



Hearing Aids: OTC, DTC, and Connectivity

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My journey in audiology



BOCES of Greene County NY



Audiology & Speech Pathology of
Huntington, WV



Powers Consulting



My NJ farmhouse



Purpose of the Lecture

This lecture will also provide insights into:

1. To provide definitions for the OTC and DTC channels
2. Discuss the federal legislative and regulatory issues surrounding OTC
3. Highlight the connectivity possibilities for a variety of audio sources

I have time slots for questions during this presentation and the end of the talk

Why Focus on Hearing Health Care Now?

- Changing Demographics: Intersection of Hearing Loss and Aging
- Recognizing Hearing Loss as a Public Health Priority and a Societal Responsibility
- Rapidly Changing Technologies
- Changes in Health Care Paradigms

CDC Facts About Hearing Loss and Economic Cost

Hearing loss is the third most common chronic physical condition in the United States and is twice as prevalent as diabetes or cancer.

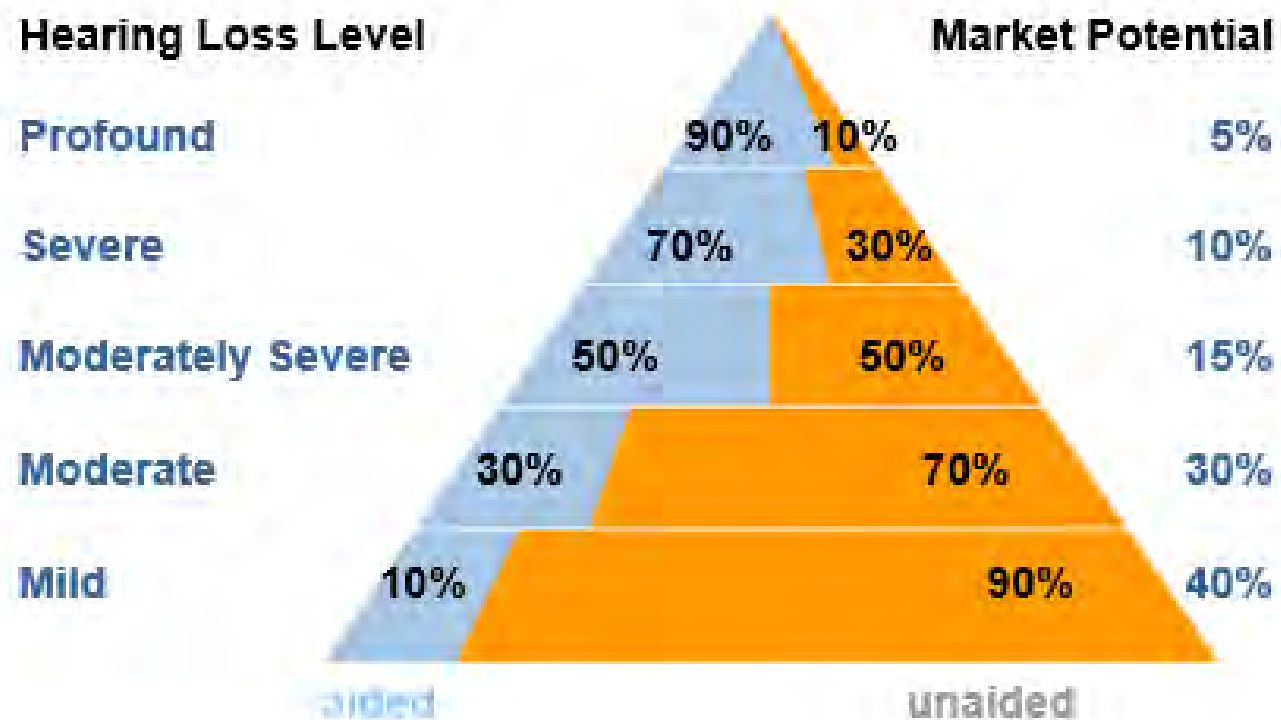
The economic cost to society of age-related hearing loss is estimated to be \$297,000 over the lifetime of every affected person.



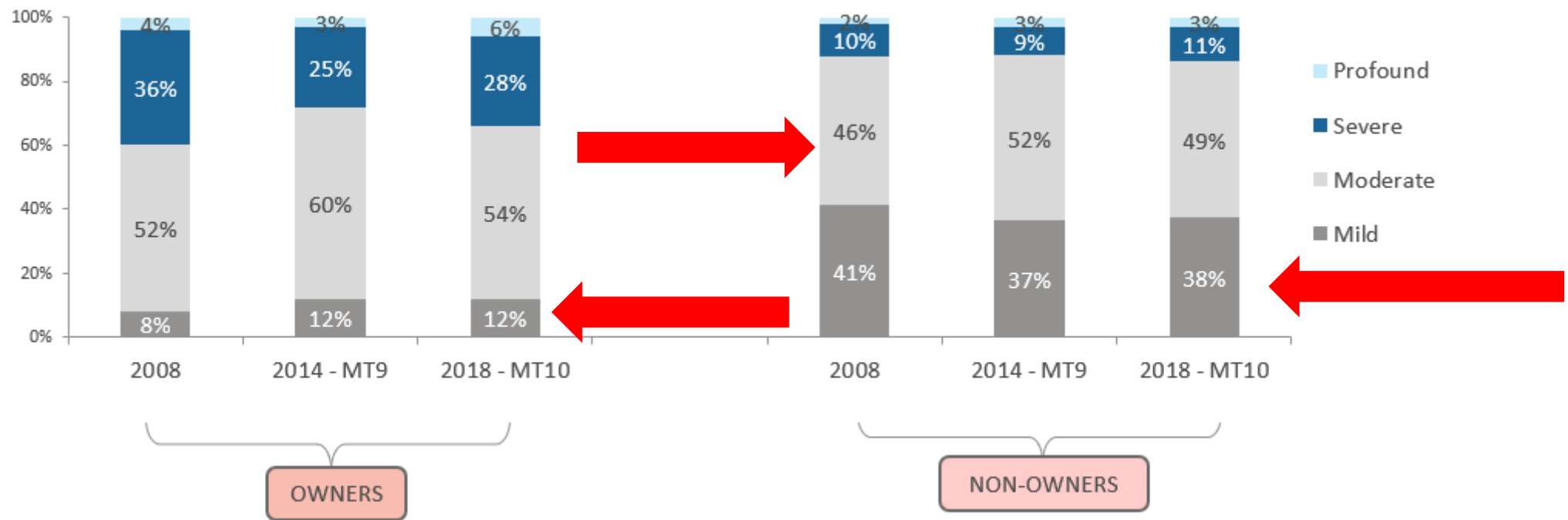
Source: Center for Disease and Prevention (CDC) 2020

https://www.cdc.gov/nceh/hearing_loss/public_health_scientific_info.html#:~:text=Hearing%20loss%20is%20the%20third,prevalent%20as%20diabetes%20or%20cancer.&text=The%20economic%20cost%20to%20society,lifetime%20of%20every%20affected%20person.

