

Rush University System for Health

OTC's: The Good and Bad

Rush University
October 28, 2023

Kara Houston, Au.D., CCC-A
Assistant Professor

OBJECTIVES

- 1 Why an OTC hearing aid?
- 2 What is an OTC hearing aid?
- 3 Who is a candidate (AND WHO IS NOT?)
- 4 What is available?
- 5 What we learned and what does the future hold?
- 6 How can we help?

Rush University

Why an OTC Hearing Aid?

**OTC: The Good and
the Bad**



OVER THE COUNTER

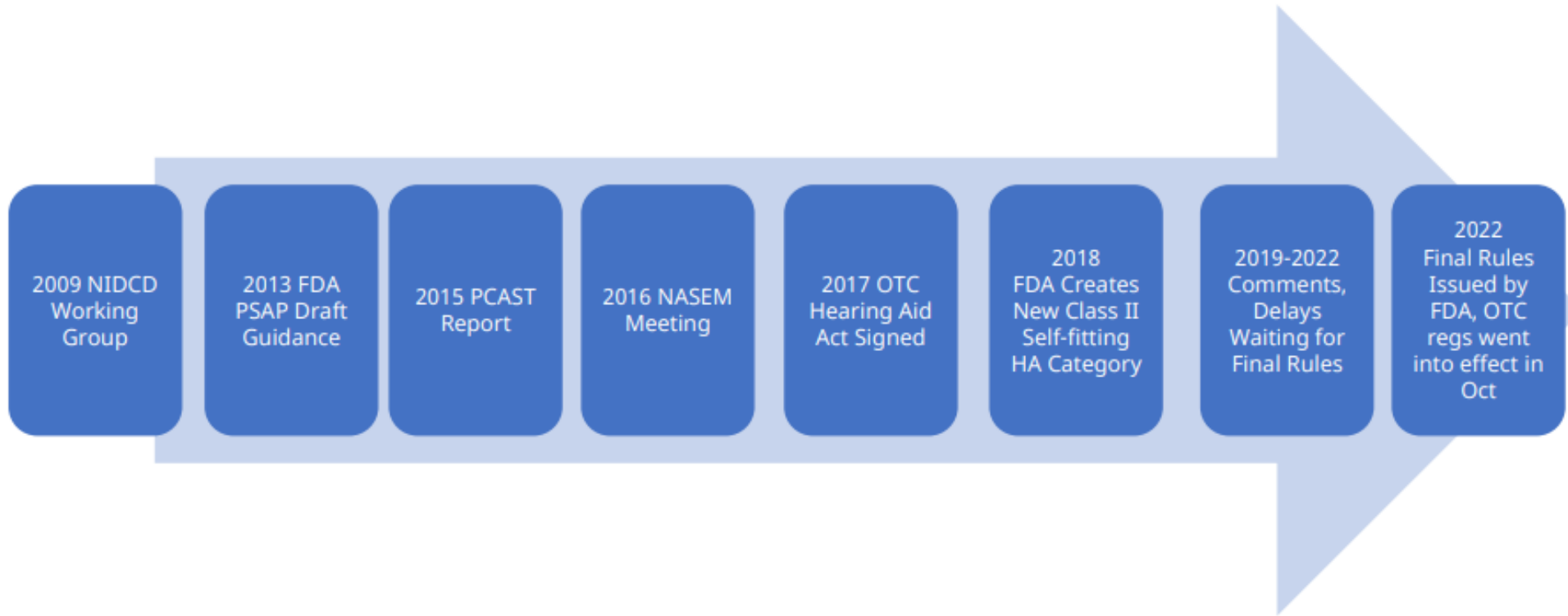


WHY OTC PRODUCTS?

- Independent personal decision
- Uncomplicated, convenient purchase
- Available
- Affordable
- Reduce stigma
- More consumer choice

EVOLUTION OF OTC HEARING AIDS

Over-the-Counter, available since Oct 2022



Rush University

Over-the-counter hearing aid

**OTC: The Good and
the Bad**



WHAT ARE OTC HEARING AIDS?

- *New* classification approved by FDA and FCC.
- Does not require medical clearance.
- Does not require fitting by licensed audiologist or hearing instrument specialist.
- Maximum output safety standard in place.
- Medical warning required on all packaging.
- Length of warrant/insurance determined by individual states.
- Most have self-hearing screenings.



Excellence is just the beginning.

Rush University

Candidacy of OTC devices

**OTC: The Good and
the Bad**

A thin vertical line is positioned to the right of the text 'OTC: The Good and the Bad'.

WHO IS A CANDIDATE?

- 18 years and older.
- Mild to moderate hearing loss only.
- Symmetric hearing in both ears
- No history of tinnitus, dizziness, ear pain, or ear drainage
- No history of ototoxic medication use
- No history of sudden hearing loss in the last 6 months

SELF DIAGNOSED HEARING LOSS

Reflect on your hearing in quiet and noisy environments, and check the column that best describes you:

This Best Describes Me	Quiet Environments	Noisy Environments
<input type="checkbox"/>	I have good to excellent hearing.	I have good hearing; I rarely have difficulty following/participating in a conversation.
<input type="checkbox"/>	I do not have problems hearing what people say.	I may have difficulty following/participating in a conversation.
<input type="checkbox"/>	I have difficulty hearing a normal voice.	I have difficulty hearing and participating in a conversation.
<input type="checkbox"/>	I can hear speech if it is loud speech.	I have great difficulty hearing and participating in a conversation.
<input type="checkbox"/>	I can hear loud speech if it is directly in my ear.	I have very great difficulty hearing and participating in a conversation.
<input type="checkbox"/>	I have great difficulty hearing.	I cannot hear any speech.
<input type="checkbox"/>	I cannot hear any speech or loud sound.	I cannot hear any speech or sound.

If you have selected an option in red text above, an OTC hearing aid may not work for you, and you should consult with an audiologist.

WHO IS NOT THE BEST CANDIDATE?

