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About CEA

To expand the global consumer electronics industry and promote innovation through:

- Policy
- Industry Standards
- Market Research
- Events, including CES®
What’s a PSAP

PSAP = Personal Sound Amplification Product
What’s a PSAP

Here’s what the U.S. Food and Drug Administration says:

“…a PSAP is 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. PSAPs typically are simpler sound amplification devices with fewer features and less functionality than hearing aids, although some of the technology and functionality of hearing aids and PSAPs may be similar.”
Today’s Discussion Focus

• Regulatory Landscape
• PSAPs: A Study of Consumer Attitudes and Behaviors, released October 2014
• Standards Development Efforts
Regulatory Landscape

The FDA does regulate hearing aids – pursuant to the Food, Drug, and Cosmetic Act:

“A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing.” See 21 CFR 801.420 for complete definition.

Key characteristics of a hearing aid:
• usually programmed to address an individual’s degree of hearing loss across sound frequencies to improve speech intelligibility
• may be coupled acoustically or wirelessly to external electronic products such as televisions, MP3 players, and telephones
• 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
Regulatory Landscape

Hearing aids can be either air conduction devices or bone conduction devices and have a variety of styles including behind-the-ear, in-the-canal, or body worn.

Hearing aids are subject to different types of premarket review requirements before marketing to potential consumers.

[Note that cochlear implants or implantable middle ear hearing devices always require an approved premarket approval (PMA) application before marketing]
Regulatory Landscape

All hearing aids must comply with specific requirements regarding patient and professional **labeling**:

- specific labeling requirements for the hearing aid device itself (e.g., device model, serial number, date of manufacture) and

- contents of the user instructional brochure that must be provided to potential hearing aid recipients (e.g. technical data, “Warning to Hearing Aid Dispenser” statement).
Regulatory Landscape

All hearing aids must comply with required conditions for sale:

• A prospective hearing aid user must provide to the hearing aid dispenser a written statement from a licensed physician that the prospective user has been medically evaluated and is a candidate for a hearing aid.
  – this evaluation must occur within 6 months prior to the date of purchase of the hearing aid
  – the prospective user may waive this requirement for medical evaluation provided that the prospective user signs a waiver statement
Regulatory Landscape

The hearing aid dispenser must **retain records** of all medical evaluation statements and waivers for a period of three years after dispensing of the hearing aid.

According to the FDA these regulatory conditions for sale encourage prospective users to receive proper medical evaluation and treatment for treatable causes of hearing loss.
The FDA does not regulate PSAPs as hearing aids:

“Because PSAPs are not intended to diagnose, treat, cure or mitigate disease and do not alter the structure or function of the body, they are not devices as defined in the FD&C Act. As such, there is no regulatory classification, product code, or definition for these products. Furthermore, there are no requirements for registration of manufacturers or listing of these products with FDA.”

However, PSAPs are subject to applicable provisions of the Radiation Control for Health and Safety Act of 1968 and manufacturers must also comply with the requirements to repurchase, repair, or replace electronic products required under other rules.
Use Cases – According to FDA

PSAPs

- hunting (listening for prey)
- bird watching
- listening to lectures with a distant speaker
- listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations)

Hearing Aids are used in listening situations that are typically associated with, and indicative of, hearing loss

- difficulty listening to another person nearby
- difficulty understanding conversations in crowded rooms
- difficulty understanding movie dialogue in a theater
- difficulty listening to lectures in an otherwise quiet room
- difficulty hearing the phone or doorbell ring
- difficult listening situations in which environmental noise might interfere with speech intelligibility
Regulatory Landscape

On November 7, 2013 the FDA released Draft Guidance on “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products - Draft Guidance for Industry and Food and Drug Administration Staff”

CEA’s Interest In PSAPs

To increase the availability of personal sound amplification products (PSAPs) alongside hearing aids in order to give people with mild hearing loss more options and increased quality-of-life.
PSAP Study Objectives

• Determine current ownership and use of PSAPs across a variety of situations and environments

• Understand the portfolio of products consumers use for sound amplification (including both hearing aids and PSAPs)

• Establish consumer interest in using PSAPs across a variety of situations and environments

• Understand channels for exposure and purchasing of PSAPs
Why Study PSAPs?