Target Market



Target Audience: People With Self Reported Mild to Moderate Hearing Loss



Population with Auditory Dysfunction

HEARABLE

PTA < 25 dB HL
Self-perceived
Difficulty **25 M**

HEARING AID & AUDIOLOGIST

PTA > 25 dB HL
Self-perceived
Difficulty
10 M
Accepts

Hearing Aids/Audiologist

OTC & SELF-FIT

PTA > 25 dB HL
Self-perceived
Difficulty
10 M
Rejects

Hearing Aids/Audiologist

PTA < 25 dB HL
Self-perceived
NO Difficulty **?? M**

PTA > 25 dB HL
Self-perceived
NO Difficulty **25 M**

CONSUMER PRODUCTS

OTC Hearing Aid Regulation

- The OTC Hearing Aid Act of 2017, included in the FDA Reauthorization Act, was signed into law on August 18, 2017. As part of this process, the FDA must issue a proposed rule by August 18, 2020, and a final rule within six months of the close of the comment period on the proposed rule.
- Directed FDA to create a category of OTC hearing aids:
 - Intended for use by adults 18 years of age and older
 - Intended to compensate for *perceived mild to moderate* hearing loss
 - Uses the same fundamental scientific technology
 - Allows the user to control and customize the OTC hearing aid to the user's hearing needs
 - May use wireless technology or include tests for self-assessment of hearing loss
 - Available without involvement or intervention of a licensed person
 - Available in-person, by mail, or online

Regulatory Recommendations For OTC Hearing Aids: Safety and Effectiveness

The Consensus Paper is a proposal from the major U.S. hearing healthcare professional associations; American Academy of Audiology (AAA), Academy of Doctors of Audiology (ADA), American Speech-Language and Hearing Association (ASHA), and International Hearing Society (IHS). It provides five key recommendations for assurance of safety and effectiveness of the new OTC devices mandated by Congress.

Product Requirements	Outside-the-box labeling	Inside-the-box labeling	Risk Classification	Consumer Protection
<ul style="list-style-type: none">• The 2 cc coupler HFA full on gain, as measured at an input level of 50 dB SPL, is 25 dB or lower• Peak 2 cc coupler is not greater than 110 dB SPL, in combination with input compression and volume control	<ul style="list-style-type: none">• Concise labeling appropriate for OTC medical device• Recognition of intended use / usage• Notice about hearing loss being a medical condition best addressed in consultation with a licensed professional	<ul style="list-style-type: none">• Comprehensive labeling• Warning that the device is not intended for children under the age of 18• Include User Instructional Manual with direction on how to identify lack of benefit and what to do	<ul style="list-style-type: none">• Maintain same risk classification as air conduction hearing aids• Any 510(k) exemptions be limited to devices that have received a first-time FDA marketing authorization (a 510(k) clearance)	<ul style="list-style-type: none">• FDA, in coordination with the FTC, to establish strong consumer protection laws and put in place processes and resources to enforce them

Federal Preemption

- Under Section 709 of the FDA Reauthorization Act (FDARA), **Congress included a preemption provision that prohibits states and local governments from establishing or continuing any law or regulation that would restrict or interfere with access to OTC hearing aids** – including the involvement of a licensed person or prescription to access the product.
- **The potential impact of preemption** on existing state regulatory structures – most importantly, consumer protections – **may be vast** as many states regulate hearing aids through the licensee as provided under state hearing aid sales and practice statutes.
- Therefore, if the licensing structure is disrupted for the new OTC hearing aid category, then important consumer protections may also be undermined.

Enforcement: Role of FDA

- On March 3, 2021 FDA issued a statement regarding “FDA Registration Certificates” that may look like official government documents and possibly include use of the FDA logo.
- Bad actors are using these certificates or other phrases such as “FDA-cleared” or “FDA-registered” to mislead consumers to think a device has been reviewed and approved by FDA.
- Additionally, companies are advertising “Direct-to-Consumer,” a gray area that is allowing bad actors to advertise direct sales, imply FDA approval, make false claims while FDA is not enforcing.

Enforcement: Role of States

- Recent actions for advertising violations related to COVID-19 and government stimulus payments
- Companies sent mailers to consumers that suggested they could provide government stimulus money to consumers to purchase hearing aids.
 - Mailers included a document designed to look like a \$1,000 check and labeled “OFFICIAL AUTHORIZED VOUCHER”
 - Included language like “Call Today to Secure Your Stimulus Money. For Stimulus Voucher Appointments, Call Today!”
- [Warning letters](#) sent by FTC and several Attorney’s General

Questions



Delivery Models

- Healthcare is becoming Retail
- Retail is becoming Healthcare
- Online delivery models emerging
- Managed care and employer sponsored care
- Member discount programs



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lexie

Lively

 HearingPlanet™
Welcome to a world of better hearing.

