OTC – Over The Counter or Over the Cliff?

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Goals for today

• Overview of how we got to this point in the OTC journey

• Review recommendations of PCAST and NASEM

• What might be new OTC landscape look like

• What might be the path forward in the delivery of hearing healthcare
“We have an unsustainable health care delivery system, a growing generation of elderly people and we need to find new ways to deliver care differently than we have today!”

—Alexandra Pelletier, Center for Connected Health
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
Target Market:

<table>
<thead>
<tr>
<th>Hearing Loss Level</th>
<th>Market Potential</th>
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<tbody>
<tr>
<td>Profound</td>
<td>90% aided, 10% unaided, 5%</td>
</tr>
<tr>
<td>Severe</td>
<td>70% aided, 30% unaided, 10%</td>
</tr>
<tr>
<td>Moderately Severe</td>
<td>50% aided, 50% unaided, 15%</td>
</tr>
<tr>
<td>Moderate</td>
<td>30% aided, 70% unaided, 30%</td>
</tr>
<tr>
<td>Mild</td>
<td>10% aided, 90% unaided, 40%</td>
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</tbody>
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Sources: Goldman Sachs, MarkeTrack US, Carnegie, Sivantos Research / BCG
The long and winding road...

- Pre 1978 – 3-step model
- 1978 – ASHA modifies Code of Ethics, audiology adopts retail/bundled pricing model
- Today...
  - Continued struggle with retail model
  - Explosion of distribution channels: Internet, Big Box stores, Do It Yourself channels (Embrace, MDHearing, IHear, etc.), PSAPs

...all of which contribute to increased access and lower price, often at expense of professional services
Access – Confusing to consumer, ill-defined professional roles, competing financial interests and multiple points of entry

Affordability – Definition “undetermined,” 76% of non-adopters mention cost, price range is unknown

Assumption – Need to improve both
National Academies of Science, Engineering and Medicine (NASEM/IoM)

Mission – Help those in government and the private sector make informed decisions by providing evidence...

• Hearing Loss and Healthy Aging Workshop Jan. 2014
  Report on the effects of age-related hearing loss on healthy aging

• Consensus Study
  5 Meetings in 2015 – April, June, September (2)
  Report and Recommendations June 2016
  3 more meetings held in 2016 & 2017
President’s Council of Advisors on Science and Technology (PCAST)

Charge –
Leading scientists who advise POTUS...

“Aging America & Hearing Loss: Imperative of Improved Hearing Technologies”
  • Individual Interviews
  • 2 Meetings in 2015 – September, October
  • PCAST Letter Report issued to POTUS October 2015
• Age-related hearing loss is a substantial national problem.
• The market for hearing aids is characterized by high cost and low innovation.
• Current distribution channels create barriers to access.
• Modest changes...could dramatically increase accessibility and innovation for tens of millions...without compromising patient safety.
1) FDA should designate a distinct category (“basic” hearing aids) to
   • Approve for OTC sale, without the requirement for a credentialed dispenser
   • Approve for OTC sale tests appropriate to self-fitting and adjustment by end user
   • Exempt from QSRs and substitute voluntary standards from consumer electronics industry

2) FDA should withdraw its draft 2013 PSAP Guidance Document
PCAST recommendations to “increase opportunities for consumer choice”

3) FTC should require hearing care professionals to provide customer with copies of their audiogram and programmable audio profile at no additional cost and in a manner usable by others (Eyeglass Rule)

4) FTC should define a process by which patients may authorize hearing aid vendors to obtain their results at no additional cost (Contact Lens Rule)
Hearing Aids vs PSAP according to the FDA (Guidance Document - 2013)

- **Hearing aid** – “A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing.”
  - A hearing health professional (such as an audiologist or a hearing aid dispenser) is usually required to program and optimize the performance of hearing aids with these more complex features.

- **PSAP** – “A 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 certain environments, such as for hunting or other recreational activities.
  - Examples of situations in which PSAPs typically are used include hunting (listening for prey), bird watching, listening to lectures with a distant speaker, and listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations)
“Streamlining Good Manufacturing Practices for Hearing Aids”
April 21, 2016

12 invited panelists
30 public speakers, majority in support of professional involvement
Reopened comment period on 2013 Personal Sound Amplification Product (PSAP) Guidance Document
“Hearing Health Care for Adults: Priorities for Improving Access and Affordability”

June 2, 2016
Study Sponsors

• Centers for Disease Control and Prevention
• Department of Defense
• Department of Veterans Affairs
• Food and Drug Administration
• Hearing Loss Association of America
• National Institute on Aging
• National Institute on Deafness and Other Communication Disorders
Findings

• Hearing can be vital to communications, health, function, and quality of life. Individuals need to be alert to their hearing health, as hearing loss can range from mild to profound and tends to increase with age, onset can be gradual, and each individual’s hearing needs are unique.