- Almost **half (46%)** of online U.S. adults have some level of hearing loss
- There are two main options to assist: hearing aids and PSAPs
  - Hearing aids can be **complex**
  - PSAPs offer a lower barrier to entry
- FDA’s 2009 Guidance distinguished between hearing aids and PSAPs for regulatory purposes
  - But FDA’s pending 2013 Guidance makes it difficult to market PSAPs to manufacturers’ target audience
- CEA has urged the FDA to clarify its guidance
The Study

- CEA has a robust market research function
- Study administered via Internet web form between June 3 to June 10, 2014 to an online national sample of 3,459 adults (age 18 and over)
- Report focuses on the 1,551 U.S. adults (age 18 and over) with diagnosed hearing loss or at least a little trouble hearing
- Online format (to facilitate accessibility)
- Designed in partnership with hearing loss professionals
Key Conclusions

- Cost is a major barrier to consumers seeking help for hearing difficulty
  - Many are unwilling to pay the entry price of $1,000 for hearing aids

**Figure 5 – Amount Willing to Spend on Hearing Health Care or Devices**

<table>
<thead>
<tr>
<th></th>
<th>Diagnosed w/ Hearing Loss (A)</th>
<th>A Lot/Some Hearing Difficulty (B)</th>
<th>A Little Hearing Difficulty (C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0</td>
<td>21%</td>
<td>22%</td>
<td>43% AB</td>
</tr>
<tr>
<td>$1–$99</td>
<td>8%</td>
<td>18% A</td>
<td>14% A</td>
</tr>
<tr>
<td>$100–$299</td>
<td>16%</td>
<td>28% A</td>
<td>26% A</td>
</tr>
<tr>
<td>$300–$499</td>
<td>6% C</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>$500–$999</td>
<td>17% C</td>
<td>18% C</td>
<td>7%</td>
</tr>
<tr>
<td>$1,000–$2,499</td>
<td>16% C</td>
<td>10%</td>
<td>7%</td>
</tr>
<tr>
<td>$2,500–$4,999</td>
<td>12% BC</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>$5,000+</td>
<td>4% BC</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Average</td>
<td><strong>$925 BC</strong></td>
<td><strong>$265</strong></td>
<td><strong>$211</strong></td>
</tr>
<tr>
<td>Don’t know</td>
<td>48%</td>
<td>49%</td>
<td>50%</td>
</tr>
</tbody>
</table>

*Base: Online U.S. adults (n=362) | Diagnosed with hearing loss (n=248) | With a lot/some trouble hearing (n=941) | With a little trouble hearing

Letter denotes significantly higher percentage compared to other group

Q6. How much would you be willing to spend on hearing health care or devices that help you hear better in the next 12 months?

Additionally...
## Key Conclusions

### Figure 10 - Reasons for Not Owning a Hearing Aid

<table>
<thead>
<tr>
<th>Reason</th>
<th>Diagnosed w/ Hearing Loss (A)</th>
<th>A Lot/Some Hearing Difficulty (B)</th>
<th>A Little Hearing Difficulty (C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not concerned enough about hearing difficulties to purchase a hearing aid</td>
<td>33%</td>
<td>45% A</td>
<td>71% AB</td>
</tr>
<tr>
<td>Cost of medical devices associated with hearing difficulties</td>
<td>31% C</td>
<td>35% C</td>
<td>12%</td>
</tr>
<tr>
<td>Not covered by medical insurance or Medicare</td>
<td>23% BC</td>
<td>13% C</td>
<td>5%</td>
</tr>
<tr>
<td>I don’t want to be bothered with hearing aids</td>
<td>15% C</td>
<td>17% C</td>
<td>8%</td>
</tr>
<tr>
<td>I don’t care for the look of hearing aids</td>
<td>11%</td>
<td>12%</td>
<td>7%</td>
</tr>
<tr>
<td>I think hearing aids don’t work well</td>
<td>7%</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Cost of medical appointments</td>
<td>6%</td>
<td>21% AC</td>
<td>9%</td>
</tr>
<tr>
<td>Unaware of hearing aid option</td>
<td>5%</td>
<td>10% C</td>
<td>4%</td>
</tr>
<tr>
<td>Other</td>
<td>24% BC</td>
<td>13%</td>
<td>16%</td>
</tr>
</tbody>
</table>