AUDICUS

embrace hearing

HEARING
REVOLUTION 

 hear.com

 ZipHearing DISCOUNT HEARING AIDS +
LOCAL CARE

Delivery Models

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- **Managed care and employer sponsored care**
- Member discount programs



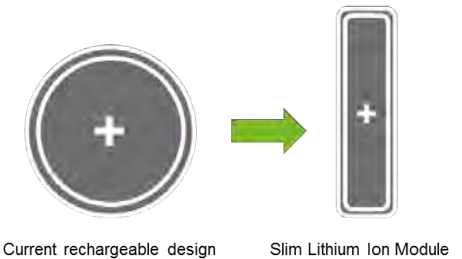
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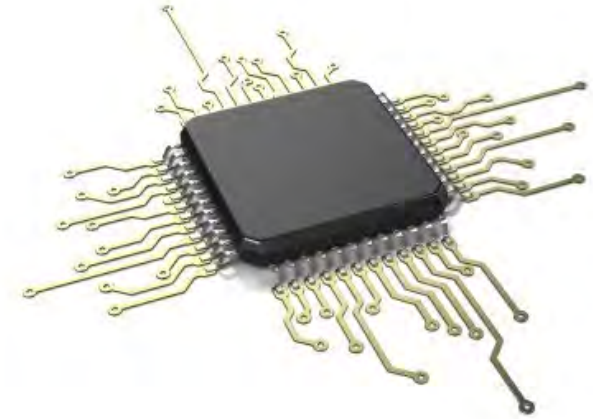
New Designs

- Size traditionally limited to accommodating power supply
- Innovations in Li-ion shape lead to new form factors
- New ways to combat cosmetic concerns
- How is this working in practice?

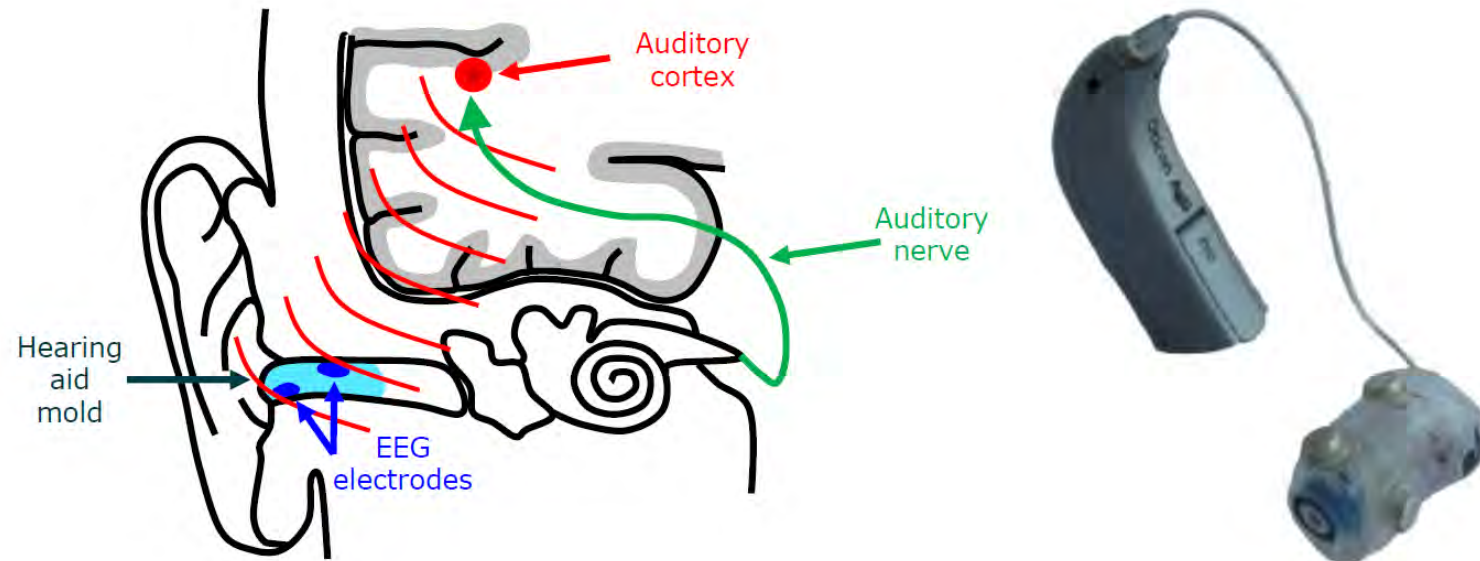


Use of Sensors

- Hearing aids are conveniently worn in a stable location for full day
- Sensors can help detect important information
 - Sensors in the phone
 - Sensors in the hearing instrument
- Value for the patient?
- Continue in expanding with these devices?



Hearing Aids with Sensors: EarEEG device example



OTC in Health Care has arrived



Early Mail Order

Mail Order Hearing Aids 100 Years Ago

Mail order catalogs from early 20th Century purveyors of hearing aids such as Mega Ear Phone, The Morley Co., Acousticon, Mears Ear Phone Co. and Globe Ear Phone Co. The Mega and Morley devices were the deep insertion non-electric "Lyric," circa 1910.



Single Brand Companies

America Hears HEARING AIDS
America Hears

Retail

HLT
Hearing Lab Technology

Sams Club
Sams Club

Lucid
Lucid Hearing

Direct

America Hears HEARING AIDS
America Hears

PSAP

Lucid
Lucid Hearing

ETYMOTIC
Etymotic

amplifon
Amplifon

Retail

Miracle Ear
Miracle Ear

hear more
Hear More Canada

National Hearing Care
National Hearing Care

elite
Elite Hearing Network

Other

IntriCon
IntriCon

Hearing Aid Brands

earVenture
EarVenture

hi
Hi

Direct

Hearing Help Express
Hearing Help Express

Other

Demant
William Demant

Hearing Aid Brands

oticon
Oticon

PHILIPS
Philips

bernafon
Bernafon

SONIC
Sonic

Audika
Audika

AGX HEARING
AGX

amplifon
Amplifon

Ryse
Ryse

Retail

HearingLife
HearingLife

AccuQuest Hearing Centers
AccuQuest

ListenUP!
ListenUP!

