Legislative and Regulatory Issues: PCAST, NASEM, FDA, FTC, and More

Kate Thomas
Senior Director, Advocacy and Reimbursement
American Academy of Audiology

Presentation Overview

- PCAST
- NASEM
- FDA
- FTC
- OTC Hearing Aid Legislation

Where to start?

PCAST

- President's Council of Advisors on Science and Technology: Broad mandate for advising the President on science and technology
  - Looks at age-related mild-to-moderate hearing loss
- Oct. 2015: letter sent to President Obama with recommendations
- Focus: Devices
  - Open up market for innovative hearing technologies
  - Increase opportunities for consumer choice
Four Recommendations:

- FDA should create a class of OTC hearing aids for persons with mild-to-moderate hearing loss
- FDA should withdraw its 2013 draft guidance of personal sound amplification products (PSAPs)
- Consider “Eyeglass Rule” for hearing tests and hearing aid fitting.
- Consider “Contact Lens Rule”. Allow FTC to define a process that would grant authorization to hearing aid vendors (e.g., online) to obtain a copy of the hearing test results at no additional cost to the consumer.

Rationale:

- Cite untreated hearing loss in adults as a substantial problem
- Only a small number of those that need hearing aids have them
- Multiple factors: cost, stigma, complex delivery system
- Goals: improve access, remove barriers to access/competition, lower cost

What is NASEM?

- National Academy of Sciences, Engineering and Medicine (NASEM)-formerly Institute of Medicine (IOM)
- “private, nonprofit institutions that provide expert advice on some of the most pressing challenges facing the nation and the world”
- Helps shape sound policies, inform public opinion, and advance the pursuit of science, engineering, and medicine
Kate Thomas, MA  
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NASEM

- Founded by Congressional Charter in 1863 by President Lincoln with the goal being to "investigate, examine, experiment, and report upon any subject of science"
- These private, nonprofit organizations share in the responsibility for advising the federal government, upon request and without fee, on questions of science, technology, and health policy.
- Many iterations: National Research Council, NAE, IOM, NAS

NASEM Reviews Accessibility and Affordability of Hearing Care

Timeline:
- November 2014 (IOM): First examination of the topic
- April 2015: Background and discussion of the individual and societal effects of hearing loss
- June 2015: Broad-panel discussions focus on devices, scope of practice for providers, and impact of hearing loss
- September 2015: International perspective, accessibility and affordability for young adults
- June 2016: Report released
- December 2016: Dissemination meeting results in FDA announcement for OTC hearing aids/medical evaluation
- June 2017: Dissemination meeting seeks to raise public awareness and introduce labeling requirements

NASEM

- June 2016: NASEM releases Hearing Health Care for Adults: Priorities for Improving Access and Affordability report
- Features 12 recommendations for improving hearing health care

NASEM

Twelve Recommendations:
1. Develop population-based information on hearing loss and hearing health care.
2. Establish and promote measures to assess and improve the quality of hearing health care services.
3. Remove FDA’s regulation for medical evaluation or waiver of that assessment before hearing aid purchase.
4. Empower consumers and patients in their use of hearing health care.
5. Improve access to hearing health care for underserved and vulnerable populations.
6. Promote hearing health care in wellness and medical visits for those with concerns about their hearing.
Twelve Recommendations (cont’d):

7. Implement a new FDA device category for OTC wearable hearing devices.
8. Improve the compatibility and interoperability of hearing technologies with communications systems and the transparency of hearing aid programming.
9. Improve affordability of hearing health care by actions across federal, state, and private sectors.
10. Evaluate and implement innovative models of hearing health care to improve access, quality, and affordability.
11. Improve publicly available information on hearing health.
12. Promote individual, employer, private sector, and community-based actions to support and manage hearing health and effective communication.

Recommendation #5: Improving Access to Underserved Populations

- Collaborate and partner with health care providers to ensure hearing health care accessibility throughout rural and underserved areas using mechanisms such as telehealth, outreach clinics (including federally qualified community health centers), and community health workers.
- Support and promote programs, including incentives such as tuition assistance, to increase diversity in all sectors of the hearing health care workforce;
- Ties into legislative initiatives.