Who can wear OTC hearing aids?

OTC hearing aids will work if you have a mild to moderate hearing loss. They are not effective for a moderate to severe degree of hearing loss. You must be 18 years or older to wear OTC hearing aids. Children should never wear them.

- ear deformity
- fluid, pus, or blood coming from the ear
- hearing loss or ringing (tinnitus) that occurs in only one ear or that is noticeably different in one ear
- pain or discomfort in the ear
- history of excessive earwax or feeling that something is in the ear
- pain or discomfort in the ear
- sudden, quickly worsening, or fluctuating hearing loss
- vertigo or severe dizziness

You must consult a medical provider before buying an OTC hearing aid if you have any of the following medical conditions:

Note: Individuals with cognitive or dexterity issues may not be suitable candidates for OTC hearing aids and should seek a consultation with an audiologist for hearing loss management.

Please visit [ASHA.ORG/OTC-HEARING-AID-TOOLKIT](https://www.asha.org/otc-hearing-aid-toolkit) for more information.

Rush University

The Good and the Bad

Benefits and Risks

**OTC: The Good and
the Bad**

A thin vertical line is positioned to the right of the text 'OTC: The Good and the Bad'.

OTC HEARING AIDS: The Good

- Increased accessibility.
- Average cost: \$1k for a pair.
- No additional medical/healthcare expenses.
- Bluetooth technology for smartphones.
- Introductory hearing device

OTC HEARING AIDS: The Bad

- Poor self diagnosis
- Risk of medical/health related going untreated.
- Not appropriate for severe to profound hearing loss.
- No true verification of appropriate amplification.
- User-related challenges: dexterity, canal shape, technology savvy, etc.
- Do not have advanced noise reduction technologies.
- Can mask underlying problems causing delay actual diagnosis and treatment
- **Can discourage patient to seek other treatment options if benefit is not seen.**

Rush University Medical Center

Current Ear-level Amplification Options

**OTC: The Good and
the Bad**

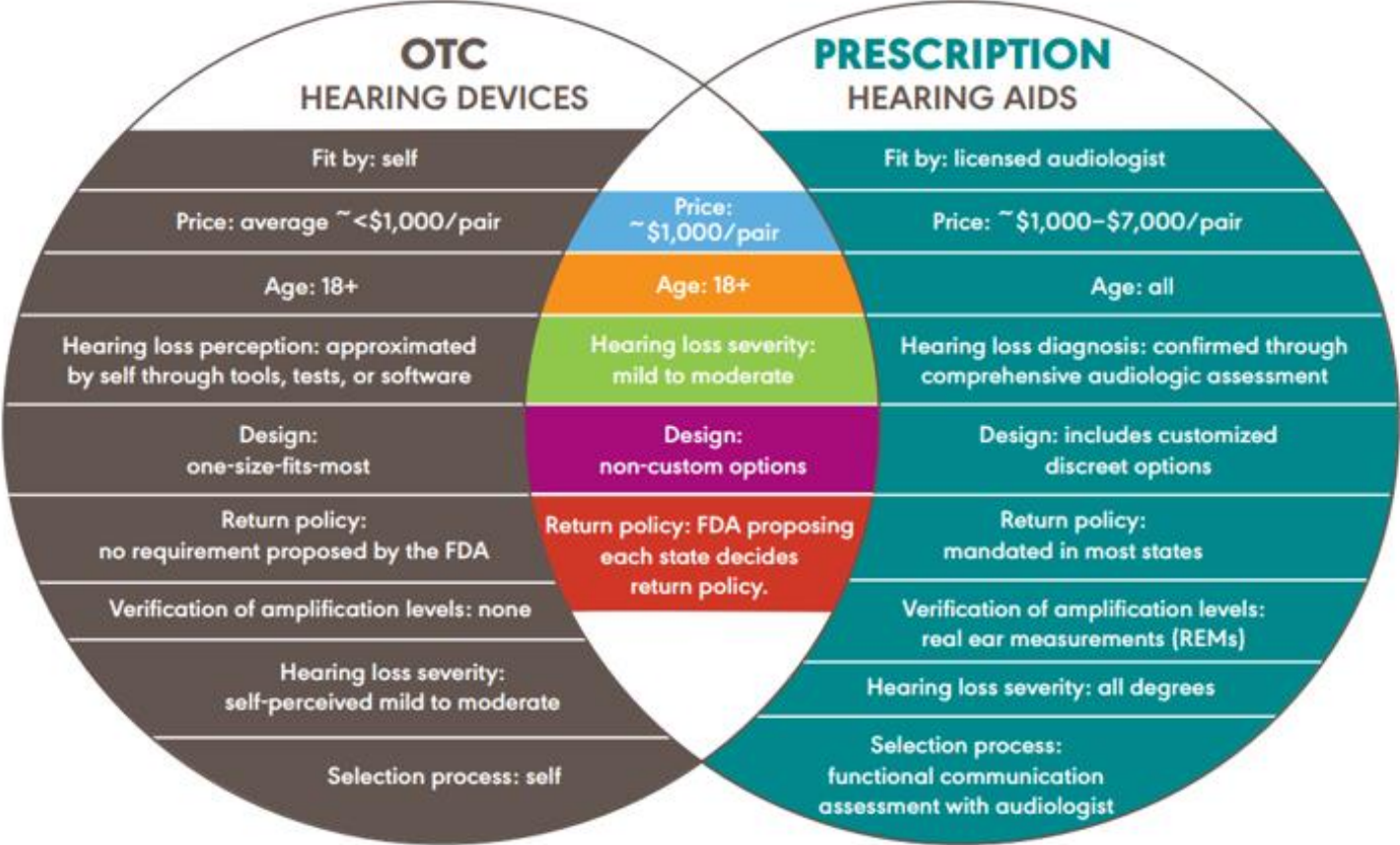
A thin vertical line is positioned to the right of the text 'OTC: The Good and the Bad'.

