

# Boundary Areas Between PSAPs and Hearing Aids, Part 2

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*In the second, and concluding, part of his remarks to the Institute of Medicine, Mead Killion makes the case for PSAP and for guidelines that encourage their safe and efficacious use. While he cites a study that found that hearing aids and (at least some) PSAPs can deliver roughly the same efficacy, Dr. Killion emphasizes another, informal, study which suggests that best practices are more essential than ever in audiology for a very important reason: most of the value lies in the skills and care an audiologist provides, not the technology. He ends with some important, and perhaps to some, provocative recommendations. (Richard Einhorn, Digital Disruptions Editor)*

## Comments on the Boundary Areas between PSAPs and Hearing Aids: Definitions and Regulations

**Mead Killion, PhD.** Presented at the June 30 IOM meeting regarding hearing aid availability.

This is the second half of a discussion of the “confusion” areas between PSAPs and hearing aids. [Part I](#) discussed (1) the concealed cost of current regulation, and (2) the cost of imprecision in language: Definitions of hearing aids and PSAPs.

### 3. The Myth That Professionally Fitted Hearing Aids are Best for Everyone

The established hearing aid industry does an exceptionally good job of designing and delivering hearing aids that are a technological marvel, almost beyond belief. Even though I have normal hearing, I was given for evaluation a pair of deep CIC aids that were essentially invisible in my ears, could stream music to me from my smartphone and — even more impressive — allow me to answer the telephone by connecting my smartphone to my hearing aids and streaming the hearing aid

microphones to my smartphone. They can turn down the gain when the GPS in the small remote control senses that I have arrived home. The remote control can also function as a remote microphone.

The hearing aids I just described have been a benefit to many of the 20% of those who need amplification, and who can afford to purchase it. While modern hearing aids have become wonderfully sophisticated, they have become so expensive that they are neither affordable nor accessible to many Americans; 45 million of whom are [below the poverty level](#)<sup>[1]</sup>.

Now let's consider those persons who are among the 80% who don't buy hearing aids. *Why don't they obtain them? **Because they don't think they need them.*** They function reasonably well by turning up the TV and forcing those around them to speak louder, although both of those tend to annoy their friends and family. If turning up the TV is all that is required to understand the dialog, then a good personal sound amplifier is obviously all that is required to reduce the annoyance of those around the wearer. It probably doesn't have to have compression: The TV broadcasts have built-in compression, and friends learn how much they need to raise their voices.

Until recently, many of us assumed that a well-fitted hearing aid will always provide substantially better intelligibility in noise than a personal sound amplifier. In fact, there is evidence that disproves that assumption from a well designed experiment at Walter Reed Army Medical Hospital (now Walter Reed National Military Medical Center)<sup>[2]</sup>. In that study, thirty-two self-referred patients were offered a pair of high-quality personal sound amplifiers while waiting for their hearing aids. Comparison testing showed an Articulation (audibility) Index of 67% for the personal sound amplifiers and 70% for the custom hearing aids. The Speech-in-Noise SNR was 0.8 dB better with the custom hearing aids. The average results were essentially equivalent. *(This is all the more remarkable because those personal sound amplifiers had no fitting adjustments, only a LO-HI switch allowing an across-the-board 8 dB increase in gain. (The circuits incorporated an updated version of the basic 1989 K-AMP® "TILL-type" high-fidelity signal processing.)*

As an anecdotal story, a woodwind player from the Chicago Symphony Orchestra called me because his digital aids were not satisfactory when he played fortissimo. When he visited the lab, I gave him Etymotic's "BEAN" personal sound amplifiers, and he said "that is fine" when he played fortissimo. I tested him in the sound booth and he had 1 dB better SNR with the BEAN than with his digital hearing aids. He now wears one in his left ear during rehearsals so he can hear the conductor. His thresholds are appropriate for his age.

There is no question that a good licensed professional can provide the highest standard of care, regardless of whether the hearing loss is due to aging or something else. The most important part of that care is the counseling and personal interaction given the patient. According to one informal survey, nearly 60% of the perceived value in professionally fitted hearing aids is the audiologist, just as study after study has shown the most important factor in healing is not the medicine — which can often be substituted by a placebo — but the doctor, who cannot be substituted with a placebo. Not everyone can afford the highest standard of care, however. For those whose budget excludes even the least expensive hearing aids, a high-quality direct-to-the-consumer personal sound amplifier offers an affordable alternative.

With adequate information, the consumer can make an informed decision between hearing aids and personal sound amplifiers, just as they can choose to see a doctor or take aspirin. In either case, the consumer who is not satisfied can simply obtain a refund<sup>[3]</sup>. But for many, a personal sound amplifier makes good hearing assistance much more available and affordable.

Fortunately, an increasing number of audiologists view personal sound amplifiers as a useful addition to their practice, in which case the purchaser can have the best of both worlds: low cost and professional care.

#### **4. Recommendations and Expectations for Improving Affordability and Accessibility of Hearing Health Care**

- Rather than oppose the availability of PSAPs, all stakeholders should recognize the benefits to hearing health that PSAPs can provide, and endorse using PSAP labeling to reach the underserved hearing impaired population. PSAP labeling might be a valuable means to convey health information to prompt many hearing impaired individuals to seek professional help. FDA should allow manufacturers to provide information on the basis of which the consumer with normal age-related hearing loss can make an informed choice between hearing aids and PSAPs.
- FDA should withdraw its November 7, 2013 [draft guidance document](#) entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products—Draft Guidance for Industry and Food and Drug Administration Staff”<sup>[4]</sup> and cease all attempts to expand the scope of regulatory action against PSAP manufacturers, which it originally clearly identified by the statement “which we do not regulate.”
- After changing its position that personal sound amplifiers are not meant for those with age related hearing loss, FDA should reissue the FDA Consumer Health Information bulletin “[Hearing Aids and Personal Sound Amplifiers: Know the Difference.](#)”<sup>[5]</sup> Enormous good could come from impartial information from the highly respected FDA itself, especially to those below the poverty level.
- Finally, I personally believe that it would be good thing if FDA got out of the hearing aid regulation business. It would save them a lot of time and those who purchase hearing aids are already amply protected by the laws in 50 states that hearing aids must be purchased from a licensed professional.

#### ***Expectations***

- Many of those who can't or won't afford hearing aids will purchase affordable and accessible personal sound amplifiers.
- Many of those who believe their own hearing loss is simply the result of aging, and feel it is not serious enough to justify doing anything about it, will decide to try a low-cost personal sound amplifier many years before they would spend thousands of dollars on “a medical device” called a hearing aid.
- If they can obtain an excellent but inexpensive sound amplifier from a hearing professional, they will trust that professional in the future when they decide to obtain custom hearing aids.

## **Footnotes & References**

1. Center for Disease Control and Prevention (2014). Poverty Numbers, Table 2, page 56:45.8 million<sup>e</sup>
2. Walden, et. al. (2008). Walter Reed National Military Medical Center, Bethesda, MD. Unpublished study results for 32 self-referred patients wearing personal sound amplifiers while waiting for their hearing aids<sup>e</sup>
3. Killion, M. (2015). Personal communication: "Etymotic's return for credit for THE BEAN personal sound amplifier is, pleasantly enough, lower than that we expected. It is comparable to that reported for hearing aids."<sup>e</sup>
4. Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products – Draft Guidance for Industry and Food and Drug Administration Staff (Document issued on: November 7, 2013)<sup>e</sup>
5. FDA Consumer Health Information (2009): Hearing aids and personal sound amplifiers: Know the difference<sup>e</sup>