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# An Introduction to Navigating the Risks and Rewards of Non-Custom Amplification Devices

Brian Taylor

## Disclosure

- Director, Clinical Audiology, Fuel Medical Group
- Editor, Audiology Practices and Hearing News (HHTM)
- Advisor, Resonance Medical

## Learning Objectives for Today

- 1.) Become knowledgeable about the 2016 NASEM recommendations with respect to improving affordability and accessibility of hearing care for adults
- 2.) Grasp the shortcomings of the current audiology practice delivery model
- 3.) Define non-custom amplification, who is a candidate for it and how it could be used to improve access, affordability and outcomes.
- 4.) Review risks and rewards to patients and professionals

## 5-Part Series

- Jan Blustein: Hearing loss: Public health and consumer perspectives
- Vinay Manchaiah: Literature review
- Nick Reed: Baltimore HEARS project
- Lori Zitelli: Non-custom amplifiers in the clinic

## Overarching Goal of Series

- Have a plan for the future, involving:
  - Involvement of public health & primary care
  - OTC and “non-custom” products
  - Unbundled services
  - Tele-audiology (remote programming & adjustment)
  - Smartphone-based Apps
  - Automated testing
  - Patient centric care & counseling

## Mantra in Healthcare

- Reduce Costs
- Increase Access
- Improve Quality



## Emergence of Consumer-driven Healthcare

- Aging baby-boomers
- Cheaper, Faster, Better Technology
- Requires us to refine our professional value:  
“Your clinic can no longer be defined by what it sells.  
It must be defined by what consumers want.”

## Agenda for Today

- The Core Problem (Why OTC and re-regulation is on the table?)
- Key Findings of NASEM (A roadmap for the profession?)
- Non-custom amplification
  - Types
  - Candidates
  - Risks & Opportunities

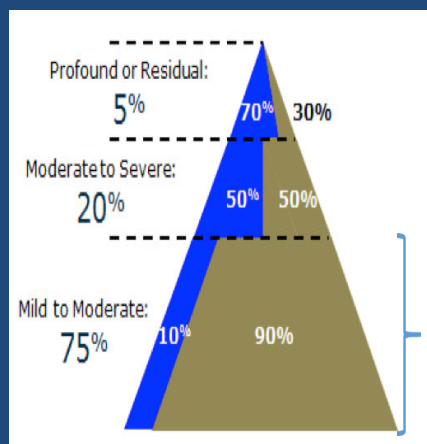
## The Core Problem: Access and Affordability

- High costs to individual
- Social stigma
- Challenging to use
- Cumbersome to buy
- Complex state regulations
- Lack of engagement by healthcare providers
- Lack of innovation and competition

## Key Stat

- 1 in 5 individuals with hearing loss own hearing aids

## The Unmet Need



Seeking a lifestyle enhancement through an anonymous transaction

## High Costs

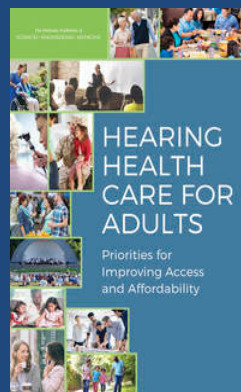
- 33% of Americans have an annual income of less than \$35,000.
- 50% of Americans aged 65 and older have an annual income below \$24,150.
- Average cost of pair of hearing aids: \$4,000

## 2009 NIDCD Working Group

- To develop a research agenda to increase the accessibility and affordability of hearing care for adults with mild to moderate hearing loss

## June 2016 NASEM Report

- Committee from multiple professions
- 6 Guiding Principles
- 12 Recommendations



## 6 Guiding Principles

1. Prioritize the needs of people with hearing loss
2. Emphasize hearing as a public health concern with societal responsibilities and effects
3. Move toward equity and transparency of service & product delivery

## 6 Guiding Principles, cont.

4. Recognize that hearing loss may require a range of solutions
5. Improve outcomes with focus on value, quality and safety
6. Work toward an integrated approach that provides options for consumers

## NASEM Recommendations

- Promote best practices
- Create metrics to evaluate outcomes
- Develop & strengthen research
- Improve access to care
- Promote awareness of consequences of hearing loss

What are the current products available for consumers today?