THREE TYPES OF AMPLIFYING PRODUCTS

	Over-the-Counter Hearing Aids	Prescription Hearing Aids	Personal Sound Amplification Products (PSAPs)
Type of Product	Medical device	Medical device	Consumer electronic
Intended User	Adults, aged 18 and older with perceived mild to moderate hearing loss	Any age, any degree of hearing loss	Persons with normal hearing who want enhancement of sounds in their environment
Conditions for Sale	No medical exam, no hearing test needed. Must be 18 years or older	Purchase from a licensed professional	No conditions for sale per FDA
Standards	ANSI CTA 2051 (2017) Specifies device performance for consumers	ANSI S3.22 2014 (R2020) Specifies test methods and tolerances for professionals who compares to specs	No required standards

Taylor et al ,2023

OTC vs. Prescription Hearing Aid: What Is the Difference?



*Information on this diagram is based on the FDA proposed over-the-counter (OTC) hearing aid regulations posted in October 2021. As new information is released, ASHA Audiology Practices will update the chart accordingly. Updated 4/5/2022.



PRESCRIPTION HEARING AIDS



OTC HEARING AIDS

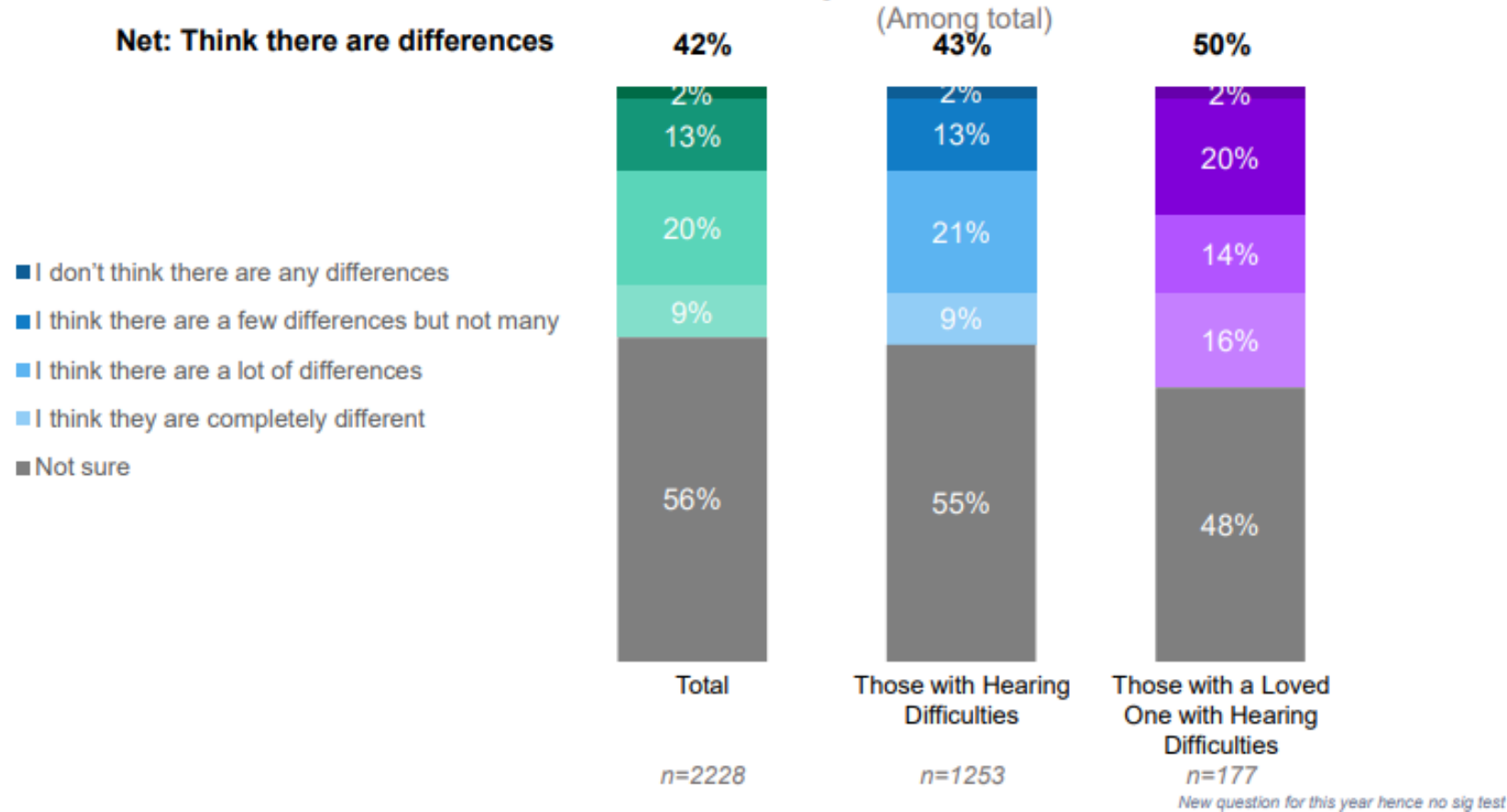


PSAPS



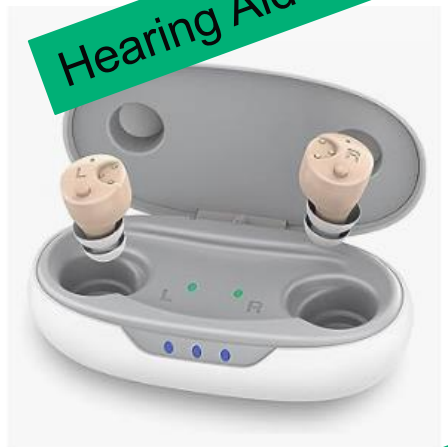
About 4-in-10 American adults perceive sound amplifiers and OTC hearing aids to be different, similar among all groups.