• Hearing health care involves a wide range of services and technologies with ever-expanding and evolving options, however, many people do not have access to these options or cannot afford them.
Findings

• Hearing loss is a public health and societal concern; engagement and action are needed across the spectrum of relevant stakeholders, including individuals and families, professionals, nonprofit organizations, industries, government, and the health care community.
Recommended actions

- Improve population-based information on hearing loss and hearing health care
- Develop and promote measures to assess and improve quality of hearing health care services
- Remove FDA's regulation for medical evaluation or waiver of that evaluation prior to hearing aid purchase
- Empower consumers and patients in their use of hearing health care
- Improve access to hearing health care for underserved and vulnerable populations
- Promote hearing health care in wellness and medical visits for those with concerns about their hearing
- Implement a new FDA device category for over-the-counter wearable hearing devices
- Improve the compatibility and interoperability of hearing technologies with communications systems and the transparency of hearing aid programming
- Improve affordability of hearing health care by actions across federal, state, and private sectors
- Evaluate and implement innovative models of hearing health care to improve access, quality, and affordability
- Improve publicly available information on hearing health
- Promote individual, employer, private sector, and community-based actions to support and manage hearing health and effective communication

* All findings and recommendations are of equal importance and are not prioritized.*
Goal 3: Remove FDA Regulation for Medical Evaluation or Waiver to Purchase a Hearing Aid

Recommendation 3: The Food and Drug Administration should remove the regulation that an adult seeking hearing aids be required to first have a medical evaluation or sign a waiver of that evaluation and should ensure consumers receive information about the medical conditions that could cause hearing loss through continued inclusion of that information in hearing aid user instructional brochures.
Goal 4: Empower Consumers and Patients in Their Use of Hearing Health Care

Recommendation 4: Hearing health care professionals, professional associations, advocacy organizations, and relevant governmental agencies such as the Office for Civil Rights at the Department of Health and Human Services should ensure patients are aware of, and understand how to exercise, their rights of access to information about themselves under the Health Insurance Portability and Accountability Act Privacy Rule (45 C.F.R. Section 164.524), including their audiograms and hearing aid programming history.
Goal 7: Implement a New FDA Device Category for Over-the-Counter Wearable Hearing Devices

Recommendation 7: The Food and Drug Administration should establish a new category of over-the-counter (OTC) wearable hearing devices. This device classification would be separate from “hearing aids.” OTC wearable hearing devices would be defined as wearable, OTC devices that can assist adults with mild to moderate hearing loss. 

*Specific actions detailed in bullet points that follow the recommendation.*
Goal 8: Improve the Compatibility and Interoperability of Hearing Technologies with Communications Systems and the Transparency of Hearing Aid Programming

- Develop standards that ensure that hearing aids and over-the-counter (OTC) wearable hearing devices are compatible and interoperable with other technologies and communications systems;
- Increase public awareness and consumer-friendly information on the availability, connectivity, and use of hearing aids and hearing assistive technologies; and
- Develop and implement standards for an open platform approach for hearing aid programming that allows any hearing health care professional (or, as evolving technology allows, the device owner) to program the device settings, and require point-of-sale information about the programming features and programming portability of hearing aids in order to enable more informed purchasing decisions.
Goal 9: Improve Affordability of Hearing Health Care

• Hearing health care professionals should improve transparency in their fee structure by clearly itemizing the prices of technologies and related professional services to enable consumers to make more informed decisions;

• CMS should evaluate options, including possible statutory or regulatory changes, in order to provide coverage so that treating hearing loss (e.g., assessment, services, and technologies, including hearing aids) is affordable for Medicare beneficiaries;

• CMS should examine pathways for enhancing access to assessment for and delivery of auditory rehabilitation services for Medicare beneficiaries, including reimbursement to audiologists for these services; (cont’d.)
Regulatory Issues

- Changes were proposed with a goal of making hearing aids more accessible and affordable
- PCAST and NASEM reports cited conditions for sale as a barrier to availability and accessibility of hearing aids
  - FDA need authority from Congress to implement these recommendations due to state laws related to hearing aids
  - FDA could have allowed hearing aids to be sold OTC, but preempting state laws would have been difficult
“Over-the-Counter Hearing Aid Act of 2016”