## Types of Hearing-Related Technologies

- Medical Devices for Hearing Loss
  - Hearing aids (regulated)
  - Over-the-counter wearable hearing devices (proposed)
- Consumer Electronics Not Intended for Hearing Loss
  - PSAPs (unregulated)
- Hearing Assistive Devices
  - FM, infrared, loop systems (unregulated)
- Communication Technologies
  - Captioning, emergency information, etc.

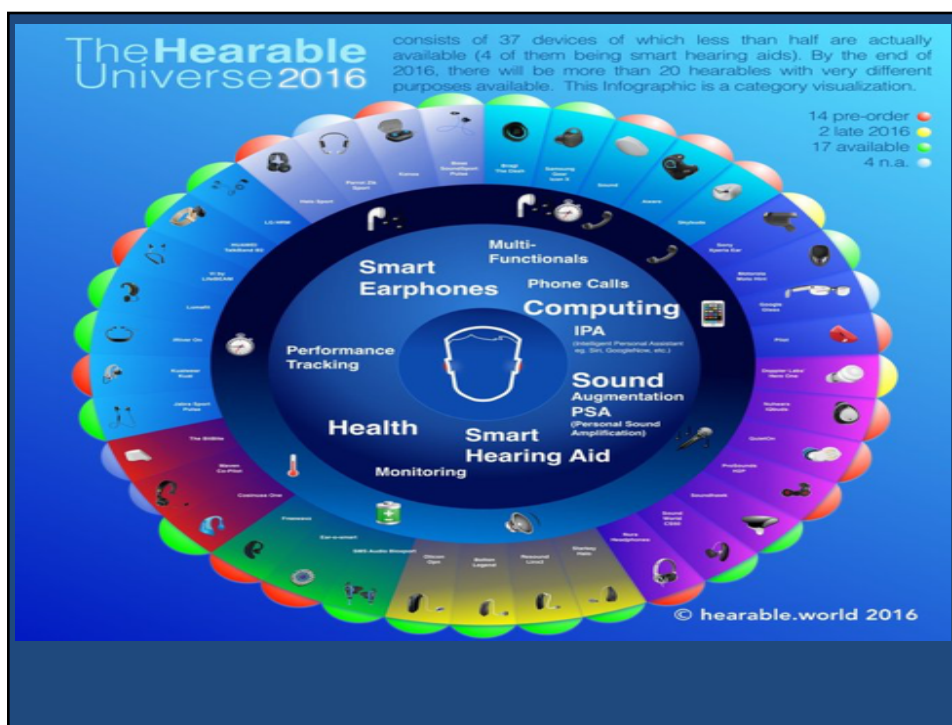
NASEM Report, 2016

## Federal Regulatory Agencies

- FDA: safety and efficacy of devices
- FTC: fairness and competitiveness of market, balance needs of business with those of the consumer

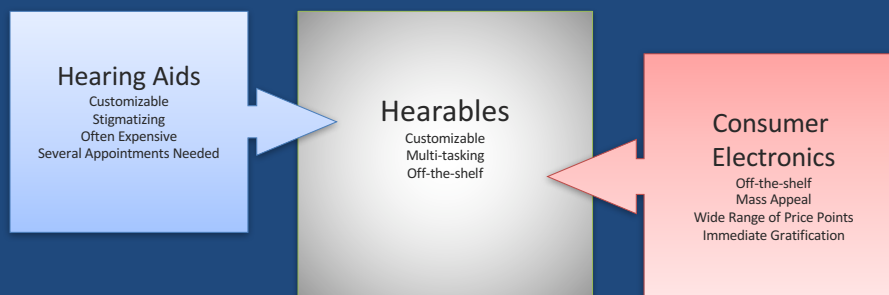
## To learn more about proposed re-regulation