Recommendation #10: Evaluate and Implement Innovative Models of Hearing Health Care to Improve Access, Quality, and Affordability:

- Direct CMS, the VA, NIH and other agencies to review existing delivery models; to improve the evidence base for current and innovative payment and delivery models for treating hearing loss
  - Demonstration project to evaluate impact of direct access to audiology services (minus vestibular services)
  - Alternative Payment Models?

Major takeaways...

- Accessibility and affordability of devices (OTC hearing aids, PSAPs)
- Transparency- unbundling
- Public education and outreach
- Coordination and education within provider/health community
  - Physician outreach/hearing loss focus at wellness; community health workers
- Research, quality metrics
NASEM

• May 2017: NASEM releases The Promise of Assistive Technology to Enhance Activity and Work Participation report
• Draws 5 conclusions

What are the implications?
• FTC Interest
  – Eyeglass rule
  – Unbundling
• FDA Changes
  – OTC Device
  – Removal of Medical Evaluation or Waiver
• OTC Hearing Aid Legislation
• Value of audiologist/access to audiology services

NASEM

Five Conclusions:
1. Qualified providers and clinics with the knowledge, skill, and expertise to properly evaluate, prescribe, and train people in the use of hearing devices are needed.
2. Proper fitting and training are complex but necessary elements of maximizing performance among users of hearing devices. Consumers who work with providers trained in the use of properly prescribed and fitted hearing devices can expect better results than those who use off-the-shelf products.
3. Even with advances in technology, hearing aids and other hearing assistive devices may help but do not fully mitigate impairments or restrictions on participation caused by hearing loss. Environmental and personal factors are as important in determining the overall communicative functioning of individuals with hearing loss.
4. The establishment of objective measures of real-world communicative functioning is vital to promoting a better understanding of the effects on this functioning of audiometric hearing function and hearing devices.
5. The widespread lack of insurance coverage for hearing devices and related services is an impediment to optimizing communicative functioning and maintaining gainful employment among adults with hearing loss.

FDA and FTC Involvement

Navigating the Dynamic Complexities of Practice Management
July 26, 2017 (Chesapeake)
American Academy of Audiology
FDA vs. FTC
US Food and Drug Administration (FDA)
Federal Trade Commission (FTC)

FDA vs. FTC: Who does what?
The FDA:
- Has a broad charge that includes regulation of food, drugs, biologics, vaccines, medical devices, electronic products, cosmetics, veterinary products, tobacco products, etc.

The FTC:
- A federal agency that regulates many types of advertising.
  - The FTC protects consumers by stopping unfair, deceptive or fraudulent practices in the marketplace.

FDA
- Focus on the device; hearing aids, OTC hearing aids, PSAPs
- Labeling requirements; adults only, listing medical conditions; recommend hearing evaluation?
- Safety and efficacy; report adverse effects

QUALITY

FDA
- Action derived from PCAST report; later NAS recommendations
- Holds Public Workshop on Good Manufacturing Processes for Hearing Aids (April 2016)
- Makes announcements at NAS Meeting (December 2016)
  - Looking to create a category of OTC devices
  - Will no longer enforce medical evaluation requirement
**FDA**

Medical Evaluation Requirement: What does this mean?
- FDA releases guidance document saying they will not enforce medical evaluation requirement for adults
- Does not establish legally enforceable responsibilities
- Waivers may be required by your state, some payers
- No formal change to law/regulation
- Does NOT apply to Medicare physician referral requirements

**FTC**

- 4/18/17: Hosts Workshop “Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care”
  - Convene researchers, health care providers, industry representatives, consumer representatives, policymakers
  - How can enhanced competition and innovation increase the availability and adoption of hearing aids by those consumers?
  - Balance consumer health and safety with innovation and competition

**FTC Workshop Topics:**
- Innovations in Hearing Technology
- Innovations in Hearing Health Care Delivery
- FDA Regulation of Hearing Aids and PSAPs
- The Benefits and Costs of Regulation
- Informing Consumer Choice in Hearing Health Care