Familiarity With OTC Hearing Aid & Sound Amplifier Differences



PRODUCTS AVAILABLE ONLINE ON AMAZON

Hearing Aid



Aimsumy Hearing Aids for Seniors Rechargeable with Noise Cancelling - Nearly Invisible Digital Hearing Aid for Adults-Beige
 4.6 ★★★★★ (117)
 400+ bought in past month
\$179⁹⁹
 Save \$40.00 with coupon

Hearing Aid



Sponsored ⓘ
 Lexie B1 OTC Hearing Aids Powered by Bose - Bluetooth-enabled Hearing Aids with Invisible Fit and All Day Comfort | Replaceable Batteries,...
 3.9 ★★★★★ (153)
 100+ bought in past month
\$849⁰⁰

Amplifier



Sponsored ⓘ
 MSA 30X My Tone Sound Amplifier BTE PSAD | 30X Amplification | Recharging Station, 6 Silicone Tips & 1 Cleaning Brush | Unisex | Right or...
 3.9 ★★★★★ (427)
\$19⁹⁹

Hearing Aid



Sponsored ⓘ
 Rechargeable Hearing Aids for Seniors Severe Hearing Loss, Earrrck Digital Hearing Amplifier with Noise Cancelling, Hearing Aid with Magnet...
 4.4 ★★★★★ (63)
 200+ bought in past month
\$199⁰⁰
 Save \$50.00 with coupon

Amplifier



Hearing Aids, Mini Hearing Amplifiers with Noise Cancelling, Rechargeable Hearing Aid for Seniors Into Ear No Squealing Hearing Assist Device wit...
 4.2 ★★★★★ (243)
 500+ bought in past month
\$89⁹⁹ Typical: \$99.99
 Save 10% with coupon

Hearing Aid



DROWELL EAR Hearing Aids, Hearing Aids for Seniors Rechargeable with Noise Cancelling Hearing Amplifiers for Seniors & Adults Hearing Loss...
 4.3 ★★★★★ (169)
 300+ bought in past month
\$98⁹⁹
 Save 20% with coupon



Rush University

What we have learned (so far).

**OTC: The Good and
the Bad**

A thin vertical line is positioned to the right of the text 'OTC: The Good and the Bad'.

22 August 2023

ASHA OTC Hearing Aid Survey

YouGov®

Full Report

“Embargoed Until September 12, 2023, 6 a.m. EST.”

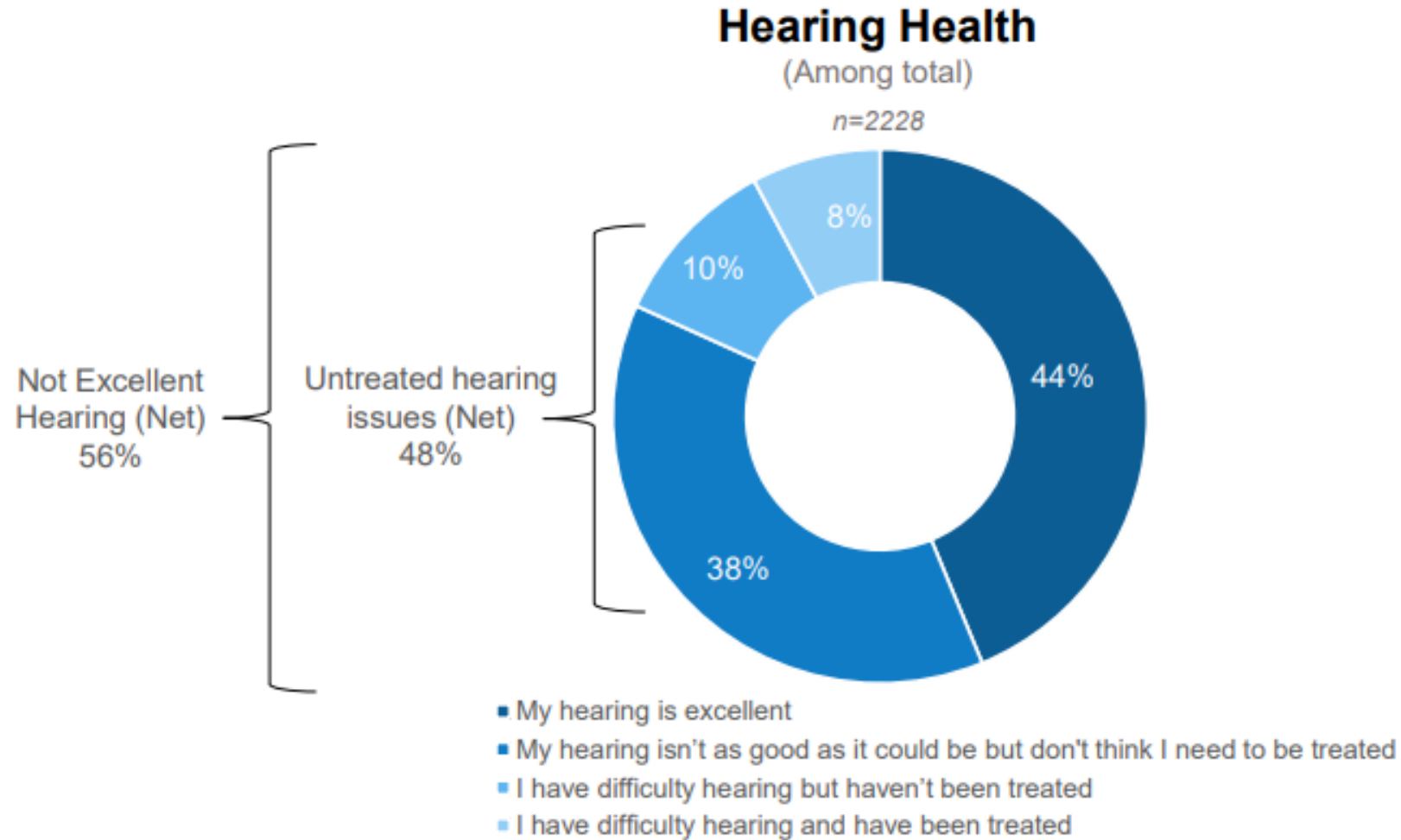


Living Consumer Intelligence | business.yougov.com

ASHA SURVEY: Published September 2023

- **Participants with perceived hearing loss and/or their loved ones**
- **Sample size 2228**
- **Adults 40+ year old**
- **Online survey lasting 10-15 minutes**
- **OTC vs Prescriptive Hearing Aids**

More than half of American adults, 56%, acknowledge lacking excellent hearing abilities, but just 8% have been treated.