Base: Online U.S. adults who do not own a hearing aid and (n=229) | Have been diagnosed with hearing loss; (n=215) | Have a lot/some trouble hearing; (n=864) | Have a little trouble hearing
Letter denotes significantly higher percentage compared to other group
Q9. You indicated you do not own a hearing aid. Which of the following, if any, are reasons you do not own a hearing aid?
Key Conclusions

• Yet, there is a demand for PSAPs among consumers with trouble hearing
  – Nearly 40% would be interested in an over-the-counter product

• Retailers are the preferred (73%) purchase channel for non-prescription hearing devices
  – Additionally, most (84%) consumers with trouble hearing would consult a medical or hearing professional about their hearing loss
Key Conclusions

• Most use PSAPs for listening to TV, but there is strong interest in using them for a wider range of activities
  – 41% report willingness to use PSAPs every day, in any listening situation.

• Consumers with hearing difficulty support the ability to purchase PSAPs in the same way they purchase reading glasses
Other Findings

• Reasons for **not** seeking medical care for hearing difficulties
  – 52% with a lot of trouble hearing say that hearing difficulties are not bad enough to do anything about it
  – 34% with a lot of trouble hearing cite costs, and 29% also cite separate cost of doctor’s appointments
  – 21% with a lot of trouble hearing say they’re not sure what options are available
  – Other reasons include not wanting to wear a hearing aid; social stigma; and they don’t think the hearing aid will work

• Most (68%) of those with only a little trouble hearing are **not** planning to address their hearing issues in the future.
  – Ironically, those *already* using a hearing device of any kind are most likely to seek further help for their hearing loss
Standards Activities

Advances in several technologies are now making it possible to provide **personal sound amplification with devices other than a traditional hearing aid**. The U.S. Food and Drug Administration is reviewing guidance on the differences between traditional hearing aids verses other devices which can enhance hearing.
Standards Activities

• CEA is accredited by the American National Standards Institute (ANSI) to developed standards and other technical documents for the consumer electronics industry.

• CEA has more than 70 committees, subcommittees and working groups and roughly 1,100 participants, in its Technology & Standards program.

• CEA maintains an unmatched reputation as a credible and flexible standards making body.
Standards Activities

• CEA committee R6WG20, *Personal Sound Amplification*, is actively engaged in a project to develop standards for Personal Sound Amplification Products.

• Specifically, R6WG20 develops performance criteria, measurement protocols, and other technical guidance for products which provide personal sound amplification.
Standards Activities

• Active participation from *industry leaders* including Apple, Audio Precision, Bose, Dolby, Etymotic, LG, Panasonic, Plantronics, Qualcomm, VOXX, among others

• Active participation from *representatives of the hearing disability community* including the Hearing Loss Association of America, Helen Keller National Center, and Gallaudet University
Standards Activities

• ANSI/CEA-2051, *Personal Sound Amplification Performance Criteria*, describes minimum performance levels for PSAPs. This standard should help ensure that PSAPs are high quality devices with great performance characteristics.

• A second standard with a glossary of terms will ensure that everyone uses the same terminology when discussing these technical characteristics.
Standards Activities

- frequency response bandwidth
- frequency response smoothness
- distortion control limits
- noise levels
- short/long term acoustic output
- tone control

- battery life
- latency
- automatic level control
- active noise suppression
- speech optimization
- feedback control
- signal-to-noise enhancement
Standards Activities

Future Work?

• Develop additional standards and technical documents related to PSAPs. For example, the Working Group has already begun discussing the benefits of a logo program that would identify products meeting our high quality performance standard. Such a logo program would provide a “good housekeeping seal of approval” to help consumers identify high quality PSAPs.
Standards Activities

Future Work?

• Once published, many CEA standards become international standards via our leadership in the International Electrotechnical Commission (IEC), Technical Committee (TC) 100. IEC TC100 is the home of globally harmonized standards for Audio, Video and Multimedia Systems and Equipment.
Standards Activities

Any organization with a material interest in a standard we are developing can participate in the committee work.
Thank You!

For more information, or to participate in our standards activities, please contact Bill Belt at bbelt@CE.org