Regulation of Hearing Aids vs. Personal Sound Amplification Products (PSAPs)

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Presentation Outline

- Definitions: Device, Hearing Aids, PSAP
- Regulatory Classification of Hearing Aids
- Hearing Aid Regulations (21 CFR 801.420-1)
- Considerations with Unrestricted Marketing of hearing aids
- Mail Order/Internet Sales
- FDA Initiatives regarding hearing aids
Definition of a Medical Device

• Intended to diagnose, cure, mitigate, treat or prevent a disease/condition, or

• Intended to affect the structure or function of the body, and

• Does not achieve intended use through chemical action or metabolism
Definition of Hearing Aid

- *Hearing aid* means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

(21 CFR 801-420)
Personal Sound Amplification Products (PSAPs)

- No formal regulatory definition
- PSAPs are intended to amplify environmental sound for non-hearing impaired consumers for use in a variety of listening situations (hunting, bird watching, listening to lecturers, “eavesdropping”)
- PSAPs do NOT meet the regulatory definition for a medical device
The Diversity of Medical Devices
### Medical Device Amendments of 1976:

Created a tiered, *risk-based* classification with regulatory requirements gauged to risks:

<table>
<thead>
<tr>
<th>Class</th>
<th>Risk</th>
<th>Regulatory Requirements</th>
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<tbody>
<tr>
<td>Class I</td>
<td>Low</td>
<td>General Controls</td>
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<tr>
<td>Class II</td>
<td>Moderate</td>
<td>General Controls and Special Controls</td>
</tr>
<tr>
<td>Class III</td>
<td>High</td>
<td>General Controls and Premarket Approval (PMA)</td>
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</tbody>
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Hearing Aid (21 CFR 874.3300)

- **Class I (low risk) for air conduction hearing aid; exempt from Premarket Notification [510(k)]**

- **Exemption subject to limitations (21 CFR 874.9):** New intended use or new technology that could impact safety or effectiveness requires 510(k)
Class I (Low Risk) : General Controls

- prohibition of adulterated or misbranded devices
- GMPs
- Registration of manufacturing facilities and listing of device types
- Record keeping
- Repair, replacement, refund
- Premarket notification [510(k)]: most Class I devices now exempted
## Classification of Hearing-Related Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Regulation</th>
<th>Class</th>
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<tbody>
<tr>
<td>Air Conduction Hearing Aid</td>
<td>874.3300</td>
<td>I</td>
</tr>
<tr>
<td>Bone Conduction Hearing Aid</td>
<td>874.3300</td>
<td>II</td>
</tr>
<tr>
<td>Transcutaneous Air Conduction Hearing Aid System</td>
<td>874.3950</td>
<td>II</td>
</tr>
<tr>
<td>Implantable Middle Ear Hearing Device</td>
<td>N/A</td>
<td>III</td>
</tr>
<tr>
<td>Cochlear Implant</td>
<td>N/A</td>
<td>III</td>
</tr>
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</table>
**Hearing Aids**
- Class I (General Controls)
- Hearing Aid Regulations re: labeling and conditions for sale (21 CFR 801.420-1)

**PSAPs**
- Radiation Control for Health and Safety Act of 1968
- Note: there are no FDA regulations precluding purchase by hearing impaired consumers should they choose this option
Most air-conduction hearing aids are **not** prescription devices,

**BUT**

Hearing aids are **restricted** by regulation with respect to device labeling (21 CFR 874.420) and conditions for sale (21 CFR 874.421).
Senator Charles Percy (Chair)

“Twenty million hearing impaired Americans are being denied top-flight treatment by a delivery system that simply is not working.”

