

Boundary Areas Between PSAPs And Hearing Aids, Part 1

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This is first in the Device Disruptions series edited by Richard Einhorn.

Editor's Note: In the 70s, Mead Killion, PhD, ScD (hon), urged high sound quality for hearing aids when hardly anyone else cared, let alone understood, its crucial importance. He is the inventor of the legendary K-Amp, the Digi-K, the QuickSin, some of the best earphones and Bluetooth headsets ever made, and recently, the gorgeous-sounding Etymotic Bean Quality Sound Amplifier. He is an indisputable genius with a sense of whimsy that rivals Lewis Carroll's, a terrific musician. Really, Dr. Mead Killion needs no introduction, but readers will find his bio at the end of this post.

On a personal level, Mead has been a great friend and inspiration. His articles are always a joy to read and, because he writes like a musician – that is, always from the standpoint of sound – I have found even the most technical of them models of clarity.

In the following remarks to the IOM on FDA regulations and other topics, his knowledge, scholarship, experience, and profound understanding of the multiple complex technical and social issues that swirl around hearing and hearing loss are on full display. Dr. Killion's remarks challenge us to look at the entire subject of hearing loss in a completely different fashion, not so much as a medical problem as a normative function of aging. The implications of such a paradigm shift run very deep.

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

Mead Killion, Ph.D. Presented at the June 30 IOM meeting regarding hearing aid availability.

Background

For 53 years, I have been designing things and sharing my opinions with others. I hold some 88 US patents, have published 80 papers and 20 book chapters, and for the last 32 years have taught the advanced Hearing Aid Electroacoustics course at Northwestern University.

My comments were prepared with the help of Gail Gudmundsen, who fitted some 10,000 hearing aids before joining Etymotic Research. She had an extremely low return for credit rate during the 25-year period she dispensed hearing aids, but she became increasingly concerned that a large number of people could no longer afford hearing aids as the prices went from \$300, to \$500, to \$1500 and up. Hoping to help bring about low-cost hearing aids, starting in 2001 Gail Gudmundsen and I provided FDA with a total of more than 25,000 words of advice and counsel, in the form of letters, Citizen Petitions, and 510K applications^[1]. You will be relieved to know that I will only add 2000 words to the that total this afternoon.

A wide range of persons cannot afford today's hearing aids. Even in 1934, my father was a well-

educated preacher who was assigned to build up a small and struggling Free Methodist church in Indiana. He and my mother lived on \$4.00 per week. He picked up coal along the railroad tracks to keep the parsonage warm, and the church members brought them food. \$4.00 a week in 1934 is equivalent to \$71 a week now. He had a full time job, and he was making the world a better place, but he could not have afforded hearing aids had he needed them.

Eighty years later, many Americans still cannot afford FDA regulated hearing aids at any current price. Nicole Marrone recently reported that only 4% of the Hispanic population in Arizona obtains hearing aids^[2].

I will briefly consider four topics:

1. The concealed cost of current regulation
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
4. Recommendations and expectations for improving affordability and accessibility of hearing health care

1. The concealed cost of unneeded regulation

FDA classification of hearing aids as medical devices, in combination with the laws in 50 states requiring that hearing aids be purchased from a licensed professional, restrict access to low-cost, high-quality amplification. In England and Denmark 40 to 50% of those who could benefit from hearing aids obtain them; in the US it is half that number (roughly 20 to 25%), 14% of hearing aids that are dispensed are returned for credit, and another 12% have been reported relegated to a dresser drawer^[3]. Those numbers held reasonably steady for 20 years of MarkeTrak data^[4]. Lower numbers were reported in a recent survey that queried only high-speed internet users. When Dr. Gudmundsen and I were invited in October of 2008 to address the FDA Working Group on hearing aids, one of our requests was “Tell us what you don’t regulate.” At the 2009 annual meeting of the Hearing Industries Association, we were pleased to hear that FDA had recognized a new category of unregulated products; “Personal Sound Amplification Products, or PSAPs.” FDA’s Dr. Eric Mann said “We are drawing a bright white line between hearing aids and PSAPs. “A hearing aid is a medical device... which we regulate. A PSAP is a consumer product, which we do not regulate.” The distinction is important, because it meant that PSAPs are not under FDA’s authority^[5].

Although PSAPs are not under FDA’s authority^[6], when Dr. Mann addressed the Institute of Medicine in January last year, he made it clear that personal sound amplifiers should be advertised as intended only for people with normal hearing. This is despite that fact that most PSAP purchasers have not had a hearing test and thus do not know whether they have “normal hearing” or not. FDA’s restriction on PSAP advertising impinges on First Amendment rights to disseminate accurate information to consumers. To my understanding, FDA has authority to restrict free speech on regulated products, but not on unregulated product.