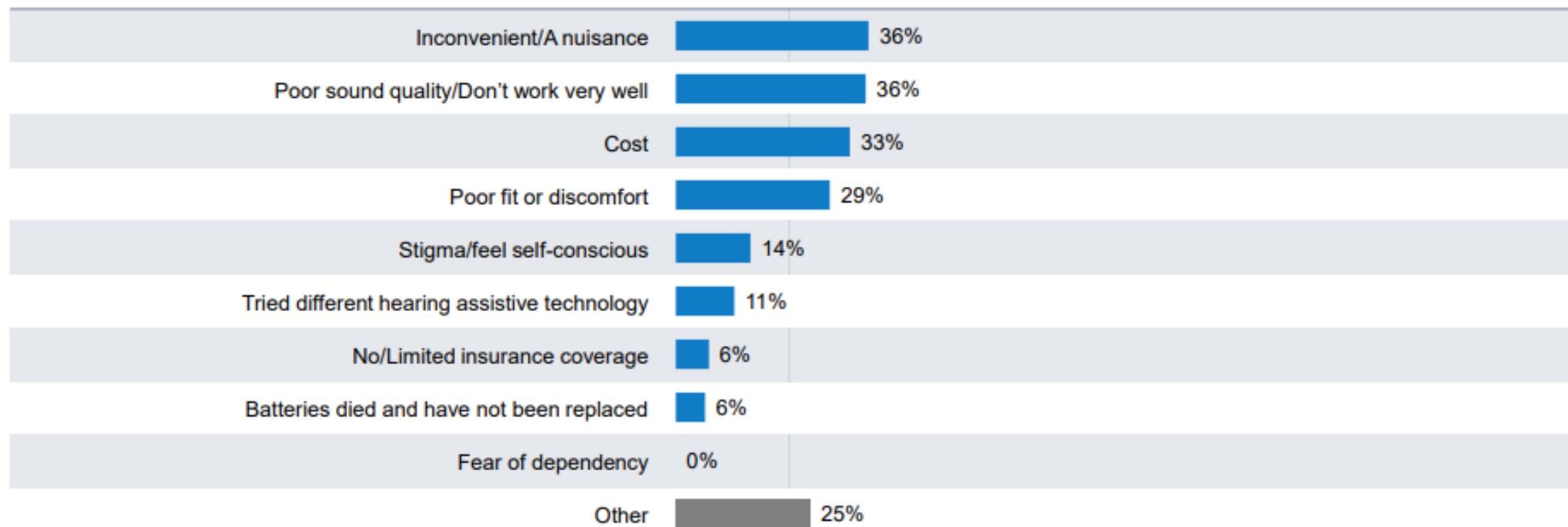


A small portion of American adults or adults with loved ones facing hearing issues chose not to use prescribed traditional hearing aids, most commonly due to inconvenience, poor sound, cost and poor fit/discomfort.

Reasons for Not Using Traditional Hearing Aid

(Among those who prescribed traditional hearing aid and do not use)

