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Over the Counter Hearing Aids

Just the facts

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Director, Audiology, UPMC

Introductions/Disclosures

- Director, Audiology for a large integrated health system. 21 locations, 46 audiologists (pediatric and adult)
- Clinician
- AuD program Director
- Director, University of Pittsburgh Auditory Processing Research Lab (5 PhD students)
- Editor of Seminars in Hearing
Learning Objectives

- List the next steps that the OTC Hearing Aid Act must take before it is enacted
- List the decisions that the FDA must make related to OTC hearing aids
- Discuss possible pathways to market for OTC hearing aids

Just the facts... except when we don’t have any

- The focus is on facts related to OTCs
- I may slip in some opinions, but I will warn you
- When no facts are available, I might just guess, but I’ll warn you of that as well
How did we get here?

Accessible and Affordable Hearing Health Care for Adults with mild to moderate hearing loss.
How did we get here?

Guidance for Industry and FDA Staff
Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

How did we get here?

Not intended to address listening situations that are typically associated with and indicative of hearing loss
How did we get here?


FDA should approve a distinct class of hearing aids for OTC sale, without current requirements for consultation with a professional.

How did we get here?


Remove requirement that an adult needs medical clearance to obtain a hearing aid. New FDA category for OTC hearing aids, mild and moderate hearing loss.
### How did we get here?

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>NIDCD Working Group</td>
</tr>
<tr>
<td>2009</td>
<td>FDA PSAAPs</td>
</tr>
<tr>
<td>2013</td>
<td>FDA draft guidance</td>
</tr>
<tr>
<td>2015</td>
<td>PCAST</td>
</tr>
<tr>
<td>2016</td>
<td>FDA meeting</td>
</tr>
<tr>
<td>2016</td>
<td>NASEM (IOM)</td>
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<tr>
<td>2016</td>
<td>Over the Counter Hearing Aid Act</td>
</tr>
<tr>
<td>2016</td>
<td>Medical Clearance not enforced (FDA)</td>
</tr>
<tr>
<td>2017</td>
<td>OTC HA Act 115th Congress</td>
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Today, the FDA is also announcing its commitment to consider creating a category of over-the-counter (OTC) hearing aids that could deliver new, innovative and lower-cost products to millions of consumers.

### FDA re-Authorization Act

- Passed the House July 2017

Who voted no and why are they against the OTC HA Act?

The president most likely signed the bill because he has a passion for affordable and accessible hearing aids or he didn’t want the FDA to start laying people off?
FDA has 3 years to write the rules for a new regulatory class of OTC hearing aids

- They started at least a year ago.

Guess Alert

Over-The-Counter Hearing Aid Act of 2017

FDA is required to generate regulations that:

- Include reasonable assurance of safety and efficacy
- Establish or adopt appropriate output limits
- Include requirements for appropriate labeling of OTC hearing aids
- Describe requirements under which sale is permitted without involvement of a licensed person by in-person transactions, mail, or online
Who cares about labeling...

- Very low output limits and gain
- Labeling on the outside and inside of the box
  - See an audiologist first
  - This is intended for... , seek help if...

Will these be 501(k) exempt?

- Hearing aids are 501(k) exempt
  - You don’t have to notify the FDA before selling a substantially equivalent product
- Could start out non-exempt and then move to exempt
Bill included direction to finalize 2013 FDA draft guidance

- New guidelines for PSAP advertising
- Differentiating medical devices from electronic product
- PSAPs
  - Accentuate sounds in specific listening environments
  - Rather than everyday in multiple listening situations
  - Not intended to address listening situations that are typically associated with and indicative of hearing loss
    - Difficulty hearing a person nearby
    - Difficulty hearing in a crowded room
    - Difficulty understanding movie dialogue in a theater
    - Difficulty hearing on the phone
    - Difficulty hearing in noise
  - Cannot be considered an over-the-counter substitute for a hearing aid

Consumer Electronics People Have a Strong Opinion about this

Once they’ve finalized the draft guidance, will they start enforcing the rules?
What will the process look like?

- **Maybe:** FDA Workshop?
- **Definitely:** Publish the new rules in the Federal Register with a mandatory period for public comment.

What about state laws?

- The bill is clear that the final FDA rules will preempt State Laws (for OTCs only)
On April 18, 2017, the Federal Trade Commission hosted a workshop to examine competition, innovation, and consumer protection issues raised by hearing health and technology, especially hearing aids. FTC Announces Workshop on Hearing Health and Technology

Federal Trade Commission: The Wild Card

What do the professional organizations have to say?