It seems ironic that FDA grants freer access to many drugs than it does to hearing aids; allowing a large number of previously prescription-only medicines to be available over the counter. With drugs, FDA has followed the principle that over-the-counter status is justified when lay users can read instructions and achieve satisfactory results with little harm. Even if indirect harm — such as an undetected brain tumor — might result from someone purchasing aspirin for a headache, that was not considered sufficient reason to withhold over-the-counter status for aspirin. We are all

better off from the careful balancing of risks normally performed by FDA.

In contrast to the reasonable position on OTC medications, FDA enforces an unreasonable “indirect harm” justification for regulating hearing aids. While there is no direct evidence that hearing aids have ever harmed anyone, access to hearing aids is more limited than access to FDA regulated cigarettes, which according to CDC kill 480,000 Americans each year.

The often cited indirect harm of an undetected brain tumor from purchasing a hearing aid without seeing a doctor is vanishingly small — especially because people seldom seek medical advice for a gradual-onset unilateral hearing loss, but typically wait until the tumor causes them to stumble on the tennis court.

A gradual hearing loss can go unnoticed even by professional musicians who live by their hearing: Charlie Geyer, fourth trumpet for the Chicago Symphony Orchestra for 12 years, sitting next to the percussion section, told me (with permission to tell his story): “It happens so slowly you don’t notice it happening until you realize you can’t carry on a conversation with the telephone on one ear.”

2. The cost of imprecision in language: Definitions of hearing aids and PSAPs

My first observation regarding definitions is that it is not design or technology that differentiates hearing aids from personal sound amplifiers, but “intended use.”

The FDA definition of a hearing aid is: “...a wearable sound-amplifying device that is intended to compensate for impaired hearing” (21 CFR 874.3300)^[7]. Similarly, the [FDA Consumer Health Information bulletin](#) quoted Dr. Mann as saying “...the products are different in that only hearing aids are intended to make up for impaired hearing.” In other words, the difference is in the labeling and otherwise the products may be identical.

Ironically, in 2007 Etymotic Research submitted a pair of 510K applications for two identical devices, one labeled a hearing aid and the other labeled a Sound Amplifier. To our astonishment, FDA responded that despite the different intended use, they were both hearing aids. While FDA’s position has shifted, the agency still maintains that it is [inappropriate for manufacturers to publicly acknowledge that PSAPs may be purchased by individuals with impaired hearing](#).

My second observation regarding definitions is obvious to any company that has developed low-cost, high-performance personal sound amplifiers: It is essentially dishonest to pretend that they were developed for those who don’t need them. That is so important that I will repeat it. It is essentially dishonest to pretend that we develop personal sound amplifiers for those who don’t need them. Moreover, it is a disservice to consumers to withhold important information on the basis of which they could make an informed decision.

My third observation is that “hearing impairment” can be defined in different ways. If we consider age-related hearing levels, the definition of “impairment” is relative, as it is in real life. It makes much more sense to focus on those with age-related hearing loss, many of whom might want low-cost amplification.

The shaded region on the audiogram of Figure 1 shows the 10-to-90%tile range of normal hearing for males in the 30-year and 70-year age brackets, taken from the international ISO-1999 Annex A standard, re-affirmed in 2013. Note that these hearing levels correspond to otologically normal persons, who have been highly screened to exclude those with a history of noise exposure. In other words these have normal hearing for their age. The FDA position that hearing loss is a medical condition appears to ignore the natural aging process.

A personal example may be useful. Until about 8 years ago, each year I ran a 26 mile marathon; for a total of 32 marathons. At age 76, I am content with shorter distances. At one time I could run a 10K (6.2 miles) in 39 minutes, clicking off each mile in under 6 1/2 minutes. At 76, I am much slower, but my loss of speed is not a result of a medical condition, it is typical for my age. My