December 1, 2016

Senator Elizabeth Warren (D-MA)
Senator Charles Grassley (R-IA)
Representative Patrick Kennedy (D-MA)
Representative Marsha Blackburn (R-TN)
• FDA should create new device category
• For adults only with mild-moderate hearing loss
• No professional involvement
• FDA should update PSAP Guidance Document
Federal Trade Commission (FTC) Workshop

“Now Hear This: Competition, Innovation and Consumer Protection Issues in Hearing Health Care”

April 18, 2017

- Innovation in Hearing Health Delivery
- Innovation in Hearing Technology and Treatment
- The Benefits and Costs of Regulation
- Consumer Information and Search Costs
- FTC will not take a role in regulating OTC hearing aids, but may issue a report or policy statement, that may influence FDA regulations (eyeglass and contact lens rules)
Traveling at the Speed of Sound

December 1, 2016 – Introduction of Warren/Grassley Over the Counter Hearing Aid Act of 2016
December 7, 2016 – NASEM Workshop, FDA announcement of non-enforcement of physician evaluation/waiver prior to purchase
January 4, 2017 – Announcement of FTC Workshop
March 21, 2017 – Reintroductions of Over the Counter Hearing Aid Act of 2017 (S. 670 and H.R. 1652)
April 18, 2017 – FTC Workshop
June 9, 2017 – NASEM Workshop
July 12, 2017 – H.R. 1652 passed as part of FDA Reauthorization Act of 2017
August 3, 2017 – S 670 passed as part of FDA Reauthorization Act in form IDENTICAL to HR 1652
What does the legislation provide for?

- Section 709 permits sales of both air conduction and wireless air conduction hearing aid to ADULTS OVER 18

- PSAP’s remain excluded from the regulation

- Defines OTC hearing aids as specifically intended to address “mild to moderate” hearing loss
What does the legislation provide for?

• The bill expressly preempts all state and local governments regulations specifically to hearing aids
  • Requirements such as mandatory return periods and consultations with Health Care Providers, will not be in effect for OTC hearing aids
  • Anyone will be able to sell OTC hearing aids
  • No provision to enforce “red flag” conditions
• The bill only preempts state laws specific to hearing aids
  • No effect on more general state laws such as those prohibiting false claims
Next Steps?

- Section 709 directs the FDA to issue proposed regulations to establish an OTC category within 3 years
  - Requires a Notice and Comment period
  - Usually a 60 day comment period
  - 180 days after comment period closed, the FDA must publish final rules
  - Last day for creation of the OTC category: May 14, 2021
So What Does the Future Look Like?

The OTC Act

• Requires FDA to include in the regulations:
  o Provide “reasonable assurance of safety and efficacy”
  o Establish output limits and labeling requirements
    o A conspicuous statement that the device is only intended for adults age 18 and older
    o How consumers can report adverse effects
  o Describe requirements for sale “without a prescription”
  o Any contraindications, conditions, or symptoms of medically treatable causes of hearing loss
• Directs FDA to finalize its PSAP Guidance Document to clarify which products are medical devices
So What Does the Future Look Like?

...The regulations could require:

• Identical regulatory requirements for all hearing aids:
  o Initial 510(k) clearance
  o Compliance with QSRs – design controls, documentation, supplier controls, complaint handling, compliance with ANSI 3.22 with limits on maximum amplification and distortion
  o Adoption of a self-assessment tool
  o Evidence that consumers can use safely and effectively (“clinical studies with naïve consumers”)
  o Recommendation for binaural use
  o PSAPs should be barred from making hearing loss treatment claims
So What Does the Future Look Like?

Key consumer information on the outside of the box – Proposals

• “If you have difficulty hearing or understanding normal conversational speech you should consult with a hearing professional before purchasing this device.”
• “OTC hearing aids are intended for use only by those adults with mild to moderate hearing loss.”
• If you have any of “Red Flag” conditions, do not buy this product and see a physician promptly.”
• Box and User Instructional Brochure language should be tested to confirm comprehension
July 24, 2018

Dear Hearing Aid Manufacturer:

Section 709 is not self-implementing, meaning that the OTC hearing aid category, as defined by FDARA section 709, does not exist until the effective date of a published final regulation. Until that time, no products that are claimed to address hearing loss are, or can claim to be, OTC hearing aids within the meaning of FDARA section 709. Currently, hearing aids continue to be restricted devices, for which sales must follow applicable federal and state requirements. FDA has published a guidance document stating that the agency will not enforce the requirement for a medical evaluation or waiver under 21 CFR 801.421, but manufacturers should be mindful of any similar state law requirements.
Big Questions to OTC

• Will these new devices expand the retail practice, bringing in new patient-consumers

• Will some purchase the value option, OTC.