What role will they play?
All: limited gain and output, appropriate labeling, over 18

- **AAA**
  - *Mild loss*
  - *Negative consequences of underfitting*
  - Explore CMS coverage of services

- **ASHA**
  - *Don’t undermine current insurance*

- **ADA**
  - *Finalize draft guidance*

- **AAO-HNS**
  - *Medical evaluation followed by a standardized hearing test*
  - *5 years of data collection*

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The language that has been used assumes:

- Individuals can not only identify that they have hearing loss but they will know if it is “mild to moderate”
- Individuals can select the right amount of amplification
- Accessibility and affordability if not the only issues are the largest barriers
- This is targeting seniors
Can individuals identify the degree of hearing loss they have?

Dashed Line: Percent of individuals receiving hearing aids; Solid Line: Percent of individuals did not receiving hearing aids (left-side ordinate label). Boxplots: Right ear pure-tone average of 1000, 2000, 3000, and 4000 Hz (right-side ordinate label).
Can individuals identify that they have impactful hearing loss?

~40%
Of people who have hearing loss recognize it

~50%
Of health providers recognize hearing loss

Mormer et al, CHAT – Communication, hearing, and audiometry tests, 2016
But in reality, we already expect adults to self-identify...

Identifying hearing loss is different from identifying ear disease

- Consumer Ear Disease Risk Assessment (CEDRA; Zapala et al)

I don't have any facts, you'll have to stay tuned…
How good are new hearing aid users at picking the hearing aid gain that is best for them?

*Humes et al data reconstructed by Gus Mueller*

<table>
<thead>
<tr>
<th>Hearing aid chosen</th>
<th>Audiogram best match</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Left ear</td>
<td></td>
</tr>
<tr>
<td>X</td>
<td>6</td>
</tr>
<tr>
<td>Y</td>
<td>0</td>
</tr>
<tr>
<td>Z</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>71% picked wrong aid</td>
</tr>
<tr>
<td>Right ear</td>
<td></td>
</tr>
<tr>
<td>X</td>
<td>6</td>
</tr>
<tr>
<td>Y</td>
<td>1</td>
</tr>
<tr>
<td>Z</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>73% picked wrong aid</td>
</tr>
</tbody>
</table>
In fact, 36% of Humes’ participants wanted to keep the placebo aids (no gain)

This is a fact I would like to say someday...

• You will receive the appropriate audibility for your hearing loss and receive more benefit if fit by an audiologist.
### SIIs from Sanders et al (2015)
(Manufacturer’s “First Fit”)

<table>
<thead>
<tr>
<th>HA</th>
<th>SIIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAL-NL2</td>
<td>67</td>
</tr>
<tr>
<td>HA 1</td>
<td>50</td>
</tr>
<tr>
<td>HA 2</td>
<td>54</td>
</tr>
<tr>
<td>HA 3</td>
<td>57</td>
</tr>
<tr>
<td>HA 4</td>
<td>46</td>
</tr>
<tr>
<td>HA 5</td>
<td>53</td>
</tr>
</tbody>
</table>

**Average = 52**

### SIIs from Humes et al (2017)

<table>
<thead>
<tr>
<th>SIIs from Humes et al (2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Best Practice (NAL-NL2)</td>
</tr>
<tr>
<td>Consumer Decides</td>
</tr>
</tbody>
</table>

I’m left with this fact:
You will have more benefit when your ear acoustics are accounted for and the aid is set to evidence-based, frequency-specific targets. This is what an audiologist **should do**. This can’t be done over the counter.
Hearing aids are free in the UK and the uptake is 40%

Accessibility and Affordability

What about accessibility?

- Accessibility is different for different people
- We created an accessible clinic and found very little uptake in hearing aids, more uptake in non-custom amplifiers

Warning, this is an opinion based on a little bit of data
• For individuals where accessibility and affordability are the primary issues, this may be a good path.
• Of course, no one has defined “affordability” for a consumer and no one knows how much an OTC will cost.

Are aging adults the target consumer group?
We don’t know how much impact treating hearing loss will have.