**FTC Workshop Takeaways:**
- Unbundling/Bundling
- Regulation vs. Deregulation
  - FDA/FTC finite resources
  - Role of the Audiologist
  - Consumer perspective/consumer protection
  - OTC devices: specific population
  - Cost: Removing Cost from Delivery
  - Improving language/terminology
  - What can the FTC do?
Over-the-Counter Hearing Aid Legislation

114th Congress (December 2016)
- Senators Elizabeth Warren (D-MA) and Chuck Grassley (R-IA) introduced the Over-the-Counter Hearing Aid Act of 2016 (S. 9)

115th Congress (March 2017)
- Senators Elizabeth Warren (D-MA), Charles Grassley (R-IA), Maggie Hassan (D-NH), and Johnny Isakson (R-GA) introduced the Over-the-Counter Hearing Aid Act of 2017 (S. 670)
- Representatives Marsha Blackburn (R-TN) and Joe Kennedy (D-MA) introduce House companion bill (H.R. 1652)

S. 670 / H. 1652 includes changes from original legislation S. 9
- Strengthens language specifying OTC hearing aids are intended to be used for adults "over the age of 18"
- Direct Secretary of HHS to take steps to ensure safety and efficacy
  - Requirements to establish output limits appropriate for OTC devices
  - Requirements for appropriate labeling, reporting adverse affects, listing contradictions, and advising to consult with physician if present
- Preempts state law
- Finalize rather than withdraw PSAP guidance
Over-the-Counter Hearing Aid Legislation

A few reminders:
- Congress: Two one year sessions; bills must be reintroduced at the start of each Congress—115th Congress: January 3, 2017, to January 3, 2019
- Committee: Established for the purpose of considering legislation, conducting hearings and investigations, or carrying out other assignments as instructed by the parent chamber
- Committee of Jurisdiction: House/Senate assigns committee(s) with jurisdiction to review the subject matter. For example, the House Energy and Commerce and Ways and Means Committees typically have jurisdiction over health-care related legislation and would be referred health-care related bills upon introduction.

115th Congress: Where are we headed?
- Sponsors intent on moving legislation
- Look for potential vehicles
- Timely- Medical Device User Fee Amendments (MDUFA)

...yes, another acronym

Over-the-Counter Hearing Aid Legislation

MDUF-Huh??
- Authorizes the FDA to collect user fee from the medical device industry to be used for reviewing medical device applications
- Congress must reauthorize every 5 years; expires September 30
- Action required- Soon!

Legislative Activity:
- 5/2/2017: House Energy and Commerce Committee Health Subcommittee holds hearing examining; Considers four bills, including OTC hearing aid bill, to be included in FDA User Fee legislation
- 5/11/2017: Senate Health Education Labor and Pensions Committee Approves FDA User Legislation with OTC Hearing Aid Provision
- 5/18/2017: House Energy and Commerce Committee Health Subcommittee Approves FDA User Fee Legislation with OTC Hearing Aid Provision
- 6/8/2017: House Energy and Commerce Committee Approves FDA User Fee Legislation with OTC Hearing Aid Provision
Over-the-Counter Hearing Aid Legislation

- Academy Position:
  - New reality
  - Affect change
  - Audiology perspective
- What’s your position?

Academy Resources

- Statement: Over-the-Counter Devices
- Statement: Accessibility and Affordability of Hearing Care for Adult Consumers
- OTC Hearing Aid Act Legislative Information
- Academy President Ian Windmill Addresses OTC Hearing Aid Legislation
- Academy Comments to the FTC - May 18

Other Legislative Priorities

- EHDI Legislation
- Hearing Aid Tax Credit Legislation
- Student Loan Forgiveness
- Veterans’ Issues
- NIH Funding
- Audiology-specific legislation
- Other opportunities: telehealth, Medicare opt-out, etc.
- Monitoring HAD-related legislation

Questions?

- Contact:
  - Kate Thomas, senior director of advocacy and reimbursement
  - kthomas@audiology.org
  - 703-226-1029