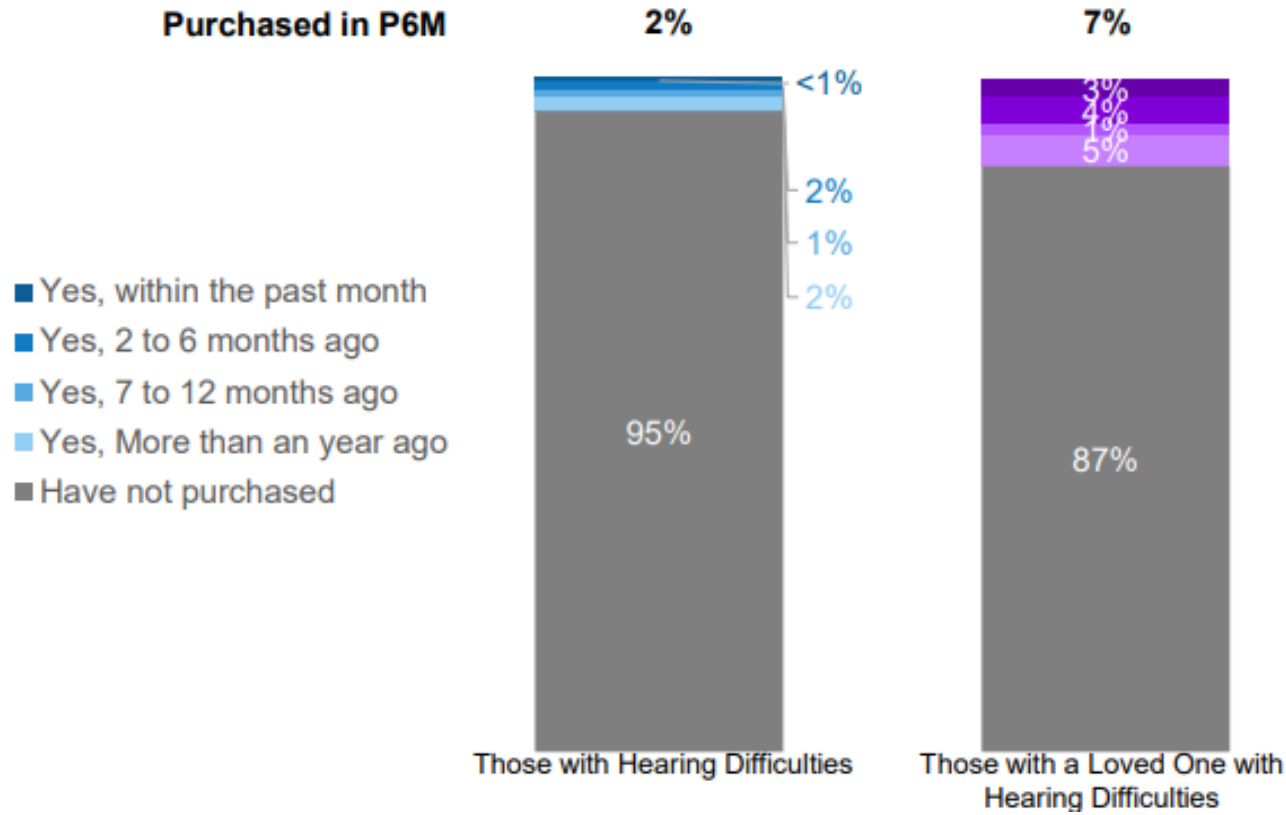
n=36*



Given recency of release, few have purchased an OTC hearing aid – just 2% of those with hearing difficulties.

OTC Hearing Aid Purchase

(Among those/a loved one with hearing difficulties)



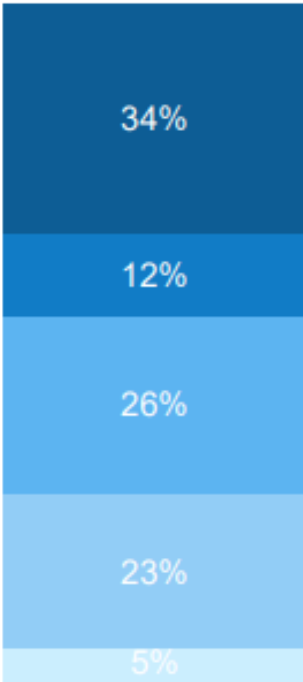
Nearly half of purchasers reported being highly satisfied with their OTC hearing aids.

Satisfaction With OTC Hearing Aid Performance

(Among buyers of OTC hearing aids)

Top 2 Box (Satisfied) 46%

- 1 Extremely Satisfied
- 2
- 3
- 4
- 5 Extremely Dissatisfied



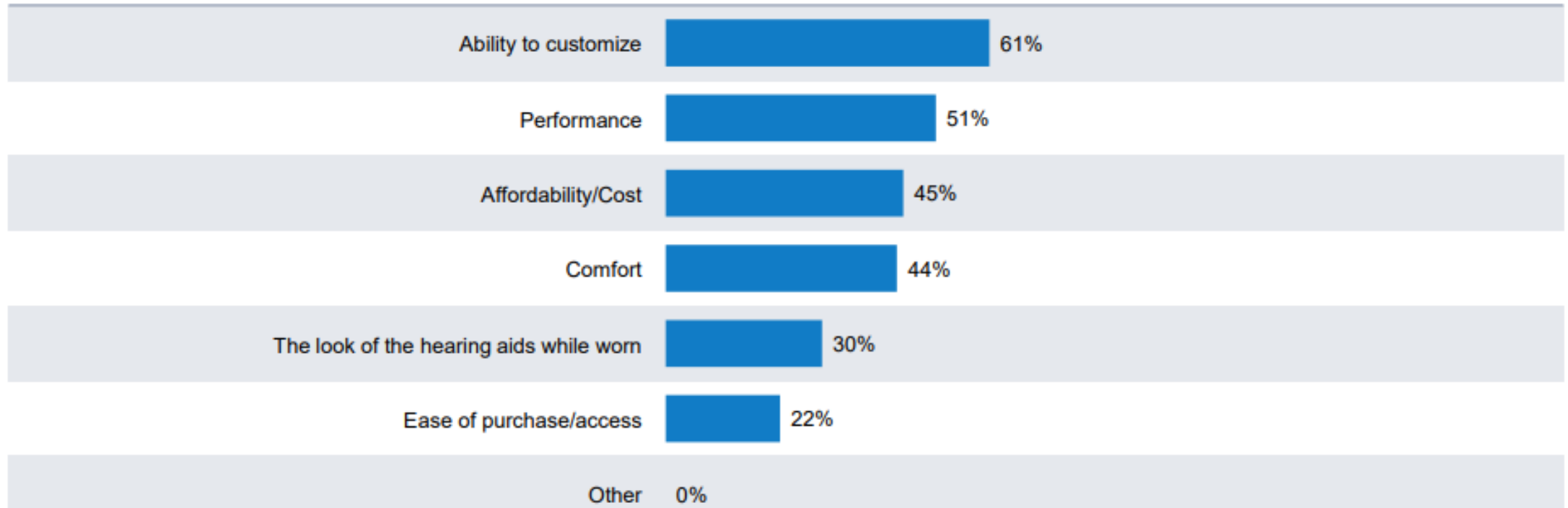
n=37*

Customization followed by performance fuelled satisfaction levels for OTC hearing aid purchasers.