*Identifying hearing loss is important and under-treatment may be costly for the patient, the family, and the health care system*

<table>
<thead>
<tr>
<th>Short term associated risks</th>
<th>Long term associated risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Increased odds of falling</td>
<td>• More vulnerable to and tended to suffer more from the ill effects of depression</td>
</tr>
<tr>
<td>• Poor adherence to treatment recommendations</td>
<td>• Prevalence of depression increased as untreated hearing loss became worse</td>
</tr>
<tr>
<td>• Increased accidental injury and further medical difficulties</td>
<td>• Associated with an increased odds of social isolation in women aged 60 to 69</td>
</tr>
<tr>
<td>• Increased preventable adverse medical events</td>
<td>• Linked to higher rates of mortality in community dwelling older adults</td>
</tr>
<tr>
<td>• Dissatisfaction with overall quality, accessibility, and receipt of information related to their healthcare</td>
<td>• Increased rates of hospitalization</td>
</tr>
<tr>
<td>• Independently associated with lower ratings patient-physician communication and overall healthcare</td>
<td>• Increased rates of general health care use</td>
</tr>
<tr>
<td></td>
<td>• Poorer overall health and burden of disease</td>
</tr>
</tbody>
</table>

Untreated hearing loss results in $3.3 billion in excess medical expenditures.
These are not meant to be arguments for or against the OTC HA Act, I just think we should acknowledge these facts in our discussions and move on...

Regardless of the labeling any adult will be able to purchase an OTC hearing aid

If someone can answer these questions, then they can see into the future!

What do the data say about the OTC Hearing Aid Technology

- Do OTCs have appropriate output limiting?
- Do OTCs have appropriate gain?
- Are OTC volume controls appropriate and provide a wide range of volume increase and decrease?
- Are OTCs comfortable?
- Are OTCs easy to use?
- Do OTCs have good sound quality?
We can talk about the delivery model if not the technology and there are some very recent data that looked at this...
Finally, Proof That Hearing Aids Help

THURSDAY, March 2, 2017 (HealthDay News) — Millions of older Americans are hard of hearing, but solid evidence about the value of hearing aids has been lacking—until now.

“solid evidence about the value of hearing aids has been lacking—until now”
What they asked...
Two Service-Delivery Models

- What is the efficacy of hearing aids in older adults using
  - Audiology best practices model
  - Alternative over-the-counter (OTC) model

What they did...
Study Overview

- Placebo-controlled double-blind randomized clinical trial with three parallel branches
  - AB: audiology best practices model
  - CD: consumer decides
  - P: Placebo model

- Outcome measures obtained before and after 6 week trial and after following 4-week AB-based trial for CD & P
What they did...
Participants
- Adults, 53 – 83 years old
- Mild-to-moderate, bilaterally symmetrical sensorineural hearing loss
- No prior hearing aid experience
- 154 participants completed the study

What they did...
Hearing Aids
- High-end digital mini-BTE open-fit
- Features include
  - Directional microphone
  - Dynamic feedback suppression
  - Noise reduction
  - Four push-button memory used as VC
What they did...
Three Groups
AB: Audiology best practice (n=53)
- Aids programmed to NAL-NL2 based on audiogram
- Push-button volume range 12 or 24 dB based on high frequency hearing loss
- Real-ear verification, LDL adjustment
- 45-60 min hearing aid orientation session

What they did...
Three Groups
P: Placebo (n=50)
- Identical to AB group except
  - Hearing aid set to 0 dB Insertion Gain
  - Push-button volume range of 3 dB
  - No LDL adjustment
  - Some aids directional and some omnidirectional
What they did...
Three Groups
CD: Consumer Decides (n=51)

- Three different hearing aids: X, Y, Z
- Programmed (NAL-NL2) to match the 3 most common patterns of loss in older adults
- Push-button volume range 12 or 24 dB based on high frequency hearing loss
- Same basic features as AB aids

What they did...
X, Y, Z Audiograms
What they did...
Unaided Baseline Measures and outcome measures

- **HHIE**: Hearing Handicap Inventory - Elderly
- **CST**: Connected Speech Test
- **PHAPglobal**: Profile of Hearing Aid Performance (5 communication subscales)
- **PHAPavds**: Profile of Hearing Aid Performance (2 distorted/aversiveness subscales)

What they concluded...
AB vs. CD

- Hearing aids are efficacious for older adults (with mild-to-moderate loss) for both AB and CD service-delivery model
- CD model service delivery yielded only slightly poorer outcomes than the AB model
Things to keep in mind (in my opinion)

• Consumer Decides did not mimic any typical version of OTC (42% of participants recruited were rejected)
• AB did not mimic best practices since best practices are all about customizing both acoustically (not just at a 65 dB SPL and max output) and physically
• Group of people who could all afford $3600.00

Most interesting data in my opinion...

