



100 N. 15<sup>th</sup> Avenue \* Suite 104 \* Phoenix, AZ 85007  
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## ACDHH Position Paper

**ISSUE:** Over-The-Counter Hearing Aids

**POSITION:** The Arizona Commission for the Deaf and the Hard of Hearing is opposed to hearing aids sold over-the-counter (OTC) without the professional involvement of an Arizona licensed hearing healthcare provider.

**ISSUE IN BRIEF:** The Federal Trade Commission (FTC), in response to the issues of accessibility to and affordability of hearing aids, is considering making hearing aids for mild-to-moderate hearing loss available OTC to adults.. A robust debate focusing on the current hearing aid distribution model of seeing a licensed hearing healthcare provider for an exam and purchase of individually prescribed regulated hearing aids is now taking place among stakeholders involved in this issue. The argument centers on whether the existing model is the root cause of people not being able to access and afford hearing aids. There is no doubt that the hearing aid acquisition rate is unacceptable and cost is a significant factor. What is in question is whether the current distribution model is the cause of this low adoption rate.

**ISSUE DEFINED:**

People who have hearing loss can be defined as follows:

- people who have hearing loss (the whole)
- people who know they have hearing loss and who may or may not take steps to do something about their hearing loss (a part of the whole)

Over 48 million Americans have hearing loss, and many of them do not know it. Of those who know they have hearing loss, many will not take action because they do not think their hearing loss is that bad and they do not understand the comorbidities<sup>1</sup> of hearing loss. Others will wait years to purchase a hearing aid, citing the belief that hearing aids do not work, stigma, and a lack of insurance coverage as reasons for delaying their hearing healthcare. In actuality though, it is the severity of the problem of hearing loss that prompts most people to initially purchase hearing aids, regardless of cost. Some people know they have hearing loss, want hearing aids, and legitimately cannot afford them.

The current proposal to make hearing aids available OTC for people with mild-to-moderate hearing loss may hurt the people it intends to help. People with mild hearing loss often do not know they have hearing loss and do not seek out hearing aids. People who suspect they have hearing loss do not take action until their hearing loss becomes more problematic. Consumers with hearing loss have a variety of levels of hearing loss and research shows that consumers are unable to self-diagnose the degree, type, and etiology of their hearing loss, including conditions that require medical intervention.<sup>2</sup> Consumers cannot perform a visual otoscopy on themselves that would reveal the presence of ear wax or other conditions. An in-person examination by a licensed hearing healthcare provider will detect FDA red flags and other medical conditions such as earwax impaction, infection, eardrum perforation, conductive component involvement, acoustic neuroma, and auditory processing disorder. Hearing aids are regulated precisely because they are medical devices and they are dispensed by highly trained and licensed hearing healthcare providers. The safety and efficacy of OTC hearing aids has not been established through research and an OTC hearing aid could cause even more hearing loss. Additionally, the implication that an OTC hearing aid would cost less than a non-OTC hearing aid is unproven.



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There is no question that hearing aids and rehabilitative services should be made available to people who need and want them. However, hearing aids are not like 'reading glasses' purchased OTC. A person cannot purchase prescription eyeglasses without an annual eye exam. Similarly, hearing aids are sophisticated medical devices and hearing loss is a complex medical issue independently associated with cognitive decline, dementia, falls, depression, social isolation, and diabetes. Preventing, detecting, diagnosing, and treating hearing loss are key elements of a comprehensive hearing healthcare program. Satisfaction with hearing aids is directly linked to the skill of the practitioner and not the cost of the device.<sup>3</sup> In addition, device instruction, aural rehabilitation classes such as Living Well with Hearing Loss, and patient counseling are integral aspects of a complete hearing loss treatment program. OTC hearing aids offer none of these elements.

