

OTC Hearing Aid Activity U.S.A.

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Disclaimer

I am an independent

*Have written extensively on PSAP and
OTC Issues on hearinghealthmatters.org*

New: OTC Hearing Aid Law - 2017

- ❖ Enacted into law this past year in the U.S.
- ❖ This presentation
 - ✓ Background leading up to this
 - ✓ The law

Government Regulation of HA Sales

1977

FDA HA Regulation - 1977

To protect the health and safety of hearing impaired Americans – 2 parts

❖ Professional and Patient Labeling

- ✓ For manufacturers – On HA/packaging
 - ID markings, technical data, UIB

❖ Conditions of Sale

- ✓ For dispensers – before HA could be sold
 - Written OK statement from physician
 - Waiver of medical evaluation (personal or religious beliefs)
 - Review patient in light of 8 red flags
- ✓ Review UIB (User Instructional Brochure)
 - To go over completely all information in UIB with prospective patient



FDA Defined the HA

Hearing Aid: Any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing (*group auditory trainers are excluded*).

- ❖ Rule (1977), and definition, remained unchanged until 2009
 - ✓ Other “hearing help” products increasingly were being sold
 - ✓ FDA **Guidance** re HA & PSAPs (2009)
- ❖ **Why did FDA propose a Guidance in the first place?**

The HA Sales Landscape Was Changing



1977



By 2009

Seeds of Change Had Been Planted



With most seeds, early change is mainly below the surface

Many Seeds Had Been Sown

Hearing Aid Sales Options Multiplied

Disturbing for dispensing audiologists/licensed HA dispensers

- ❖ Explosion in the sale of HAs directly to consumer
- ❖ Some sold under the advertised claim of being an ALD
 - ✓ ALDs were exempt from the FDA 1977 Hearing Aid Rule
- ❖ Some were sold as hearing aids
 - ✓ In violation of the 1977 Hearing Aid Rule
- ❖ Number of unit sales significant?



Additional Seeds - Citizen Petitions in 2003

❖ Citizen Petition by Mead Killion to FDA to create an **OTC hearing aid classification**

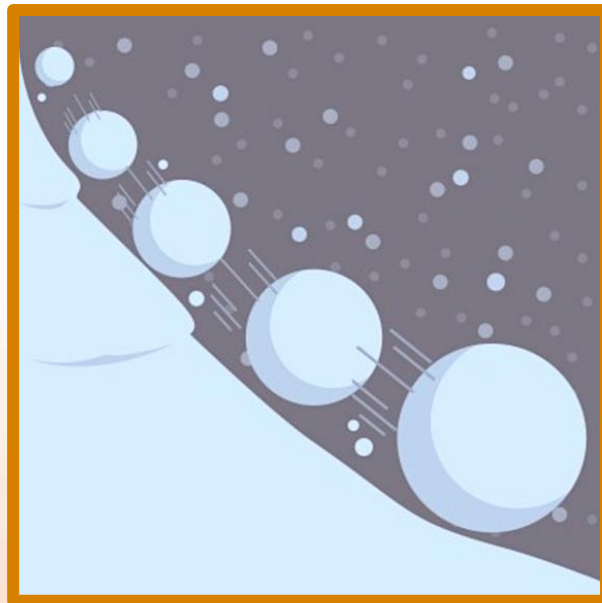
- ✓ For one-size-fits-most HA type devices that meet safety and efficacy requirements
- ✓ Coincidentally, followed Songbird intro



❖ Citizen Petition by Gail Gudmundsen to FDA to do away with parts of the 1977 HA Rule

- Waiver – to decline medical clearance for HA use – used almost always
- UIB – User Instructional Brochure labeling included data of little understanding to clients
- ✓ **FDA rejected petitions in 2004** because they believed that physician involvement was required
- ✓ **But then** eliminated physician requirement as necessary in 2016

The Snowball Builds



1977 - 2013

“HAs” sold in a variety of ways:

- ❖ Classified ads
- ❖ Direct mail
- ❖ Catalogs
- ❖ Magazine/newspaper ads
- ❖ Television ads
- ❖ Internet
- ❖ Big Box stores
- ❖ Traditional Distribution

Direct Mail

ADVANCED HEARING AID TECHNOLOGY
For Less Than \$200

Try it **RISK-FREE** for 45 days!
Complete Refund Guarantee!

How can a hearing aid that costs less than \$200 be every bit as good as one that sells for \$2,250 or more?

The answer: Although tremendous strides have been made in Advanced Hearing Aid Technology, those cost reductions have not been passed on to you. Until now...