• Will others upgrade to traditional hearing aids?

• Or, is it possible OTC hearing aids will cannibalize traditional hearing aids, leaving the professionals struggling to serve patients profitably?
Three Pathways to purchase of OTC product by consumer

**Purchase from office with assistance**
- Self/Family Identifies HL
- Searches internet (products)
- Searches for local office
- Makes appointment
- Testing and counseling
- Professional recommendation
- Purchase of PSAP or “OTC” with assistance

**Purchase from office**
- Self/Family Identifies HL
- Searches internet (products)
- Finds acceptable product
- Searches for local office
- Purchase from local office without assistance

**Direct consumer purchase**
- Self/Family Identifies HL
- Searches internet (products)
- Finds acceptable product
- Purchase
How can you compete?

- Evidence based practice
- Needs assessment

- Hearing aid selection
- Verification

- Post fitting care
- Validation
Ten Best Practices

1. Develop a comprehensive treatment plan.
2. Use a patient-focused "income" measure.
3. Use meaningful clinical tests.
4. Establish patient-specific treatment goals.
5. Select hearing aid features on the basis of the treatment goals, not the audiogram.
6. Verify the hearing aid performance parameters with test box and probe microphone measures.
7. Validate your treatment plan.
8. Evaluate for and prescribe hearing assistive technology, as appropriate.
9. Itemize your fees.
10. Provide post fitting audiologic rehabilitation services.

Harvey Abrams, Ph.D.
Type of practice

• **Specialty Product Portfolio.** The professional focuses on consumer/patients who are not eligible for OTC hearing aids—those with severe hearing loss and under the age of 18—as well as consumer/patients who demand more service and functionality and have the ability to pay for it. The practice sells high-end hearing aids only, essentially continuing with business as usual.

• **Broad portfolio** The audiologist remains committed to serving patients of all ages, with hearing loss varying from mild to severe. The practice offers a full range of products, from value-priced OTC hearing aids to higher-end hearing aids and implantable devices, such as cochlear implants, recommending the best devices based on patients’ needs.
Retail Portfolio

PSAP
Self-Fitting

OTC

Entry Level

Mid Level

High Level

Specialty Product Portfolio

Broad portfolio
Unbundling Pricing Models

- These will be drive 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
TeleHealth
Potential tele-health applications

- Remote screening/assessment of hearing
- Remote fitting/adjustment/troubleshooting of hearing aids and cochlear implants
- Post-fitting home-care follow-up
- Facilitated home based aural rehabilitation
- Tinnitus Counseling
Disruptive Technology
New Entries

Eargo

Nuhera

iHear
Self Fitting Hearing Aid

- Professional input
- Computer support
- Telephone access
- Ear impressions

- Onboard, in situ measurement of hearing thresholds
- Prescription formula
- Automatic application of prescriptive fitting algorithm
- Real ear to coupler difference
- Adjust hearing aid

User responsible for:
- ✓ assembly
- ✓ fitting
- ✓ fine-tuning
- ✓ management
World’s first modular self-fit hearing aid
Healthcare Developments

**Walmart and Humana**, a large insurer with a sizable business offering private Medicare plans (early discussions)

Health insurer **Cigna** announced in March that it was proposing to acquire **Express Scripts**. Under review by DOJ

**JPMorgan Chase, Amazon, Berkshire Hathaway**
Joint venture announced to reduce health costs for their 1 million employees
Think of an idea where we have 10,000 new front doors to the healthcare system, where people can walk in, they can ask for some help, get guided through the system.

We can make the insurance the back room of the operation, we can waive prior authorizations, we can waive copays as people use the system in a way that’s more effective so we can reduce costs. It’s simpler, it’s customized for the individual based on what they need and it’s cheaper.

CVS Health agrees to acquire Aetna in $69B deal

CEOs of CVS Health, Aetna say merger will offer new front door to healthcare
So……..
So What Does the Future Look Like ...
Who will be our new patients?

You will likely meet a new consumer in your practice who has:

- More information and opinions about hearing loss
- More information and requirements for hearing aids
- Belief that hearing aids are Do It Yourself and you add time, hassle and expense
- Already tried OTC hearing aids or PSAPs (and doesn’t know which)
- Expectation that you can fix, reprogram or modify devices with which you are not familiar
- Belief that hearing aids will not help
Can we Survive?

You have the answers and opportunities:

- Explore desired services with your current patients
- Expand your practice offerings
- Educate your medical community
- Evaluate your pricing model
- Expand your telehealth knowledge and expertise
- Embrace the new reality...

...AND THRIVE!
Thank you

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