

# **Boundary Areas Between PSAPs and Hearing Aids Definitions and Regulations**

**Institute of Medicine**

**June 30, 2015**

**Affordable and Accessible Hearing Health Care**

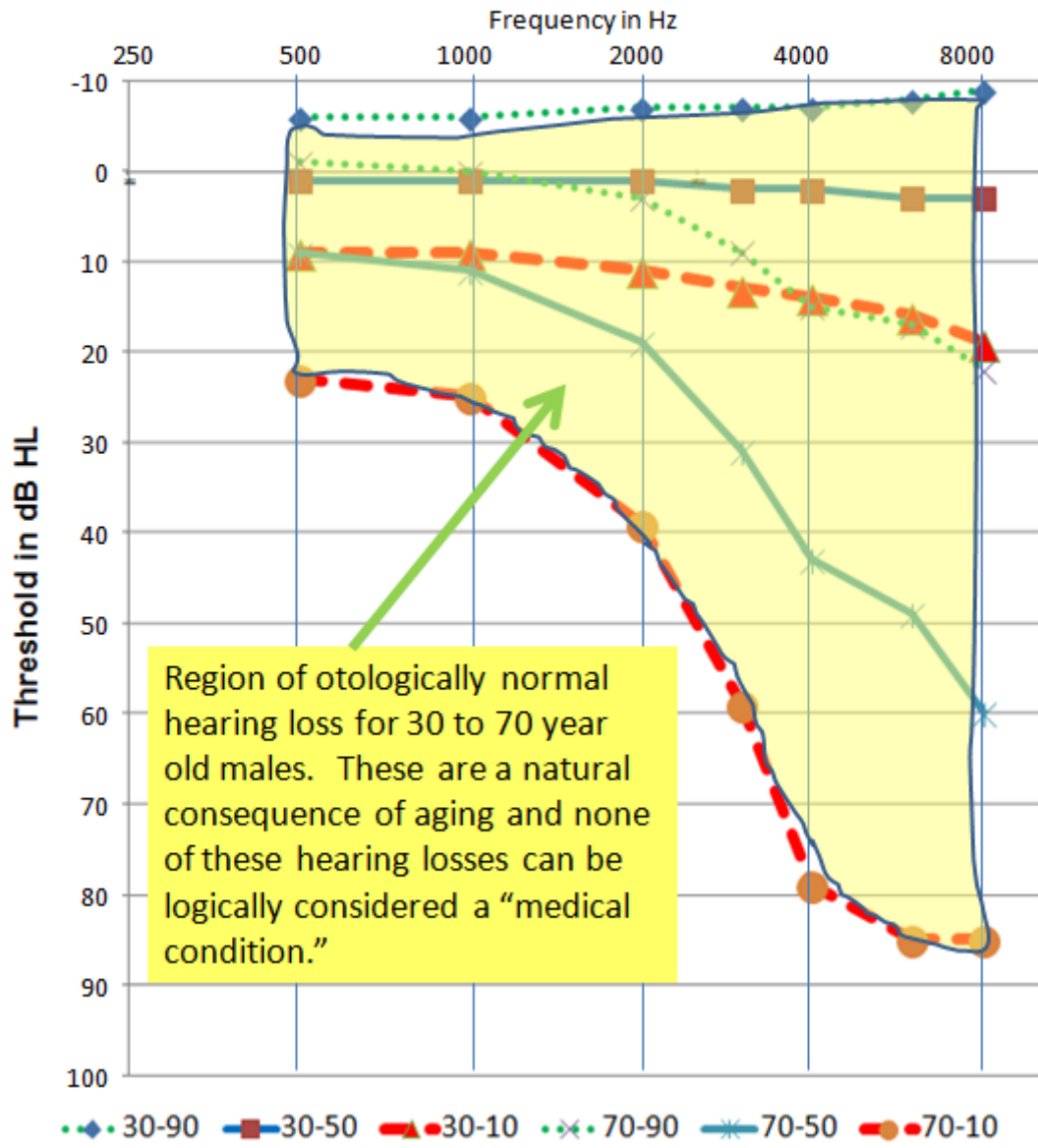
**Mead C. Killion, Ph.D.**

- 1. Concealed Cost of Unneeded Regulation**
- 2. Cost of Imprecision in Language:  
Definitions of Hearing Aids and PSAPs**
- 3. Myth that Professionally-Fitted Hearing Aids  
Are Best for Everyone**
- 4. Recommendations for Improving Affordability  
and Accessibility of Hearing Health Care**

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90 and 10 percentile threshold ranges for 30 and 70 year old  
 MALES from ISO\_1999\_2013 Annex A for an  
 otologically normal population (highly screened)



Region of otologically normal hearing loss for 30 to 70 year old males. These are a natural consequence of aging and none of these hearing losses can be logically considered a "medical condition."

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# Recommendations

- All stakeholders recognize the hearing health benefits of PSAPs
- FDA should endorse PSAP labeling that:
  - Includes warning signs
  - Reaches underserved hearing-impaired populations
  - Prompts hearing-impaired persons to seek professional help
  - Allows manufacturers to provide information on normal age-related hearing loss
- FDA should withdraw its November 7, 2013 draft guidance and cease all attempts to expand the scope of regulatory action.
- FDA should reissue its Consumer Health Information Bulletin with language that states PSAPs are appropriate for persons with age-related hearing loss.
- FDA should stop regulating hearing aids. Laws in 50 states already protect consumers.