Reasons for Satisfaction

(Among satisfied recent buyers)

n=20**

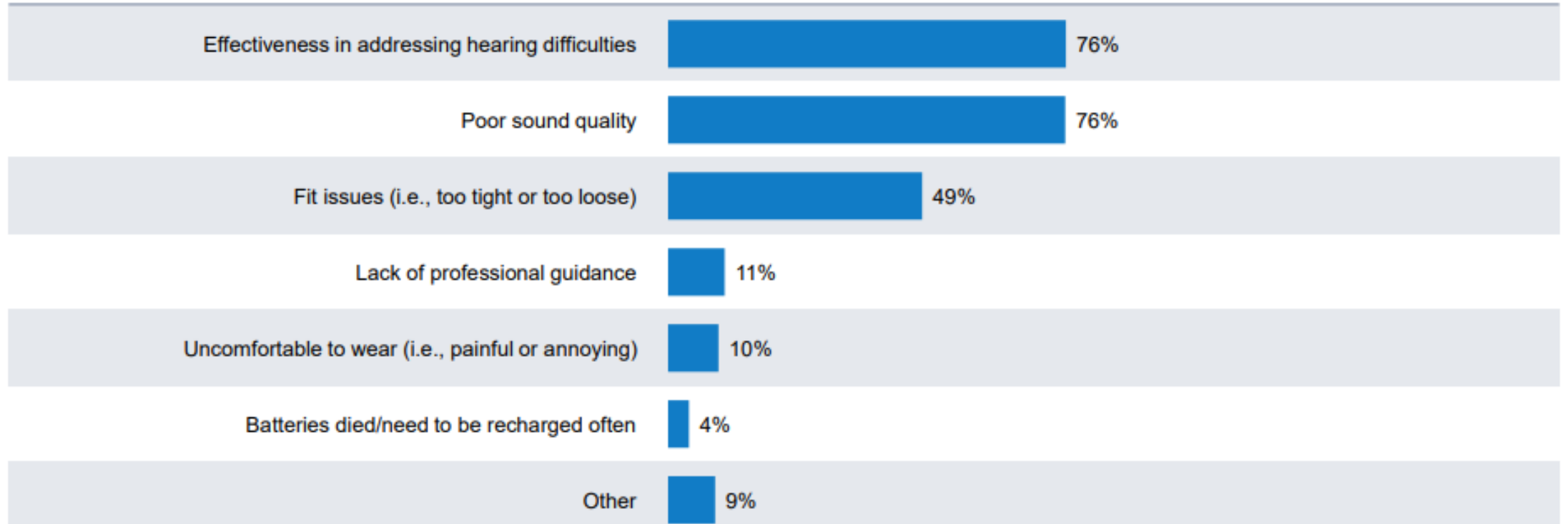


Lack of effectiveness and poor sound quality were cited as the main reasons for dissatisfaction.

Reasons for Dissatisfaction

(Among dissatisfied recent buyers)

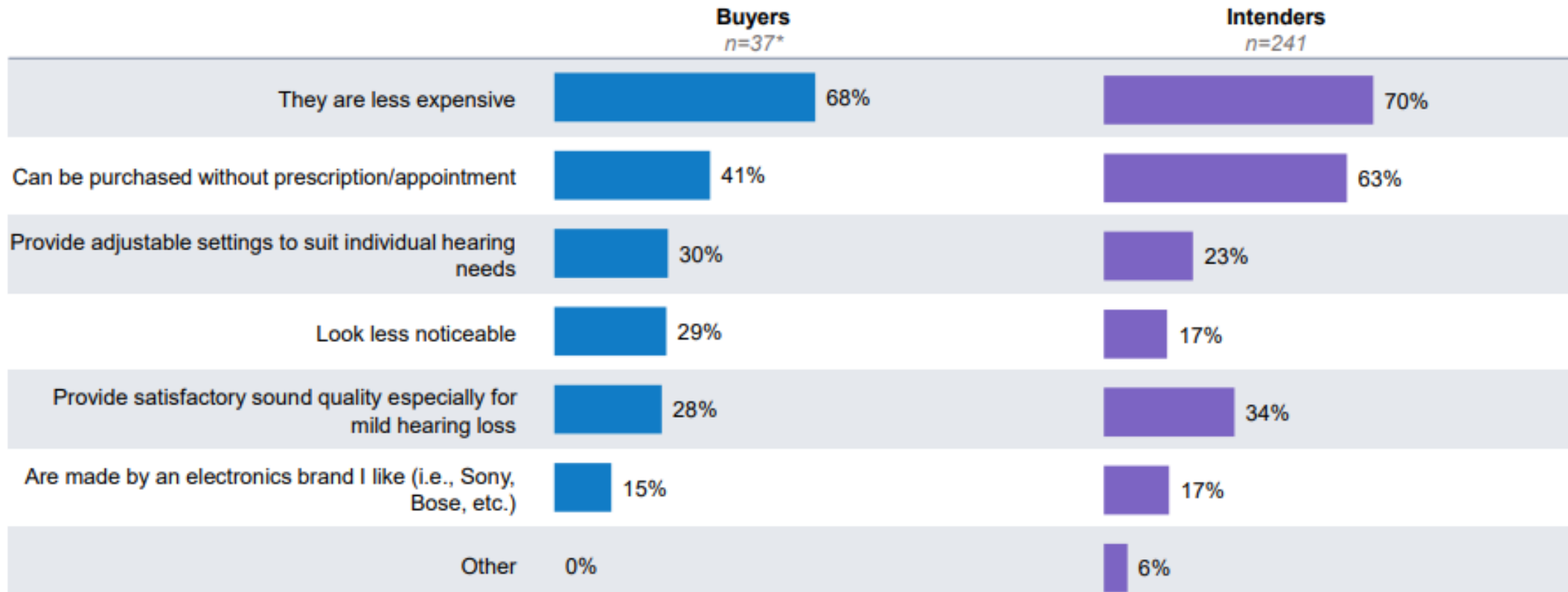
*n=7***



Perceived cost effectiveness and availability without prescription are key preference drivers.