MDHearingAid® uses the same kind of Advanced Hearing Aid Technology incorporated into hearing aids that cost thousands more at a small fraction of the price.

Over 300,000 satisfied MDHearingAid customers agree: High-quality, FDA-registered hearing aids don't have to cost a fortune. The fact is, you don't need to spend thousands for a hearing aid. **MDHearingAid** is a medical-grade hearing aid offering sophistication and high performance, and works right out of the box with no time-consuming "adjustment" appointments. You can contact a licensed hearing specialist conveniently on-line or by phone — even after your purchase at no cost. No other company provides such extensive support. Now that you know...why pay more?

"The MDHearingAid® is the BEST hearing aid I have used at ANY price!"
— Edward S., Wayne, NJ

TAKE ADVANTAGE OF OUR 45-DAY RISK-FREE TRIAL!
Hearing is believing and we invite you to try this nearly invisible hearing aid with no annoying whistling or background noise for yourself. If you are not completely satisfied with your MDHearingAid, return it within 45 days for a **FULL REFUND**.

For the Lowest Price Call 1-800-304-8570
www.GetMDHearingAid200.com

Use Code **HK79**
and get **FREE Batteries for 1 Year**
Plus FREE Shipping

MDHearingAid®
DOCTOR DESIGNED | AUDIOLOGIST TESTED | FDA REGISTERED

CO CENTER

PHONAK
bernafon®

Nearly Invisible
BIG SOUND. TINY PRICE.
BATTERIES INCLUDED!
READY TO USE RIGHT OUT OF THE BOX!

BBB
BETTER BUSINESS
Rating: A+

Professional Organizations' Reactions to the Trend

- ❖ Took steps, individually and together, to turn back the rising tide of alternate HA purchasing options.
 - ✓ Letters to FDA
 - ✓ Articles and advertising promoted professionals only, for dispensing
 - ✓ Indicated their professions were necessary to protect consumers against the dangers of fitting without an audiogram or a licensed professional
- ❖ Included the major non-medical professional organizations in hearing care:
 - ✓ American Academy of Audiology (AAA)
 - ✓ International Hearing Society (IHS)
 - ✓ American Speech-Language-Hearing Association (ASHA)
 - ✓ Academy of Doctors of Audiology (ADA)

FDA Responded to Their Input

Responded to pressure and complaints from the HA industry and dispensing groups concerning the sales of "hearing aid" products they felt were:

- ❖ Outside hearing professionals' control, and
- ❖ Outside the 1977 Hearing Aid Rule

Feb. 25, 2009

FDA published a nonbinding **Guidance for Industry and FDA Staff on Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products**

- ❖ **First mention of PSAPs in any regulatory action**

2009 Guidance Defined HAs and PSAPs

- ❖ Both affect ability to hear sound,
- ❖ But have different intended uses,
- ❖ Therefore subject to different regulatory controls
 - ✓ HA - Medical device
 - ✓ PSAP - Consumer product
- ❖ A **hearing aid** - wearable sound-amplifying device intended to compensate for impaired hearing.
- ❖ A **PSAP** - wearable electronic product that is not intended to compensate for impaired hearing, but rather is intended for non-hearing impaired consumers to amplify sounds in the environment for a number of reasons, such as for recreational activities.

While some of the technology and function of HAs and PSAPs may be similar, the intended use determines whether it is a device or an electronic product.

Definitions Led to Confusion

- ❖ A PSAP amplifies sound – not logical to ignore this fact
- ❖ If a PSAP amplifies sound – it can help some people hear better.
 - ✓ It performs some of the same function as does a HA
 - ✓ So why not say it can be used to help some hearing losses?
- ❖ Distinction between HA and PSAP was becoming blurred.
- ❖ FDA attempted to clarify this and proposed a **Revised Guideline** in **2013** to replace the 2009 Guideline



FDA 2013 Proposed Guideline to Clarify Distinction

Proposed **revised Draft Guidance** Document

- ✓ HA description remained essentially unchanged
- ✓ PSAP description was modified

HA - For listening situations typically associated with and indicative of HL

- ✓ If a product claims to correct difficult listening situations, it is a HA and not a PSAP.
- ✓ If sold “over the counter” as an alternative or substitute for a HA, it is not a PSAP.

PSAP - Because PSAPs are not intended to diagnose, treat, cure or mitigate disease and do not alter the structure or function of the body, they are not medical devices as defined in the FD&C Act. As such, there is no regulatory classification, product code, or definition for these products.