Van Boxtel hoorwinkels
Van Boxel

Other

YHN
Your Hearing Network

consult
Local hearing network

MedRx
MedRx

SENNEBIER
Sennebier

EPOS
EPOS

EarQ
EarQ

Diagnostic Instruments

gsi
GSI

amplivox
Amplivox

Interacoustics
Interacoustics

MicroMedical
MicroMedical

MAICO
Maico

Bone Anchored Hearing Aid Brands

oticon MEDICAL
Oticon Medical

Cochlear Implant Brands

oticon MEDICAL
Oticon Medical

GN
GN Group

Hearing Aid Brands

ReSound
Resound

Interton GN
Interton

Beltone
Beltona

AGX HEARING
AGX

ReSound Denweg
Denweg

Lively
Lively

advance
Advance

amplifon
Amplifon

Retail

Beltone
Beltona

Other

AUDIGY
Audigy

Jabra GN
Jabra

sonova
Sonova

Hearing Aid Brands

PHONAK
Phonak

Lyric
Lyric

HANSATON
Hansaton

unitron
Unitron

KIRKLAND
Kirkland

NovaSense
NovaSense

Ryse
Ryse

SELECTIC
Selectic

Blamey Saunders hears
Blamey Saunders

RELATE
Relate

Vista
Vista

SHIFT
Shift

advance
Advance

amplifon
Amplifon

Retail

HearingPlanet
HearingPlanet

Connect Hearing
Connect Hearing

AudioNova
AudioNova

Lapperre
Lapperre

hearingcare
HearingCare

Cochlear Implant Brands

AB
Advanced Bionics

Starkey
Starkey

Hearing Aid Brands

NUEAR
NuEar

AUDIBEL
Audibel

microtech
MicroTech

AGX HEARING
AGX

Audiology

Retail

Starkey
Starkey

AUDIBEL
Audibel

ihear
iHear

flscnt
Flscnt

Other

American
American Hearing Benefits

WSAudiology
WSAudiology A/S

Hearing Aid Brands

WIDEX
Widex

signia
Signia

REXTON
Rexton

Miracle Ear
Miracle Ear

SIEMENS
Siemens

cosely
Cosely

Audio Service
Audio Service

AGX HEARING
AGX

A&M
A&M

advance
Advance

Retail

bloom
Bloom

Helix
Helix

audiofon
Audiofon

HearUSA
HearUSA

HearCanada
HearCanada

hear.com
Hear.com

audibene
Audibene

Other

amg
AMG

lifestyle HEARING NETWORK
Lifestyle Hearing Network

TruHearing
TruHearing

HS
Hearing Care Solutions

Direct To Consumer (DTC)

A new model/channel emerged when OTC was delayed.

FDA – mentioned it was different than OTC

Many different delivery systems have evolved

No Professional

ZVOX
Samsung

Professional via website

Audicus
MDHearing
Noopl
Nuheara
Olive Union

Professional Involved

Lively
Eargo
Lexie
ZipHearing
Hear.com
Hearing Help Express (Intricon)

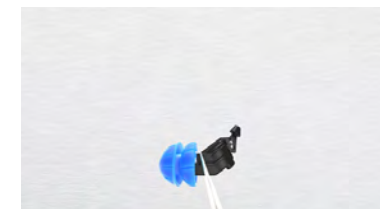
Direct to Consumer*



Eargo



Nuhera



iHear



MD Hearing



Audicus

* Source: Hearing Tracker

New Entry - BOSE



- | | | | | | | | |
|---|-----------------------------------|---|-------------------------------|---|---------------------------|---|------------------------|
|  | FOR MILD TO MODERATE HEARING LOSS |  | CLINICALLY PROVEN SELF-TUNING |  | COMFORTABLE, DISCREET FIT |  | 90-DAY RISK-FREE TRIAL |
|  | COMPREHENSIVE WORLD-CLASS SUPPORT |  | HIGH-QUALITY AUDIO |  | SELF-FIT DESIGN |  | REPLACEABLE BATTERIES |

While users may fit, program and control the Bose Hearing Aid on their own, the device must comply with applicable federal and state laws regarding the sale of hearing aids, including state laws that might require hearing aids to be purchased from or dispensed by a licensed hearing aid dispenser. The FDA is in the process of drafting proposed regulations for a new category of over-the-counter hearing aids as required by the FDA Reauthorization Act of 2017.

Currently available in MA, MT, NC, SC, and TX

Examples of DTC

AUDICUS

EARGO

Lively

 Olive

 Whisper

Examples of DTC



Nuheara Signs 3 Year Manufacture And Supply Agreement With HP Inc.

AUDICUS · Become A Member: Guaranteed Happy Hearing For Only \$98/Month



Audicus Hearing Aids

A pair of customized hearing aids from the world's no.1 manufacturer.

[\$1,798 Value]



Unlimited Audicus Support

Enjoy free programmings, reprogrammings and expert support from our friendly team.

[\$574 Value]



Audicus Protect

Experience total peace of mind. Your hearing aid is insured for loss or any damage.

[\$864 Value]

Audicus Care

New batteries, domes, and earwax guards every 3 months. Or whenever you need them.

[\$432 Value]

Audicus Refresh

Not only do you get our best hearing aids today, you get a free new pair in 18 months.

[\$1,798 Value]

Total Value \$5,466

But you can get all this today for as little as \$39 per ear/month on the Audicus All-Inclusive Membership Plan.

::: Whisper

The Whisper difference.

The Whisper Hearing System has earpieces like a traditional hearing aid, but what makes it unique is the pocket-sized power and intelligence of the Whisper Brain.



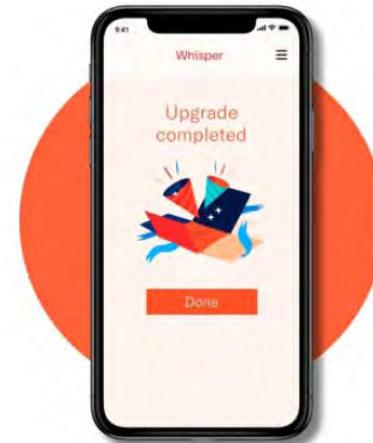
Whisper Brain

Processes and optimizes sound in real time using our Sound Separation Engine.



Earpieces

Transmit the optimized sound to your ears.



Whisper app

Delivers regular software upgrades.

