money Back Guarantee!**
- Free [Customizer App](#) for Android & iPhone
- Presets on the device also provide easy, no smartphone needed adjustment
- Size 312 non-rechargeable battery - Up to 3.5 days of use per battery
- Integrated Bluetooth for app use only, no streaming available
- Directional microphones for optimum performance in noisy conditions
- Environmental profile settings for best sound in different locations
- Flexible tube to accommodate most ear lengths from top of ear to canal opening
- Standard 1-year manufacturer's warranty included
- **Note:** Like all hearing aids, SWS products can fail when exposed to excessive moisture such as high humidity and sweating. Because moisture damage is considered normal wear, it is NOT covered by the manufacturer's warranty. To prolong the life of your devices, we suggest you remove them in high-moisture situations and consider investing in a [hearing aid dehumidifier](#) to regularly help dry them out.

Get the HD75 App here:

Available on the **App Store** | Get it on **Google play**

"Our device is sold as a hearing aid, and the same identical device is sold as a PSAP. We intend to have the same device qualify as an OTC hearing aid.

They're identical devices in any way you look at them. I made them that way to prove a point. There's no difference between the performance of these devices, only the way they are regulated."

Stavros Basseas, PhD, CEO of Sound World Solutions



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# Thank you!

coco@ohsu.edu / laura.coco@va.gov