Obvious by omission: did not say that a PSAP could be useful to some individuals having HL

Challenges to 2013 FDA Draft Guidance Proposal

Especially toward definitions and use

Citizen Petitions - 2014

- ❖ Mead Killion petitioned FDA requesting that unregulated PSAPs remain as such (as in 2009 Guidance) for free and unfettered availability as a **consumer product**, and that FDA's proposed 2013 restrictive regulations severely limit competition and make no meaningful contribution to protecting public health.
- ❖ Gail Gudmundsen petitioned that the 2013 Draft Guidance exceeds the authority of the FDA in that it negatively impacts the availability of a **consumer product**, and is not a **medical device** under the FDA authority, by definition.

Consumer Electronics Association Weighs In for PSAPs

CEA Report – June, 2014

- ❖ Based on online national survey (3459 U.S. adults):
- ❖ **Sought to strengthen the case for permitting PSAPs to be sold to address mild/mod losses**
- ❖ Cost was a major barrier, and PSAPs would help overcome this
- ❖ A strong demand for PSAPs was reported among consumers with hearing difficulties
 - ✓ 40% would be interested in purchasing PSAPs OTC
 - ✓ Of these, they would be willing to purchase from:
 - Drug store (73%)
 - Big Box store (55%)
 - Online (48%)

TIA (Telecommunications Industry Association)

Recommendations re 2013 Guidance

- ❖ Needs more clarity in defining a PSAP vs a HA
 - ✓ PSAP is NOT a medical device, but a consumer device
 - ✓ Many consumer ICT (information and communications technology) products would fall into the HA device category, including smart phones, etc.
 - ✓ ICT industry already has many products to enhance hearing in varying environments
- ❖ Urged enforcement discretion for PSAPs that may meet medical device definition, but which pose little or no potential risk to consumers.
 - ✓ As FDA has already done with mobile medical devices
- ❖ Allow for PSAP labeling and marketing materials to address HL

Government Agency Interests



**Renewed Look at HA Sales and Distribution
From a Consumer, Not Regulatory View**

Pathway to the OTC HA

2009



NIDCD

Working group on
Accessible and
Affordable Hearing
Health Care for
Adults

2015



PCAST: Report on
Aging American &
Hearing Loss

2016

Today

PCAST




The President's
Science Advisory
Group

Advisory group of nation's
pre-eminent experts who directly advise the President on
recommendations where science, technology, & innovation
are critical to national security, economic competitiveness,
and forming policy that works for the American people.

Report

2017

NASEM



The National
Academies of
SCIENCES
ENGINEERING
MEDICINE

NASEM provides nation's pre-
eminent source of high-quality,
objective advice on science,
engineering, and health matters.

PCAST Advisory Activity – 2015

- ❖ Held a series of open meetings/workshops
 - ✓ Discussed adult hearing loss and HAs
 - ✓ Delivery model
 - ✓ Goal of growing accessibility to hearing technologies