- Professional organizations
- HHTM Hearing News
- Trade Journals
- FDA website ([www.fda.gov](http://www.fda.gov))

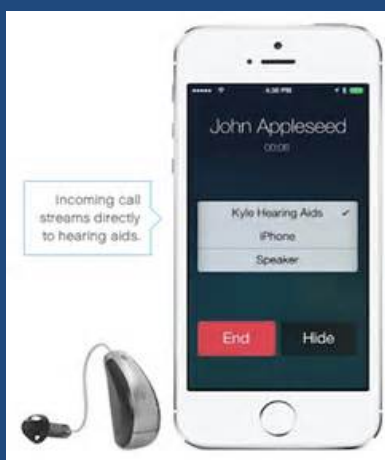




## “Hearables”: Morphing of Two Different Technologies



## Smartphone-enabled hearing aids



## Headset Amplifiers



## Personal Sound Amplification Products

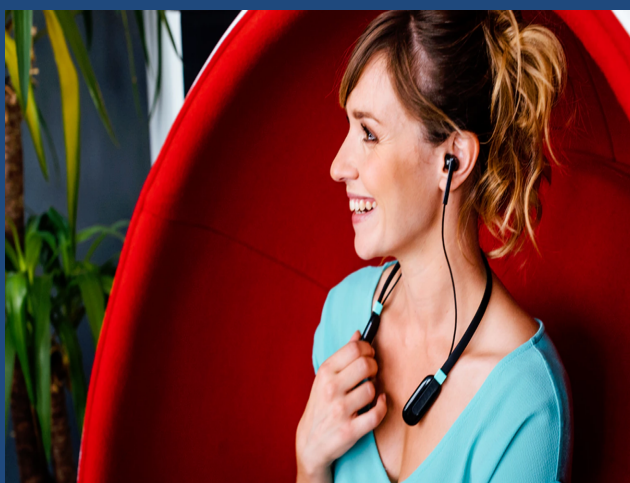
- De-featured hearing aids
- Some require app to adjust



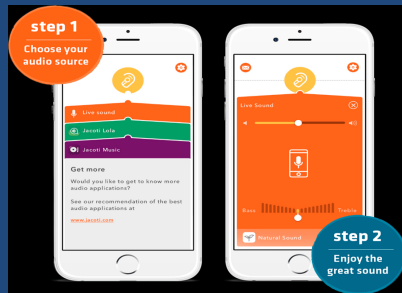
## Cordless Multi-Taskers



## Neck-band Multi-taskers



## Smartphone Apps



## Who might be a candidate for non-custom amplification?

- Situational use
- Short term or temporary use
- Nursing homes, assisted living
- Unsure about using hearing aids
- Cannot afford
- Cannot use traditional hearing aids

## How might consumers obtain these devices?

- Audiology-driven
  - Traditional clinic
  - Primary care location
  - Kiosk (store within a clinic)
  - Website
- Retail-driven
  - Traditional clinic
  - Primary care location
  - Kiosk (store within a clinic)
  - Website

## Key Questions

- What role does audiology play?
- When and how is the hand-off to audiology made?
- What unbundled services are offered?
- What are the risks of missing medically involved cases?

What are the risks to the profession  
and to patients?