NOOPL



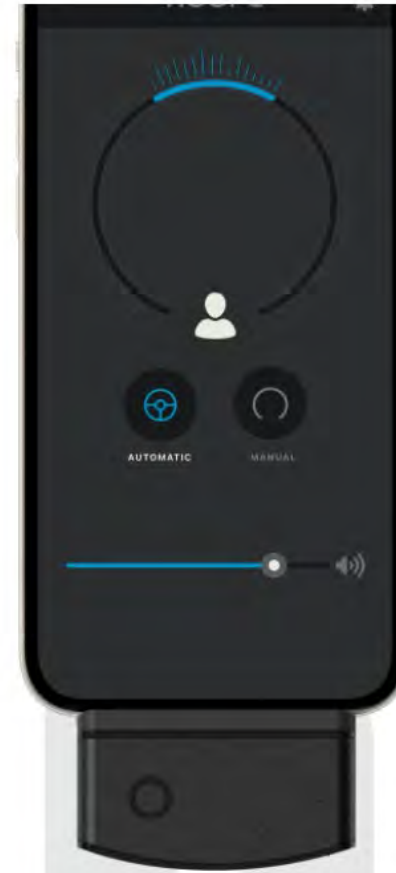
CRISP VOCAL CLARITY



**DRAMATICALLY REDUCE
BACKGROUND NOISE**



PRECISE DIRECTIONAL FOCUS

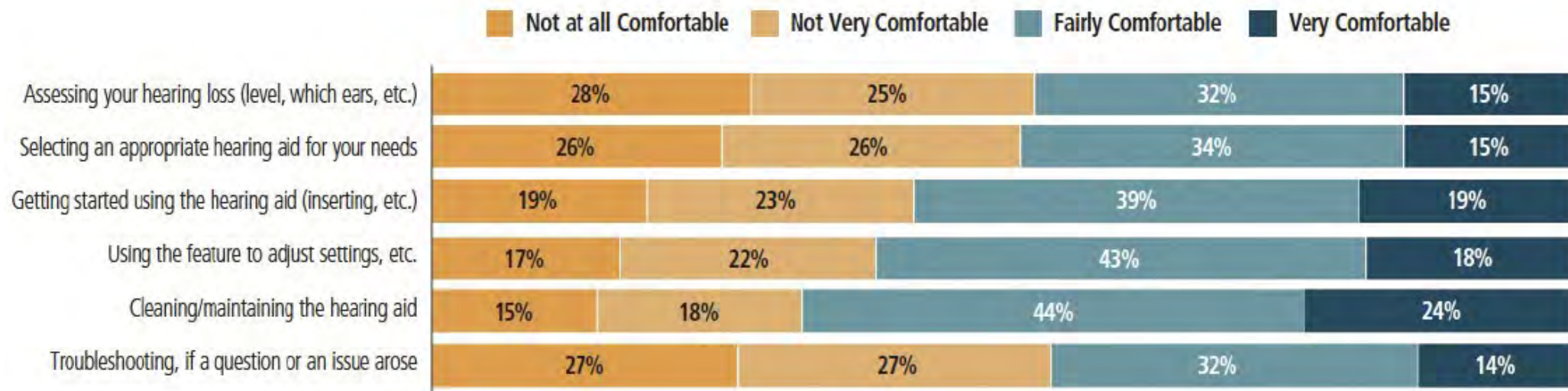




Olive Pro: 2-in-1 Hearing Aids & Bluetooth Earbuds

Enhanced Hearing for Sounds, Music and Conversations. Affordable Hearing for All.

Approximate half of those with HL (n=3113) uncomfortable doing tasks associated with OTC*



Challenge for OTC HAs Will Be Overcoming...

- Barriers to successful fit and use
- Stigma
- Lack of motivation
- Confidence in the solution
- Lack of support structure

Opportunity for HCP for a follow-up solution



Questions



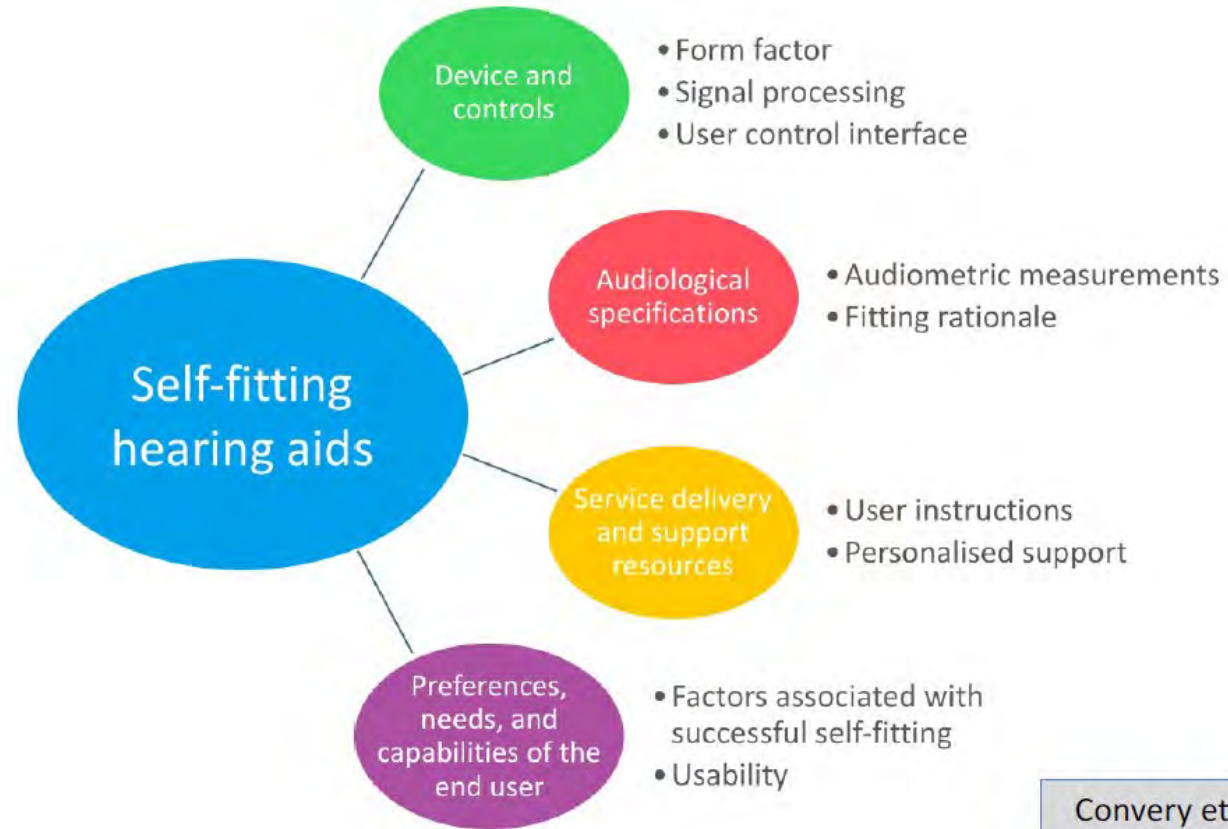
Unbundling Pricing Models

These models will be driven by one or more of the following:

- FTC rule-making
- OTC pricing
- Consumer demand

- Types of structure
 - **Single fee model** – everything is included
 - **Complete fee for Service** – all service and products are separate
 - **Combined fee for service** – Products – Services – Long term care

Self-Fitting Devices



Convery et al., 2017

Self-Fitting Devices

Self-Fitting Hearing Aids

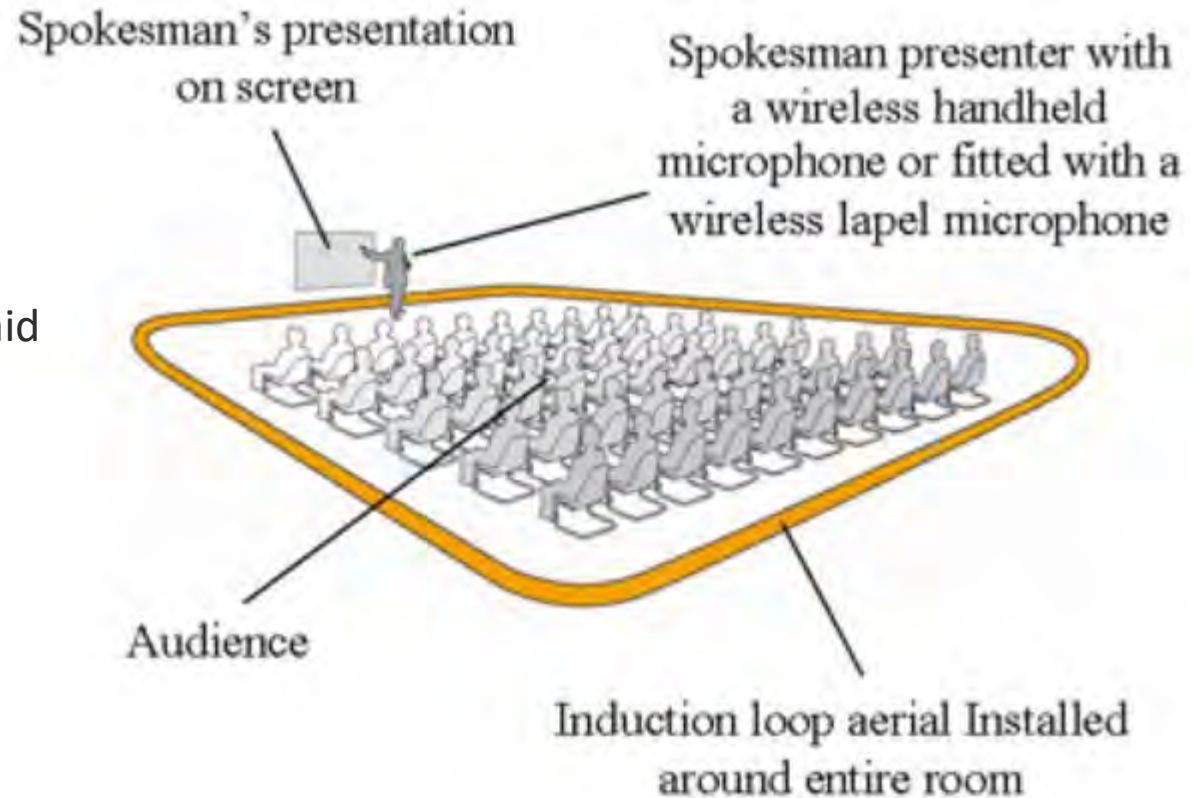
- Assessment of self-fitting ability, 60 adults

Success with Self-fitting Hearing Aid



Loop technology

- Cuts out unwanted background noise
- No need to use a receiver/headset
- Sound goes directly into the hearing aid
- Can be used by anyone with a compatible hearing aid
- It is inconspicuous
- Cost effective
- Any number of users can use the system



Support for Loops and T-coil Environments

Example of hearing aid with full Bluetooth connectivity and an optional modular T-Coil integrated in the battery door

T-Coil battery compartment

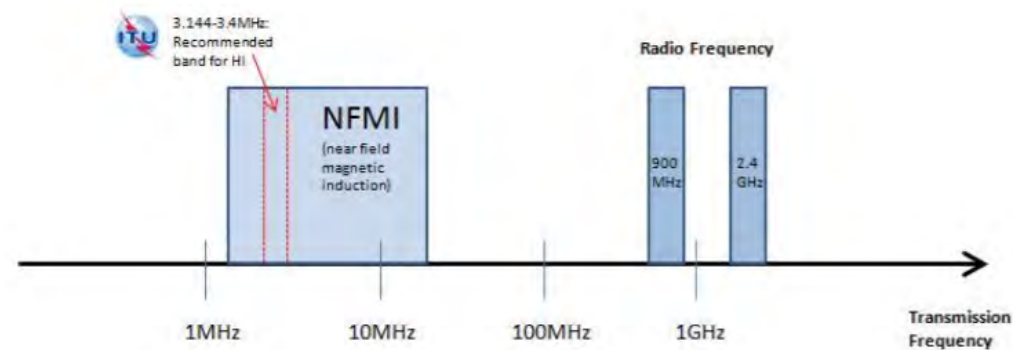
The standard battery compartment can be exchanged for one with an integrated T-Coil.