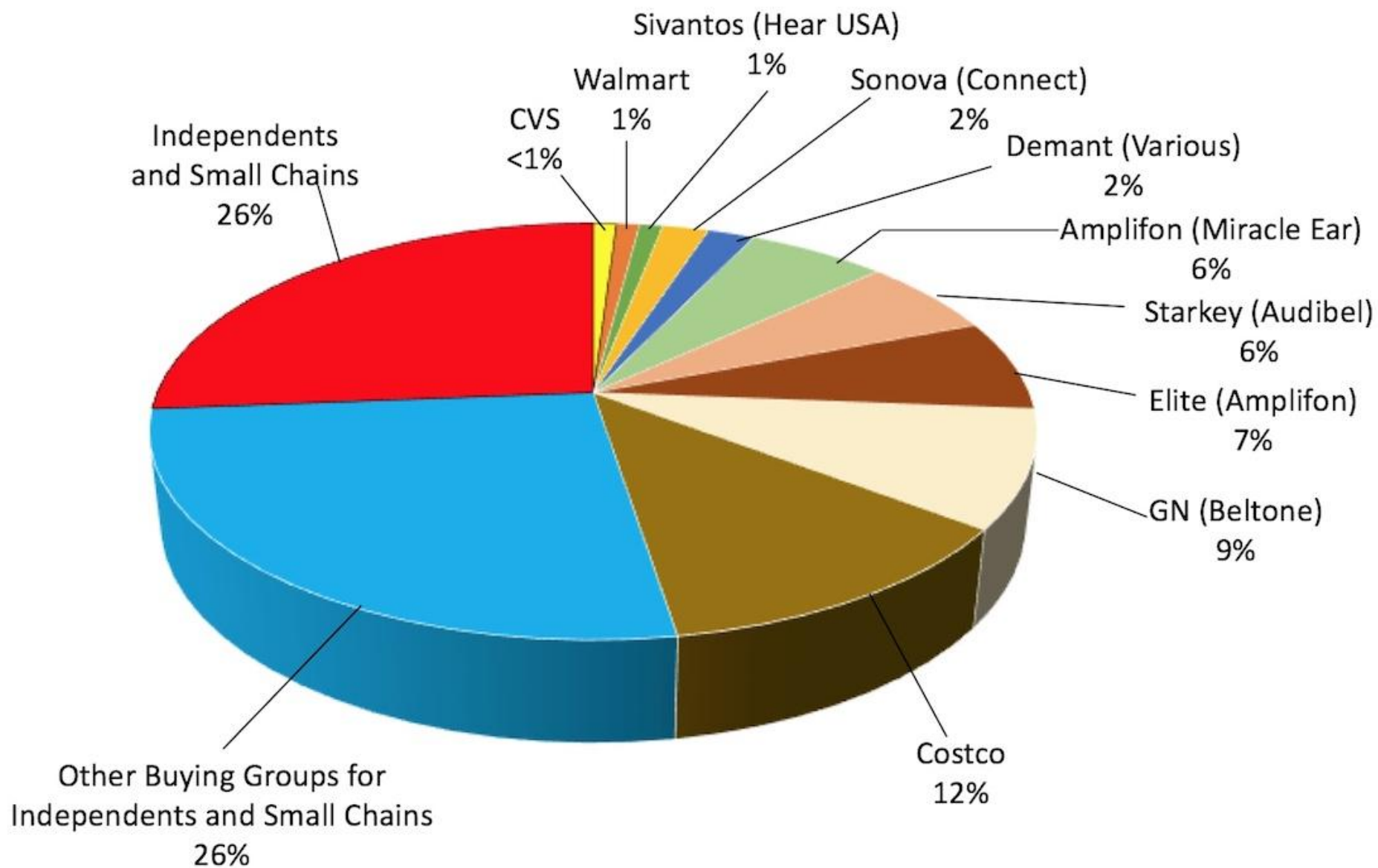


- ❖ October, 2015 Report **Recommended to the FDA**
 - ✓ **Open the market** for innovative hearing technologies
 - Designate a category of “basic” HAs and adopt rules for this class
 - Approve this class for OTC sales
 - Exempt this class from QSR (Quality System Regulations)
 - ✓ **Withdraw Draft Guidance of 2013. Instead:**
 - Broadly define PSAPs as devices for discretionary consumer use intended to augment, improve, or extend the sense of hearing in individuals.
 - FDA should not require language in PSAP labeling/advertising that excludes use by individuals with age-related HL no worse than mild-to-moderate.

PCAST Recommendations' Rationale

- ❖ Costs and risks of untreated HL relative to aging in the US is great
- ❖ Unnecessary high price of HAs exists
- ❖ Conspicuously slow pace of innovation by manufacturers as compared with other **consumer electronics**, reflected in:
 - ✓ A concentrated and increasingly vertical integrated incumbent industry
 - ✓ Operating in the context of longstanding State and Federal regulations that discourage potential new entrants
 - ✓ Recommend actions to FDA and FTC to open the market for innovative hearing technologies and increasing opportunities for consumer choice.

Private U.S. Hearing Aid Market by POS (2016)



2016 FDA Workshop (April)

❖ Followed PCAST Report

- ✓ **Reopened comment period on 2013 Guidance re PSAPs**
- ✓ Discussed GMP regulations to ensure safety and effectiveness of hearing aids

❖ Opened discussion on OTC classification

- ✓ Should traditional HAs be available for OTC sales (without medical intervention)?
- ✓ Should FDA allow PSAPs to be marketed as designed to treat hearing loss?
- ✓ What about self-fitting (self-treating) and self-monitoring?

❖ Gathered evidence from:

- ✓ Hearing aid industry
- ✓ Associated bodies
- ✓ Independent audiologists/dispensers
- ✓ Consumers
- ✓ Third parties conducting standardization and quality review

Reactions to PCAST for OTC Hearing Aids

❖ Consumers	For
❖ Audiologists	Mostly in Opposition
❖ HA Dispensers	Strongly Opposed
❖ HA Manufacturers	Strongly Opposed

AAA

❖ Re Medical Clearance Removal:

- ✓ Agrees with the withdrawal of the requirement for medical clearance to purchase a HA

❖ Released a statement applauding the decision of the FDA.