## Risks to the Profession



Extinct Professions



Marginalized Professions

## Risks to Patients

- Missing cases of ear disease
- Improperly fitted hearing aids

## Improperly fitted hearing aids

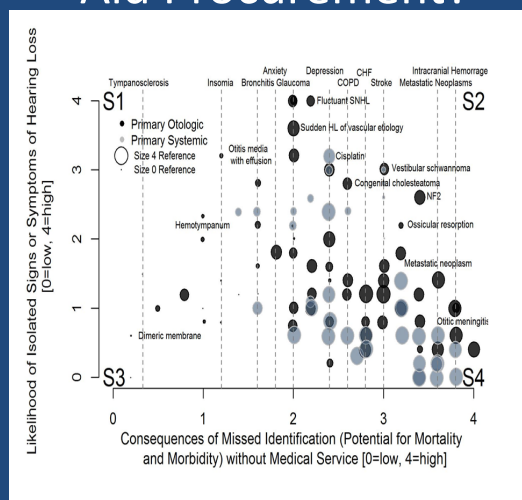
- Over-amplification: No cases in the literature for modern hearing aids
- Under-amplification: Several studies indicate this is a problem
- Non use (ITD)
- There are several studies that suggest some patients can self-adjust hearing aids (trainability studies)



## Missing cases of ear disease

- Does every person with hearing loss need to see a physician?
- What are the downsides of self-identification?

## Health and Disease: What Conditions Should be Identified Prior to Hearing Aid Procurement?



Audiology / PCP  
collaboration is important

Kleindienst et al, (2016). Identifying and Prioritizing Diseases Important for Detection in Adult Hearing H

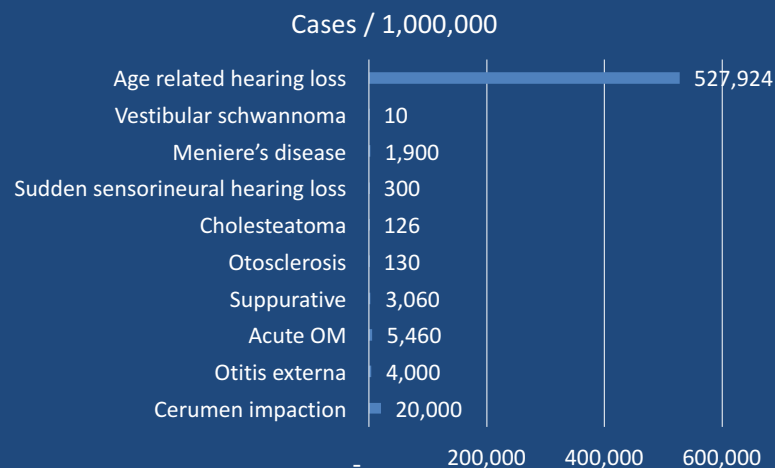
## What Does This Mean for Me?

- Prevalence of Communicatively Significant Hearing Loss in 2010:
  - 1 in 5 60-70 year olds (6,000,000)
  - 1 in 2 70 – 80 year olds (8,500,000)
  - 3 in 4 80+ year olds (8,900,000)
- Served by
  - 1300 ENTs
  - 1300 Audiologists
  - 600 Neurotologists / Otologists
  - 900 Hearing Instrument Dispensers

- Prevalence of Communicatively Significant Hearing Loss in 2010:
  - 1 in 5 60-70 year olds
  - 1 in 2 70 – 80 year olds
  - 3 in 4 80+ year olds

(NIH, 2010)

## Ear Disease Prevalence (age $\geq$ 50 yrs)



Zapala, 2015

## Risks

- Benign, age-related hearing loss is far more prevalent than ear disease
- With direct to consumer model, there remains a small risk that a more serious medical condition could be missed

**CEDRA: Consumer Ear Disease Risk Assessment**

Developed by:  
NORTHWESTERN UNIVERSITY AND THE MAYO CLINIC

Funded by NIH/NIDCD R21 DC013115

The questionnaire is to be used by health care providers. Please refer to definitions of various health care providers at the end of the questionnaire if you need clarification.