Recommended that FDA promulgate regulations to restrict sale of HA to patients having undergone medical evaluation.
Specific elements for user labeling (e.g. instructions for use, expectations)

Important Notice for Prospective HA Users

Technical performance data (ANSI S3.22-2003)

Warning for Hearing Aid Dispensers
Hearing Aid Labeling Requirements
“Warning to Hearing Aid Dispensers”

- Visible congenital or traumatic ear deformity
- Otorrhea within past 90 days
- Sudden/rapidly progressive HL
- Unilateral hearing loss
- Audiometric A/B gap > 15 dB
- Cerumen impaction/foreign body
- Pain / discomfort
- Acute/chronic dizziness
Hearing Aid Devices: Conditions for Sale (21 CFR 874.421)

- Requires medical evaluation by a licensed physician within the preceding 6 months.

- Waiver of medical evaluation possible for adults
  - Informs patient that it isn’t in his/her best health interest
  - Availability user brochure
  - Dispenser can’t actively encourage waiver
  - Signed waiver statement

- Record keeping (3 years)
Preamble (1977):

“The Commissioner emphasizes...that the medical evaluation requirement is based upon the recognition that an unnecessary or partially effective hearing aid may be substituted for primary medical or surgical treatment, thus depriving the patient of ...appropriate medical diagnosis and care resulting in a detriment to health.”
Preamble:

“The Commissioner agrees with the American Council of Otolaryngology and other physicians who commented that recognition of an organic cause for hearing impairment is of extreme importance to the health and safety of the hearing-impaired patient.”
Considerations Regarding the Importance of Medical Evaluation
Red Flag Signs/Symptoms Are Not All Self-Diagnosable

- Visible congenital or traumatic ear deformity
- Cerumen impaction/ foreign body
- Audiometric A/B gap >15 dB
Hearing Aid Benefit /Absence of Benefit ≠ Presence /Absence of Medically Treatable Cause of Hearing Loss
Importance of Early Diagnosis

- Avoidance of inappropriate hearing aid use
  - Cerumen impaction
  - Middle ear fluid

- Preservation/improvement of residual hearing/balance/cranial nerve function
  - Retrocochlear tumors
  - Cholesteatoma
  - Autoimmune/infectious causes
Importance of Early Diagnosis (cont’d)

- Surgical risks increase in larger, more extensive operable lesions
  - Facial and Vestibulocochlear nerve injury
  - Semicircular canal fistula
Incidence/Prevalence of Selected Causes of HL

- **Acoustic neuroma**: 2000-3000 cases diagnosed per year; 1:100,000
- **Otosclerosis**: 1:100
- **Meniere’s Disease**: approximately 4 million cases in U.S.
- **Cholesteatoma, autoimmune**: unknown
- **Chronic middle ear effusions, cerumen impactions**: relatively common
“Screening and Management of Adult Hearing Loss in Primary Care”

- Search of MEDLINE, HealthSTAR, EMBASE, Ageline, and National Guideline Clearinghouse from 1985-2001
- Most hearing loss in older adults is sensorineural due to presbycusis
- Cerumen impaction and chronic otitis media may be present in up to 30% of elderly patients with hearing loss (hospitalized study population)*

*J Adv Nursing.1990;594-600
Mail order hearing aids and internet sales must comply with all regulations regarding labeling and conditions for sale.

Written vs. electronic signatures for waivers.
Potential Sources of Data on the Incidence of Medically Treatable Causes of Hearing Loss

- Veteran’s Administration/DoD databases
- Foreign country registries (Denmark)
- In-depth literature search
- Survey/consult of U.S. clinical experts
FDA Initiatives Regarding Hearing Aids

- “Guidance document: Regulatory requirements for hearing aids vs. personal sound amplification devices”—final version pending
- FDA Consumer website for hearing aids
- Other outreach activities (webinar, FDA Consumer articles)
IOM STUDY: ACCESSIBLE AND AFFORDABLE HEARING HEALTH CARE FOR ADULTS

- Co-sponsored by NIDCD, FDA, CDC, NIA, DoD, VA, HLAA

- Statement of Task includes: Assessment of current federal regulations: necessary safeguard vs. barrier to access?

- Currently underway and scheduled for completion in June 2016