- ✓ “The Academy is thrilled that the FDA has heeded the comments from stakeholders in the hearing health community and has taken immediate steps to improve HA accessibility for patients and remove unnecessary barriers for those seeking hearing health-care.” –Ian Windmill, PhD, AAA President



ASHA (American Speech-Language Hearing Association)

- ❖ ASHA's comments to the FDA focused on:
 - ✓ Need for an audiological evaluation
 - ✓ Continued need for audiologists to be involved in determining an individual's degree and type of hearing loss.



IHS (International Hearing Society)

“IHS is aware of no evidence to support the efficacy or safety of these recommendations, nor the existence of evidence that they would positively impact responsible accessibility, cost, or the use of hearing aids in a meaningful way.”



NASEM



Independently Evaluating Affordable and Accessible HA Care
(Formerly Institute of Medicine)

NASEM Advisory Group Activity - 2016

Committee on Accessible and Affordable Hearing Care For Adults

- ❖ Workshop for stakeholders
- ❖ Five public meetings
- ❖ Deep dive analysis



NASEM Report – June, 2016

The National
Academies of | SCIENCES
ENGINEERING
MEDICINE

❖ NASEM/NAS Report

✓ *Hearing Health Care for Adults: Priorities for Improving Access and Affordability.*

❖ Report stated

✓ *People who need hearing health care services and technologies should be at the center of their own care, with the option to make decisions about what is the most appropriate care for them.*

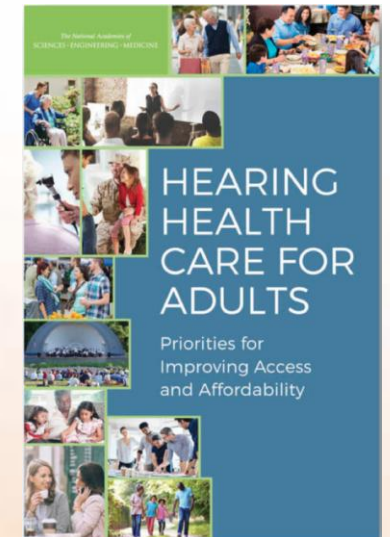
❖ Recommended:

✓ Support of PCAST

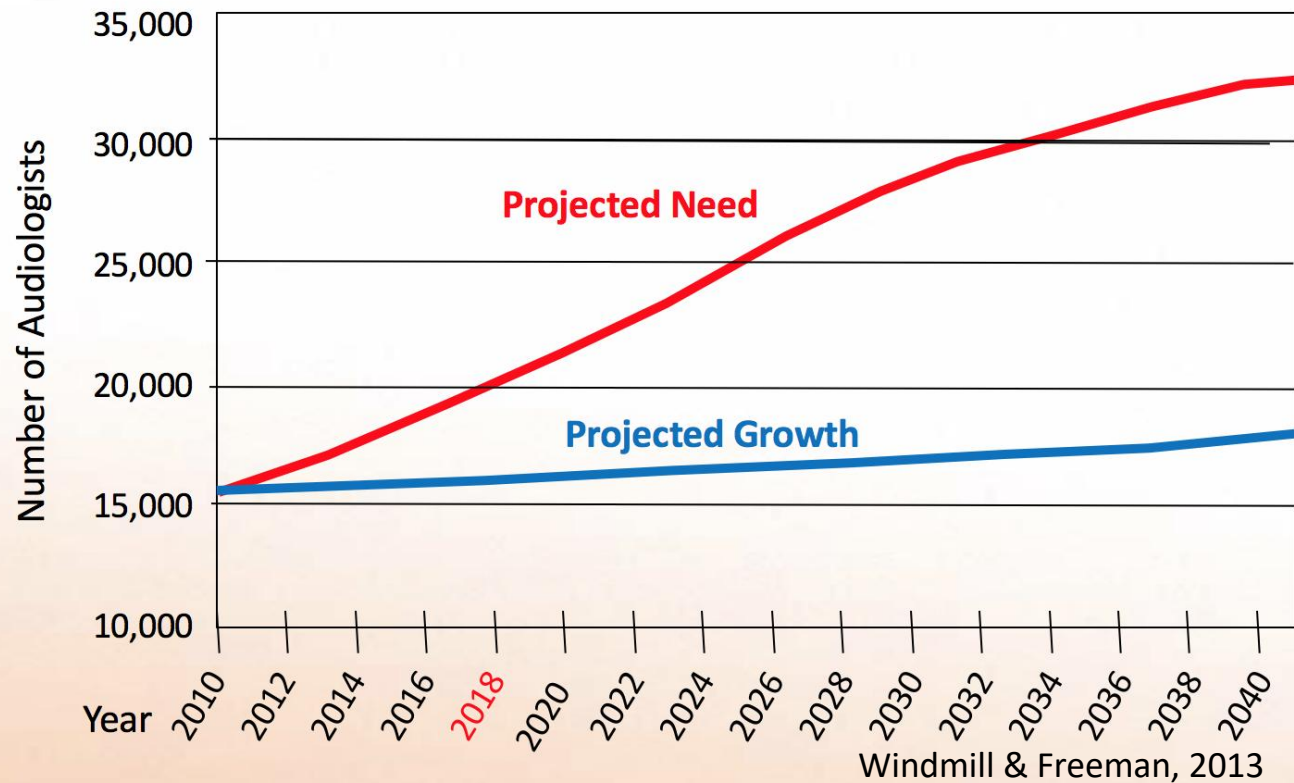
✓ Removal of the medical waiver

✓ Deregulate the market

✓ Called on the FDA to establish a new OTC category of HAs for mild-to-moderate HL



Access – Major Issue With Current Distribution



**Going forward -
Link open to encroachment**

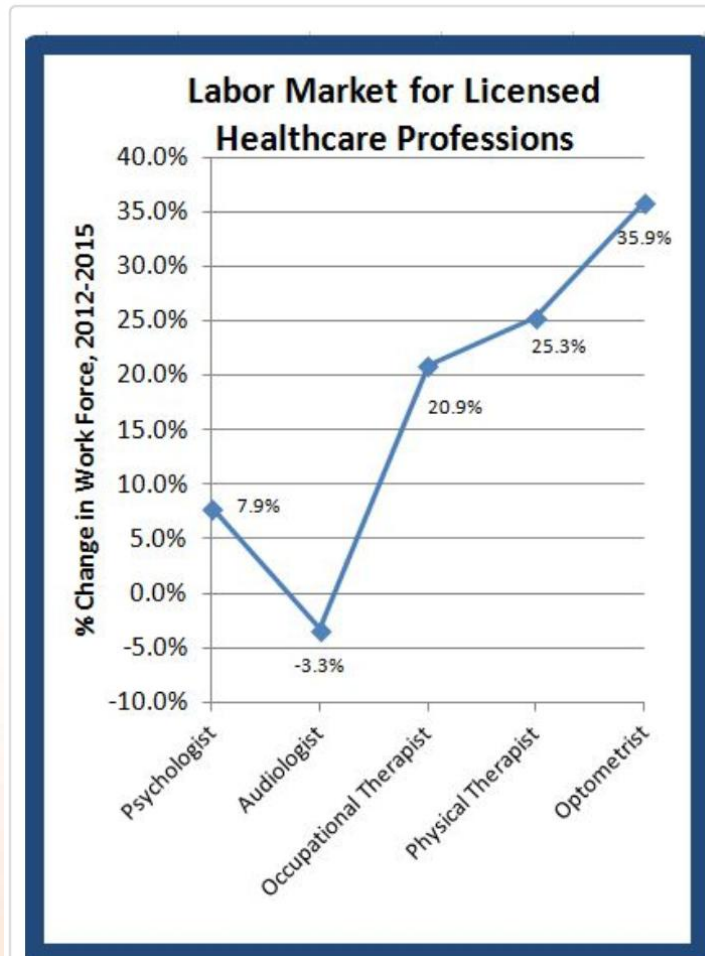
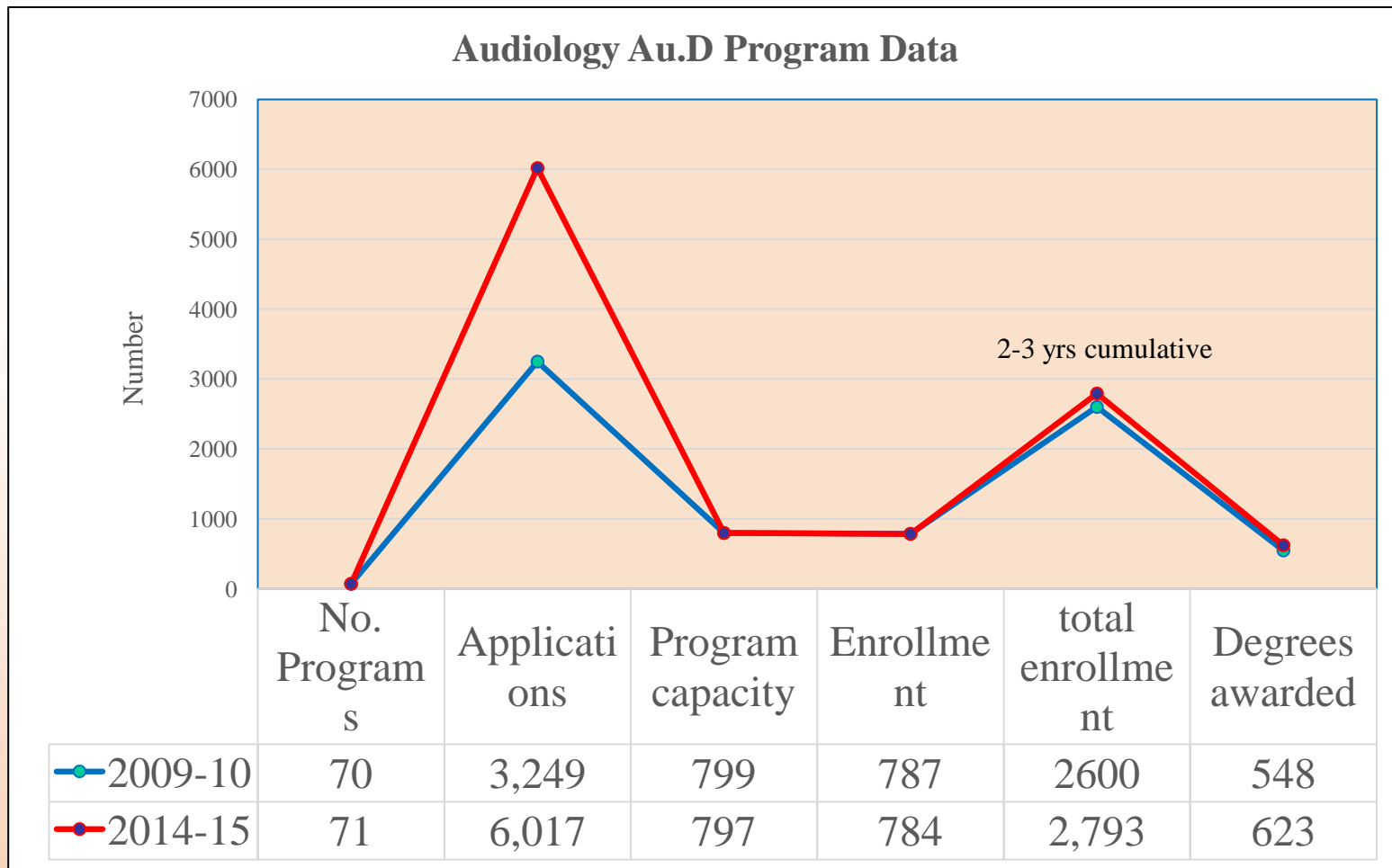