**Demographic Data**

Identification Number: \_\_\_\_\_ Today's Date: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Sex: ☐ M ☐ F

Native Language: ☐ English ☐ Spanish ☐ Other (please specify): \_\_\_\_\_

**Highest Level of Education Completed:**

☐ Did not finish high school

☐ High school diploma (or GED equivalent)

☐ Some college or Associates Degree

☐ Bachelor's degree

☐ Graduate degree

- Machine learning
- Likelihood ratios
- Probabilistic decision making

## Rewards / Opportunities

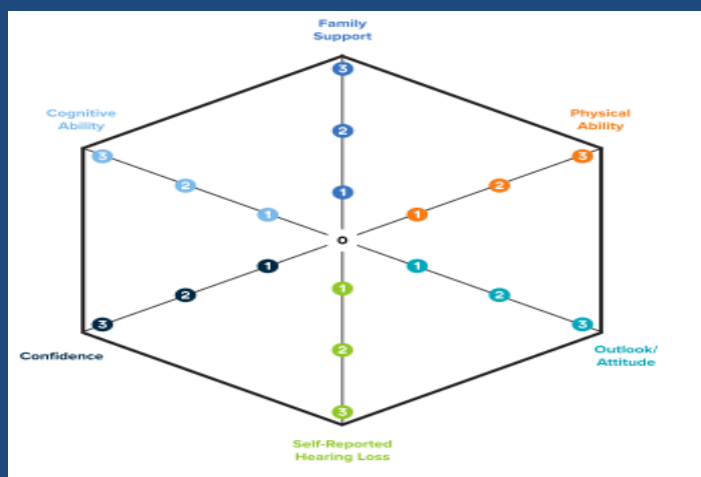


A rising tide lifts all boats

## Rewards / Opportunities

- Non-custom (OTC) devices allow individuals to take an active role in their hearing care
- Humes study indicates that 20% of direct to consumer users could use assistance of professional
- Probably higher than 20% (Humes study rejected a high number of OTC candidates)

Successful use of any device is multifaceted and often complex



## Alternative Service Delivery Models

- Community Health Care Workers
- Audiology Assistants
- Tele-health Services
- Retail Clinics
- Kiosk (store within a store)

## The Role of Audiology

- Capture unhappy OTC users, offer:
- Customization
  - Physical fit
  - Acoustic parameters
  - “Right device for right person at right time”
- Counseling
  - Talk about emotions & maladaptive behaviors
  - Set shared goals
  - Involve communication partner

## August 9: Hearing loss: Public health and consumer perspectives

Jan Blustein, M.D., Ph.D.  
Professor of Health Policy and Medicine  
New York University

### Topics

- In approaching hearing loss, audiologists typically take a clinical perspective, which focuses on the individual patients that they treat, but....
- Thinking about other perspectives can be illuminating
- Dr. Blustein describes (a) the public health perspective (which focuses on whole populations), and (b) the consumer perspective (which focuses on the informed purchaser of hearing health care)

## August 16: Applications of direct-to-consumer hearing devices for adults with hearing loss

Dr. Vinaya Manchaiah, Lamar University, Texas

## Topics

A literature review on applications of direct-to-consumer hearing devices for adults with hearing loss. The summary is presented on three themes, including: (1) electroacoustic characteristics; (2) consumer surveys; and (3) outcome studies.

- 1) Define and name different types of direct-to-consumer hearing devices
- 2) Discuss the benefits and limitations of direct-to-consumer hearing devices
- 3) Discuss the practice implications of direct-to-consumer hearing devices



## August 23: Efficacy and Effectiveness of Direct to Consumer Devices and Interventions

Nicholas Reed, AuD  
Jonathan Suen, AuD  
Johns Hopkins University  
School of Medicine

### Topics

- Introduce background information on direct to consumer hearing care
- Present study comparing direct to consumer devices and a hearing aid using speech-in-noise measures
- Explore pilot data comparing user fitting and audiologist fitting of direct to consumer devices on speech-in-noise measures
- Review the Baltimore HEARS community intervention program

## August 30: Clinical Implementation of Non- Custom Amplification

Lori Zitelli, AuD  
UPMC

### Topics

- Clarification of FDA language and definitions
- Description of how non-custom amplification is used in our clinics
  - Inpatient settings
  - Outpatient settings
- UPMC Interventional Audiology initiative
- Future areas of expansion?

Questions?