Evolution of Connectivity

Binaural Link between Hearing Instruments

- Volume Control Coupling
- Push Button Coupling
- Coupling of Signal Processing (e.g. situation detection)



Connectivity to Consumer Devices

- Television
- Telephones
- Mobile Phones
- Stereos
- Computers / Laptops



What hearing aid features are being used ?

Volume controls

Program controls

Directional performance

Tinnitus signals

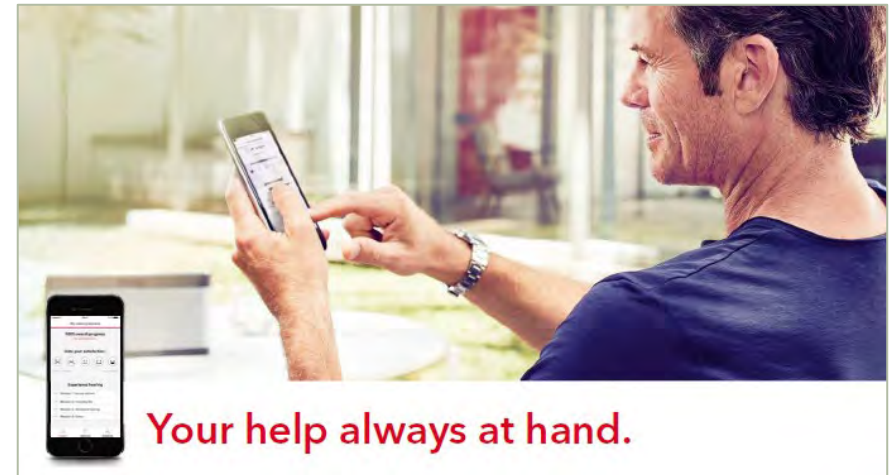
Connectivity to devices

Connectivity to their hearing professional

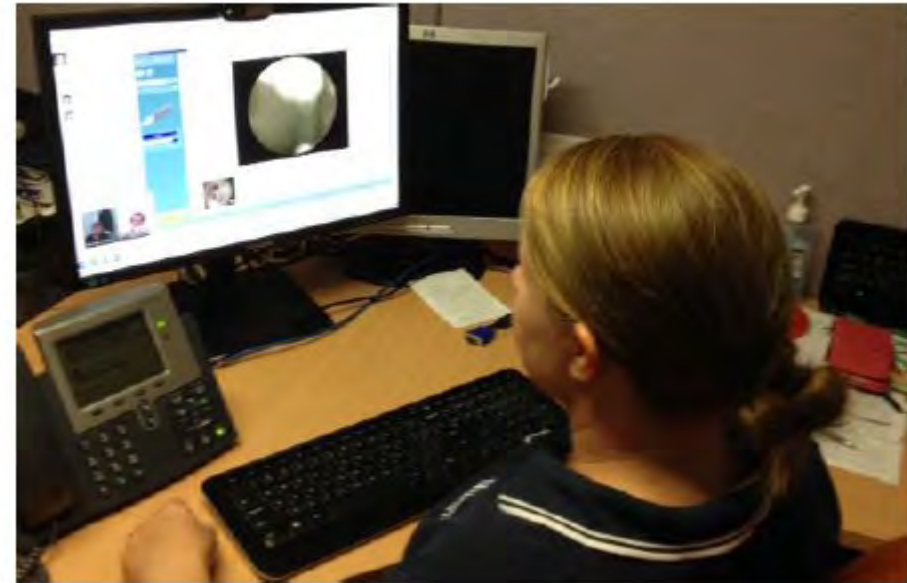


Use of Tele-Health

- Many aspects of healthcare are done in a “tele” format
- Telehealth for hearing care is currently in the market place
- Two key aspects of current approach
 - Counseling tool
 - Remote programming
- All current traditional manufacturers have developed this technology



Teleaudiology (Connected Hearing Health), has transformed audiology and hearing healthcare



FUNCTIONALITY AT A GLANCE



Remote control

- Hearing program and volume control
 - Sound Balance Adjustment
- Continuous monitoring of the hearing aid's connection and battery status



Directional hearing

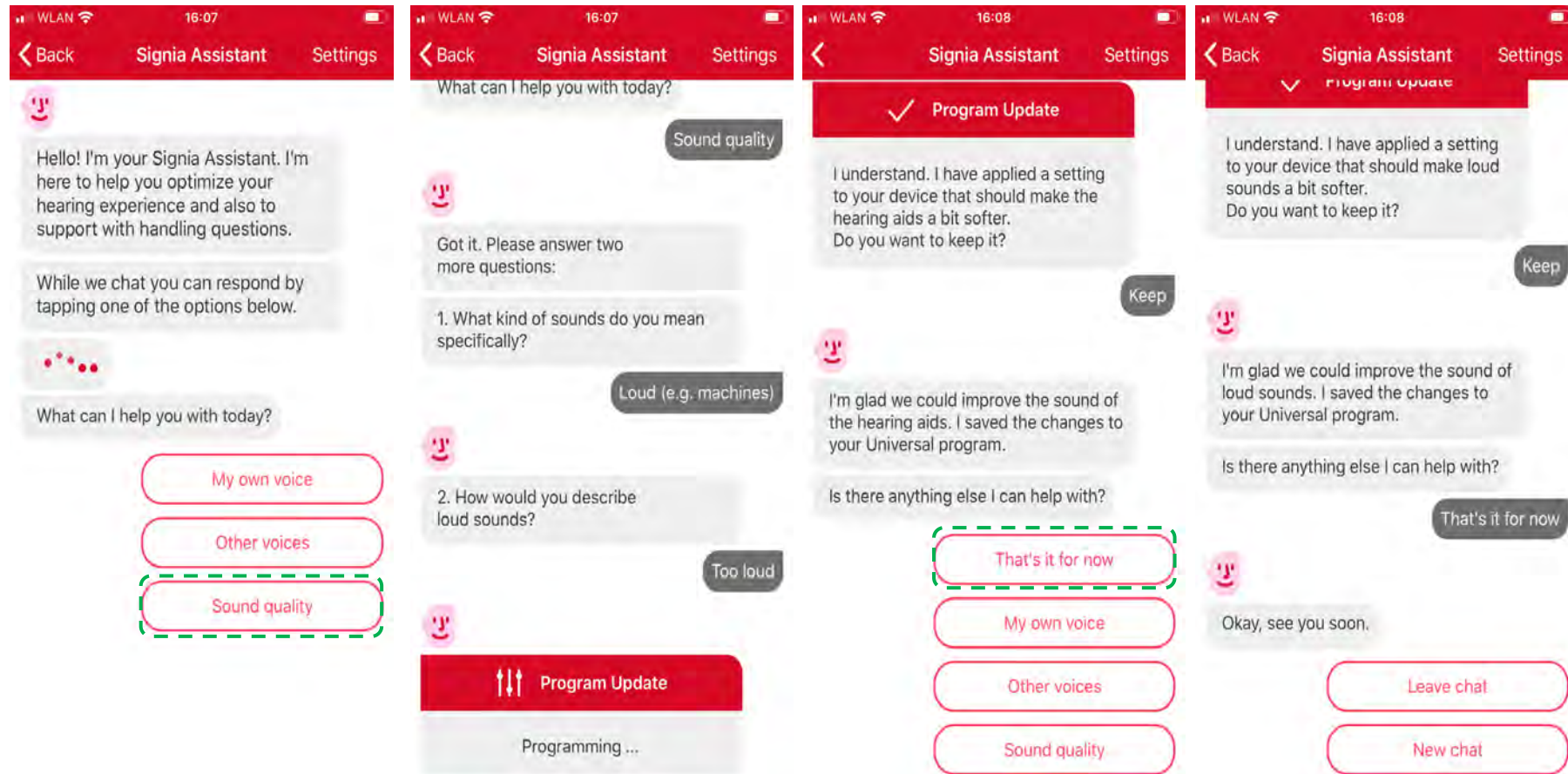
- 360° Spatial Configurator for individual adjustment of directionality