Without a scientifically valid hearing test and a professional discussion of options and alternative treatments, the consumer purchasing hearing aids OTC is leaving their hearing healthcare needs to the consumer electronics market and retail salesperson who may not have their best interests at heart. In fact, consumers are not persuaded that OTC hearing aids are the answer.<sup>4</sup>

**COMPETITION & INNOVATION:** Not only does competition among hearing aid manufacturers exist, it also exists between individual and group-owned dispensing practices with a variety of hearing aid price points available. People who suspect they have hearing loss already have easy access to a robust market that includes a variety of affordable Personal Sound Amplification Products (PSAPs) including 'hearables'.<sup>5</sup> In fact, increased competition in the PSAP and hearable market has spurred innovation, and the entry of 'big box' stores into the hearing healthcare arena has helped drive down the cost of hearing aids.

**UNINTENDED CONSEQUENCES:** If OTC hearing aids purchased by the consumer and do not improve their hearing, the OTC aids will end up in the drawer. While a person might receive some benefit from an OTC device, that does not mean they will be satisfied with the device. Not only will the person lose the money spent on the device, they will then believe hearing aids do not work and will tell others about their negative experience, decreasing the number of people who utilize hearing aids.

Parents may purchase these for their children. Children cannot and must not be treated with OTC hearing aids. Any amount of hearing loss in a child is a serious issue needing professional intervention.

Insurance coverage of hearing healthcare would help alleviate the problem of access to and affordability of hearing aids and ACDHH issued a position statement in January 2013 supporting that coverage. If hearing aids become available OTC, insurance companies will be less likely to include hearing aids as a covered benefit, more people who currently receive a hearing aid insurance benefit will suffer, and fewer people will have access to prescription hearing aids.

**SUMMARY:** Governmental policy decision-making should be evidence-based and not unduly influenced by market forces. Only one recent study<sup>3</sup> has examined the efficacy of a few OTC hearing aids and the results cannot be generalized to the public. Disruption can create positive changes in an industry, however allowing hearing aids to be sold OTC jeopardizes the health and safety of the consumer with hearing loss.

ACDHH supports:

- insurance coverage of hearing aids
- hearing aid tax credits
- greater transparency of hearing aid prices and the costs of various services to include unbundling
- accountability of the practitioner to the consumer

602-364-0990 TTY \* 602-542-3323 V/VP \* 800-352-8161 V/TTY \* 602-542-3380 FAX \* info@acdhh.az.gov



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- longer trial periods
- direct access to hearing healthcare providers by Medicare and Medicaid beneficiaries
- teleaudiology
- the removal of proprietary locks on programming and adjustment of hearing aids
- easier comparison of hearing aid features across brands

We applaud the national attention being given to this critical issue and support a broader awareness of the prevalence and effects of hearing loss. Furthermore, we encourage a concentrated effort to increase consumer education of these issues. We believe that with a coordinated effort between industry, the hearing healthcare profession, government policymakers, researchers, consumer advocates, non-profit organizations and other stakeholders, these objectives can and will be accomplished over the next decade and greater access to and affordability of hearing aids will result. Consumer health and safety remain at the forefront of our concerns and we will not waiver from our mission to improve the quality of life of people with hearing loss through proven methods. Speculative experiments in hearing healthcare like this one could cause great harm to consumers and that is not something we can support.

#### Notes

1. [http://www.audiologist.org/\\_.../Chronic%20Disease%20and%20Co-Morbidity%20with%20Hearing%20Loss.pptx](http://www.audiologist.org/_.../Chronic%20Disease%20and%20Co-Morbidity%20with%20Hearing%20Loss.pptx)
2. Tedeschi/Kihm (2016). <http://www.hearingreview.com/2016/12/implications-counter-approach-hearing-healthcare-consumer-study/>.
3. Humes LE et al. (2017). The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial. *Amer J Aud*, 26, 53-79.
4. <http://www.healthyhearing.com/report/52742-Otc-hearing-aids-survey-says-consumers-aren-t-sold>
5. <https://www.everydayhearing.com/hearing-technology/articles/hearables/>

*This position paper was unanimously adopted by the ACDHH Board of Commissioners as ACDHH's formal opinion on this issue at the Board of Commissioners meeting on Thursday, May 11<sup>th</sup>, 2017.*