Fig 2. Percentage change in professional work forces from 2012-2015. (Source OES databases, Bureau of Labor Statistics).

Access – Limitation re Audiologists



Data Provides the Answer

- ❖ 71 = Au.D. programs
- ❖ 8.7 = Students/program
- ❖ 11 = Capacity/program
- ❖ 80% = Graduate
- ❖ 7 = Per/yr Graduates
- ❖ 20% = Attrition
- ❖ Maybe half go to HAs?

HIAs Response to NASEM Stakeholders Meeting

❖ Regulatory Review

- ✓ Critically important that OTC hearing aids be subject to the same regulatory oversight as traditional HAs including, in particular, OTC hearing aids with wireless features.
- ✓ Require 510(k)
- ✓ Must meet FDAs Quality System Regulation (QSR) for medical devices
 - *Consumer Electronics Industry had argued that general quality standards for consumer products will be sufficient to ensure the safety and effectiveness of OTCs*
- ✓ Must meet ANSI Standard 3.22
- ✓ Adopt additional requirements
 - Self-assessment – consumer must have proven, verified, and validated tool
 - Require evidence demonstrating consumers can use OTC safely and effectively by self
 - Should be barred from making HL treatment claims
 - Need professional guidance, even for self testing
 - FDA should modify its Draft Guidance to reflect all of this.



General Audiologists' Comments re OTC

- ❖ OTC/DTC hearing aids have their place.
- ❖ However, for the majority of adults with mild-to-moderate age-related hearing losses, a guided process including fitting verification and auditory rehabilitation is needed to achieve maximum benefit with amplification.
- ❖ Specify need for audiological care.
 - ✓ *But, did not mention the issues related to **affordability and accessibility**, and how these will be overcome.*
- ❖ OTCs may be a reasonable self-treatment option, used in conjunction with professional collaboration, for the vast majority of people with mild-to-moderate hearing loss who do not seek treatment from the traditional hearing healthcare delivery model.

