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

Image source: https://www.wsj.com/articles/hearing-aids-are-getting-smarter-11568599441
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. (Stock/Getty Images Plus)
Background

Approximately 38 million US adults have some degree of hearing loss. Among adults ≥70 years, fewer than 1/3 use hearing aids.

Factors influencing uptake:

• Cost

Background

“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$)”
Approximately 38 million US adults have some degree of hearing loss. Among adults >70 years, fewer than 1/3 use hearing aids.

Factors influencing uptake:

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

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

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Conexiones (Connections) results

Conexiones (Connections) results

"Why aren't you currently using hearing aids?"

- Not enough hearing loss: 17
- Cost too high: 7
- Doctor did not refer: 5
- Clinic too far: 1
- Bad experience: 1

Number of participants
Background

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

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

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

Air conduction

Bone conduction hearing aids

Prescription or OTC

Prescription
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)

Self-fitting hearing aids

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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)
RESEARCH ARTICLE

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

Convery, Elizabeth1,2,3; Keidser, Gitte1,2,3; Hickson, Louise1,3; Meyer, Carly1,3

Author Information

Ear and Hearing: July/August 2019 - Volume 40 - Issue 4 - p 794-804
doi: 10.1097/AUD.0000000000000563
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MAIN OUTCOME:
68% self-fit successfully
32% were unsuccessful

Associated with successful self-fit:
• Previous hearing aid experience
• Mobile device ownership
Factors Associated With Successful Setup of a Self-Fitting Hearing Aid and the Need for Personalized Support

Convery, Elizabeth¹,²,³; Keidser, Gitte¹,²,³; Hickson, Louise¹,³; Meyer, Carly¹,³

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

Associated with seeking help:
• External locus of control
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, Sara E. Rogers, Tera M. Quigley, Anna K. Main, Dana L. Kinney, and Christine Herring
Study #2

Research Article

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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

Resound Alera mini-BTE

Standard: U.S. $3,600
Reduced: U.S. $600
Study #2

Consumer Decides (OTC) group pre-set programming
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
Self fit group, \( n = 38 \)
Audiology Best Practices Group, \( n = 37 \)
Study #3

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

Andrew T. Sabin¹, Dianne J. Van Tasell¹, Bill Rabinowitz¹, and Sumitrajit Dhar²

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 binural air-conduction hearing aid. It incorporated microphones on each of the earbuds and a flexible multiband 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

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Andrew T. Sabin¹, Dianne J. Van Tasell¹, Bill Rabinowitz¹, and Sumitrajit Dhar²

Relationship between hearing loss and field-selected gains

Self-fitters:
Overall gain correlated w/ their HL (left)
Small but significant preference for own settings
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
### Study #4

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<td>Oticon Nera 2 hearing aid</td>
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<td>Sound World Solutions CS50+</td>
<td>349.99</td>
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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

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
The Pure-Tone Average as a Universal Metric—Knowing Your Hearing
Frank R Lin 1,2, Nicholas S Reed 1,2
Affiliations + expand
PMID: 33356634 DOI: 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

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
How to comment on the FDA Proposed Rule
How to post a public comment

**Go to the Federal Register** at Federalregister.gov
Search for the Over-the-Counter Hearing Aids proposed rule
Click on the green button “submit a formal comment”
How to post a public comment

**Direct link:**
Bose SoundControl™ Hearing Aids

4.2 (53)

$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

BUY NOW  TAKE THE HEARING SCREENER

Order within 17 hrs 54 mins and choose 2-Day shipping to receive your product by Monday, Jan 17

PAY  Pay as low as $71/mo. with Bose Pay. Learn more

FOR MILD TO MODERATE HEARING LOSS
COMFORTABLE, DISCREET FIT
COMPREHENSIVE WORLD-CLASS SUPPORT
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
<table>
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<th>Feature</th>
<th>Eargo 5</th>
<th>Traditional Hearing Aids</th>
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<td>Nearly invisible &amp; rechargeable</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>Fully remote telecare model</td>
<td>✓</td>
<td>?</td>
</tr>
<tr>
<td>Access to lifetime support</td>
<td>✓</td>
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<tr>
<td>Estimated delivery time</td>
<td>3-5 days</td>
<td>Up to 2 weeks</td>
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<tr>
<td>Average price per pair</td>
<td>$2,450</td>
<td>$4700+</td>
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"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

https://www.webmd.com/a-to-z-guides/features/over-the-counter-hearing-aids-pros-and-cons
Thank you!

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