Reasons for Preferring OTC

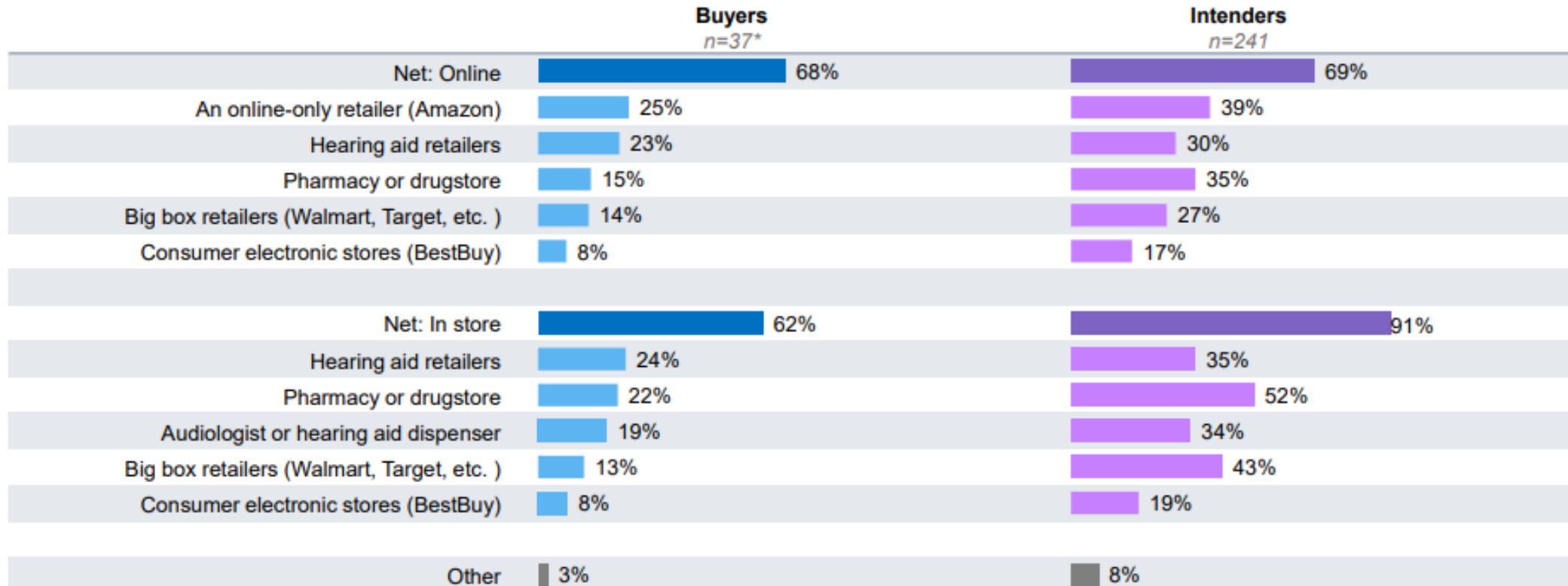
(Among buyers and purchase intenders)



OTC hearing aids are purchased both online and in store, though intenders are more likely to say they will purchase in store.

Place of Purchase

(Among buyers and intenders of OTC hearing aids)



SUMMARY OF OTC SURVEY

- More than half of American adults 40+ state their hearing is not excellent
- Almost half of those who purchased the OTC devices were satisfied with their performance
- Top 3 reasons not seeking professional help:
 - 1. Hearing was deemed “not bad enough”
 - 2. Not a priority
 - 3. Cost
- 6 out of 10 American Adults believe OTC hearing aids and amplifiers to be the same
- Online survey
- Only 2% purchased OTC hearing aids
- Less than one year on the market when study was performed

Rush University

The Future of OTC Hearing Devices

**OTC: The Good and
the Bad**

FUTURE OF OTC'S

- **Hearing aid manufacturers are joining with electronic and stereo companies**
- **Sharing research and development of products**
- **Creating mid level cost non custom hearing aids that are self fitting, rechargeable and adjustable by the patient**



SIGNIA AND SONY

- 2 styles
- 15-20 minutes to set up using Android or Iphone
- Patient checks their hearing through a test in the Sony Hearing App
- Results of the test determine which hearing profile (4 profiles) the patient should have as their programming
- Warns consumer to see a physician



\$1299.99/pair



\$999.99/pair

PHONAK AND SENNHEISER

- Offer three types of hearing solutions: TV Hearing, Conversation Hearing, and All Day Hearing
- Wireless connectivity to phone and TV
- Multiple programs



Conversation Hearing \$849.95

All Day Hearing \$1399.95-\$1499.95



TV Hearing \$299.95

RESOUND AND JABRA

- **RIC Style: Three different levels offering different amounts of noise reduction**
- **Blue tooth and rechargeable**



\$799.00 per pair



\$1195-\$1995 per pair

THINGS TO KEEP IN MIND...

- **How much hearing loss does the patient have?**
- **Word recognition?**
- **Dexterity?**
- **Tech savvy?**
- **Realistic expectations?**

- **Ask an Audiologist!**



Excellence is just the beginning.

Rush University

How HCP can help?

**OTC: The Good and
the Bad**

A thin, vertical black line is positioned to the right of the text "OTC: The Good and the Bad".

OTC HEARING AIDS: Healthcare Providers' Role?

- Help guide patient to best communication strategies and when an OTC would be a good/best option
- When needed, audiologist can provide services to improve chance of success with OTC hearing aids
 - Orientation to maximize user proficiency
 - Verification to ensure hearing aid is maximizing patient's access to speech
 - Formal hearing test would be required
 - Realistic expectations

EDUCATION is Needed



#1: Help to reflect on need.



#2: Discuss the evidence in support of technology benefits.



#3: Seek out guidance from Audiology.



#4: Awareness of financial support and options

REFERENCES:

1. *ASHA OTC Hearing Aid Survey*. (n.d.). Retrieved October 1, 2023, from <https://www.asha.org/siteassets/press-room/asha-otc-hearing-aid-survey-report-2023.pdf>
2. Benefits and Risks of Self Medication. Hughes, Carmel.M., McElnay, James. C., and Fleming, Glenda. F. *Drug Safety*. 24, 1027-1037 (2001).
3. *Over-the-Counter Hearing Aids: Tools for Audiologists*. (n.d.). American Speech-Language-Hearing Association. <https://www.asha.org/aud/otc-hearing-aid-toolkit/tools-for-audiologists/>
4. Taylor, B. (2023, July). *Hearing Device Classification: Definitions of OTC, DTC, PSAPs and Hearables*. Lecture, Colorado University; Colorado University.