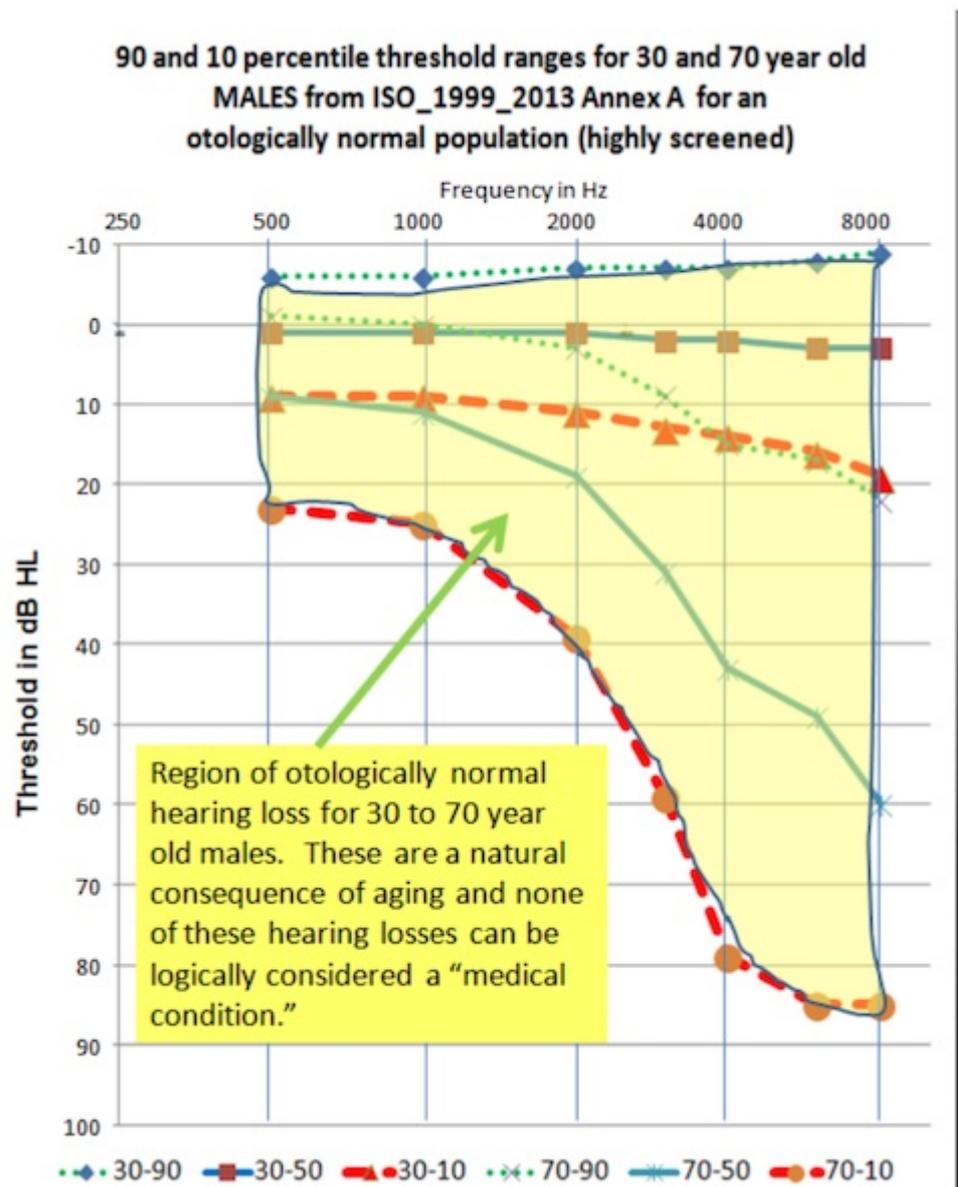


Figure 1. The 10-to-90%tile range of normal hearing for males in the 30-year and 70-year age brackets, taken from the international ISO-1999 Annex A standard, re-affirmed in 2013. These hearing levels correspond to otologically normal persons who have been highly screened to exclude those with a history of noise exposure. In other words these have normal hearing for their age.

doctor says I am quite healthy.

Similarly, the vast majority of those with hearing loss do not have a medical condition, they have normal hearing for their age and enough good judgment to decide for themselves whether they want a hearing aid or a personal sound amplifier. The only problem is that ***accurate information about PSAPs is being withheld from them by an organization that states it does not regulate PSAPs.***

Part II, to be presented in next week's post will continue with discussions on (a) The myth that professionally-fitted hearing aids are best for everyone, and (b) Recommendations and expectations for improving affordability and accessibility of hearing health care.

Mead C. Killion, Ph.D., Sc.D.(hon)

Mead Killion is the founder and CTO of Etymotic Research, Inc. He has been Adjunct Professor of Audiology at Northwestern University for 33 years, and is a trustee of *Vandercook College of Music*. He enjoys sharing his thoughts with others. He has published 88 papers and 20 book chapters, has lectured by invitation in 19 countries and holds 90 U.S. patents. Aside from his work, Dr. Killion has been a dedicated choir director for 32 years, a violinist, an amateur jazz pianist, has run 32 marathons, and has recently taken up flying.

Feature image courtesy of eugenio pirri

Footnotes

1. Killion, MC.(2014): Citizen Petition (2014-P-0159) dated January 28, 2014 in Figure 3
2. Marrone, N. (2015) Community-based Participatory Research on Hearing Loss in a Border/Low-Resource Community, presented at American Auditory Society meeting, Scottsdale, AZ March 7
3. Testimony of Arlinger (Sweden), and of Bisgaard (Denmark), and of Fabry (U.S.) before NIDCD Working Group on Accessible and Affordable Hearing Health Care for Adults with Mild to Moderate Hearing Loss, chaired by Drs. Judy Dubno, Lucille Beck, and Amy Donahue, August 25-27, (2009), Bethesda, MD
4. Abrams, H. and Kihm, J. (2015). An introduction to MarkeTrak 9 – A new baseline for the hearing aid market. Hearing Review, June
5. Mann, E. (2009) Talk given at the 2009 Hearing Industries Association Annual Meeting, February 26-27, under the theme “Consumer Connections”, Scottsdale, AZ
6. FDA Consumer Health Information (2009). Hearing aids and personal sound amplifiers: Know the difference
7. Regulatory definition of a class I hearing aid, 21 CFR 874.3300, Hearing Aid