Legislative Action

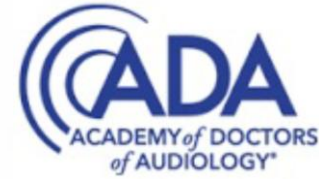
2016/2017



Over-the-Counter Hearing Aid Act of 2016

- ❖ Introduced late in 2016, but ran out of time for year end action
- ❖ Goals
 - ✓ Make certain types of HAs available OTC for mild-to-moderate HL
 - ✓ Remove unnecessary and burdensome requirements for consumers who could benefit from such aids.
 - ✓ Required the FDA to issue regulations containing safety and labelling requirements for OTC
 - ✓ Update/revise its Draft Guidance as related to PSAPs

ADA Supported OTC Legislation With Caveats



ADA supports, but recommends:

- ❖ All OTC products be specifically labeled and include:
 - ✓ A strong recommendation that a patient seek a *comprehensive audiological evaluation* from an audiologist or physician prior to purchasing any device for the treatment of HL
- ❖ Labeling should state that the device is a “nonsurgical, air conduction HA intended to address *mild-to-moderate* hearing loss.”
- ❖ All amplification devices adhere to defined *maximum output thresholds*.
- ❖ *Risk statement* that OTC is no different than with current unregulated Internet market.

HIA (Hearing Industries Association)

- ❖ Agrees with the basic idea of increasing accessibility and affordability, but....
- ❖ Concerned that the proposed legislation intends to create a new category - OTC HAs
- ❖ Primary concerns pertain to requirements that would require consumers to self-diagnose both the cause and degree of HL prior to purchasing HAs without the guidance of a professional.



AAA Staking its Position to OCT Law

- ❖ AAA will remain proactive to ensure that federal policy makers understand the importance of audiological care.
- ❖ Efforts will shift towards directly engaging with the FDA and FTC to shape new OTC HA regulations.
- ❖ The AAA represents audiology's interests relative to priority issues, such as:
 - ✓ OTC HAs,
 - Timing and rulemaking
 - Provided FDA with list of suggestions re OTC HAs
 - Ensure that FDA considers HAs as medical devices and will regulate them as such
 - ✓ Reimbursement policy
 - ✓ Advocacy



AAA Labeling Suggestions re OTC

1. Advise the user that better outcomes are achieved when a comprehensive audiological examination is conducted prior to the acquisition of an OTC device.
2. Address utilization of OTC devices, including both HAs and/or PSAPs, by individuals under the age of 18. Under 18 use should only occur under the direction of a licensed audiologist.
3. Advise consumers to seek an evaluation by an audiologist if they are not receiving satisfactory results with an OTC device.
4. Specify that the output may exceed levels that could cause either additional HL or initial HL in those with normal hearing. Standards for the acoustical characteristics of these devices should be set to limit these risks.

5. Advise consumers to seek an evaluation by an audiologist when they notice any change in their hearing, including temporary changes, as sustained long-term exposure to moderate-to-high output levels may have a negative effect on hearing.
6. Specify that OTC devices are medical devices and not consumer electronics.

ASHA Staking its Role

- ❖ Will work directly with the FDA to help develop the regulations for OTC devices
- ❖ OTC HAs should only be available for perceived mild hearing loss, that output limits must be set, and warnings against use for children
- ❖ The best approach to addressing HL is to seek the professional services of an audiologist



HLAA (Hearing Loss Association of America)



- ❖ Their number one issue for years:
 - ✓ People who want HAs but can't afford them
- ❖ This legislation is a step in the right direction:
 - ✓ Offers hope that the cost of all HAs will go down with the anticipated market innovation and competition it will bring.

OTC Hearing Aid Act of 2017

❖ **2016 Bill Reintroduced** and bundled with the FDA Reauthorization Act of 2017

✓ US Senate (March 21, 2017) - Passed July 12th

✓ US House (March 24, 2017) - Passed July 12th

❖ **Signed into law by the President, August, 2017**



OTC Hearing Aid Act of 2017

- ❖ Allows HAs “intended for use by adults to compensate for mild-to-moderate hearing impairment” to be sold to consumers OTC
- ❖ Eliminated the requirement for medical clearance to purchase a hearing aid
- ❖ Tasked the FDA with issuing appropriate regulations for the safety and labeling requirements for the new OTC category of HAs
- ❖ Requires updating the draft **Guidance** as it relates to PSAPs
 - ✓ Has not yet been done – 3 year timetable

Current Status of OTC Draft Guidance

- ❖ 3 Years to write Draft Guidance for OTC HAs
- ❖ Must be published in the Federal Register
- ❖ Public has opportunity to respond prior to issuance of final rule
- ❖ What would be in the rules – *speculation*
 - ✓ Labeling requirements
 - ✓ User warnings
 - ✓ Limits for gain and output



Thank you

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