• 90% of CD group tried 2-4 HAs
• 20% of the CD group needed help and/or a visit for troubleshooting
• CD and Placebo group moved to customized fit and majority kept aids
• Great data to support need for ongoing maintenance appointments
Perhaps most importantly in my opinion...

- 55% CD (N=28), after best practices 14 more wanted to keep the aids
  - Clinics need a way to move CD patients into clinic or start them in clinic and move them into more advanced services (not more advance technology)

What do you bring to the table?
A Comparison of Consumer Satisfaction, Subjective Benefit, and Quality of Life Changes Associated with Traditional and Direct-mail Aid Use

Kochkin, S

*Hearing Review, 21(1)*

Make sure you are different from over the counter

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What he found...
Overall success vs. Best Practice

![Graph showing overall consumer success compared to best practices and direct-mail aid use.](image)
What he found...
Relationship between consumer loyalty and verification / validation

<table>
<thead>
<tr>
<th>Was verification &amp; validation used to fit hearing aid?</th>
<th>% loyalty (Would recommend HFP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neither verification nor validation</td>
<td>57.4</td>
</tr>
<tr>
<td>Verification only</td>
<td>66.9</td>
</tr>
<tr>
<td>Validation only</td>
<td>75.9</td>
</tr>
<tr>
<td>Verification + Validation</td>
<td>84.3</td>
</tr>
</tbody>
</table>

N = (2020)

How do you fit hearing aids?

- With an evidence based prescriptive formula... that generates targets for the output of the hearing aid to ensure audibility across frequency at multiple input levels.
- Targets tell us what the output should be for specific frequencies at specific inputs to insure audibility
How do you know you accomplished your goal?

- Real ear aided response that shows the output across frequency for multiple input levels matching the targets.

How do we get to the targets?

- Targets across frequency for different input levels (NAL NL2 or DSL 5.0)
- Target has to be generated by SPL thresholds
- SPL thresholds have to be derived accurately from HL thresholds
- We do this by measuring the real ear to coupler difference (RECD).
- This is applied to the HL threshold to convert to SPL. This is the SPL that would have been measured at the eardrum during hearing testing.
- (note: hearing testing was done with insert earphones, RECD is done with insert earphones)
So...
- You measure the output of the hearing aid (REAR) in the individual’s ear and adjust the amplification until the output reaches the targets.

Remember, you can measure any device with a microphone and an acoustic output in the test box or on the ear.
Does it really matter in terms of patient performance?
The FACT is, it does.

The importance of audibility in successful amplification of hearing loss

Ron Leavitt and Carol Flexer *Hearing Review*, December
Performance for the aided QuickSIN presented soundfield at 57 dB SPL. Bars indicate "SNR-Loss": The average SNR disadvantage compared to individuals with normal hearing.

Improving Patient Perception of Clinical Services Through Real-ear Measurements.

Amlani AM, Pumford J, Gessling E.

Hearing Review. 23(12):12. (2016)
“The service I obtained was outstanding”

“The service I obtained improved my perception of the product”
Over whose counter?

Non-custom
Itemize, unbundle, charge for what you bring to the table

- V5275 ear impression
- V5264 earmold
- V5010 assessment for hearing aid
- V5011 fitting/orientation/checking of hearing aid
- V5020 conformity evaluation
- 92592 Hearing aid check, monaural
- 92593 Hearing aid check, binaural
- V5014 repair/ modification of HA
- V5090 Dispensing fee, binaural
- V5241 Dispensing fee, monaural
- V5299 hearing aid service, misc
- 92590 Haring aid exam and selection, monaural
- 92591 Hearing aid exam and selection, binaural

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Warning: Opinion

Evaluation and Management Codes (E&M Codes)

- You are paid for your knowledge
- Taking the evaluation data and assisting the patient on finding a course of action could be the most valuable thing we do for a particular patient
- Could save the patient time and money in the long run
- This should be a focus of AAA
Where are the facts leading us?

- How are we different from other pathways
- Customization
  - Needs assessment- matching technology to needs
  - Physical coupling of the device to the ear
  - Acoustic Fit (measured in the individual ear canal)
  - Outcome Assessment focused on the original goal
- Unbundle/itemize so anyone can access your services

A final opinion

People with hearing loss are a diverse group, in fact they are not a group

It is not surprising that they would need more than one pathway to hearing assistance and people need to allowed to change paths seamlessly.

I sincerely hope that elected leaders do not think they have solved the barriers to hearing health care