Connectivity and streaming

- Easy management of audio streaming accessories (e.g. StreamLine TV, StreamLine Mic)
- Volume level control while streaming
 - Adaptive streaming volume

Interaction with User on Assistant App

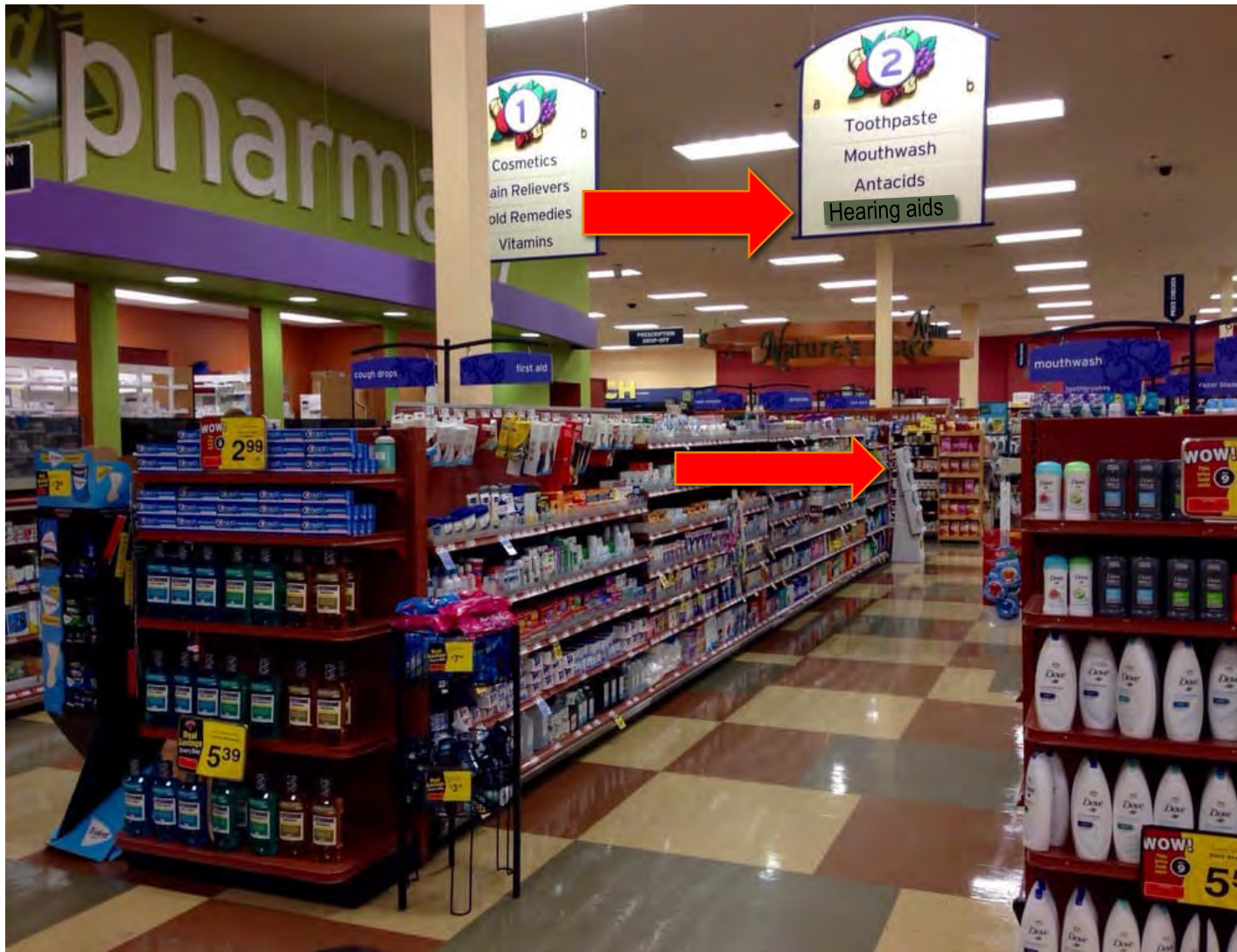


Take Home Messages

Hearing healthcare needs to go beyond those currently being helped

- **New definitions** of hearing health needs
- Support for new categories of loss and devices
- New delivery systems

Tele-audiology and **self-care** can help to address the growing demand



Thank you



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Questions

