



AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

American Speech-Language-Hearing Association
Statement for the Record for the Health Subcommittee of the
Energy and Commerce Committee
Regarding Over-the-Counter Hearing Aids (H.R. 1652)

While the American Speech-Language-Hearing Association (ASHA) continues to maintain that the best model of hearing health care features audiologists and consumers collaborating on treatment options, it recognizes instances where that model can be modified. There may be advantages to making hearing aids directly available to some consumers with mild hearing loss. Less costly over-the-counter (OTC) hearing aids could serve as an early gateway for users with mild hearing loss to explore whether they could eventually adapt to hearing technology without significant financial outlay. It is already the case that consumers with perceived mild hearing loss can seek amplification on their own, without professional involvement, by purchasing unregulated personal sound amplification products or other products and devices that are indirectly marketed for hearing loss.

ASHA recommends the following changes H.R. 1652:

- restrict OTC hearing aids to mild hearing loss;
- establish safe levels of gain and output (power) for these hearing aids;
- ensure that OTC hearing aids are only available for adults;
- establish a means for collecting information on consumer safety and other potential complaints;
- require labeling that strongly recommends seeking audiologic diagnostic and rehabilitative services; and
- require labels that provide consumers with warning signs for conditions that require medical treatment.

Furthermore, ASHA strongly encourages the Subcommittee to take a more holistic approach to access to and affordability of hearing aids. A parallel effort must be undertaken to ensure the establishment of both public and private insurance coverage for patients with hearing loss who do not benefit from OTC hearing aids. These additional categories of services would include coverage of the professional auditory rehabilitation services of an audiologist that would allow a person with hearing loss to maximize their communication abilities with amplification. Without meaningful coverage of all hearing health care services for all individuals with hearing loss, there is a high probability that these individuals will inappropriately self-prescribe OTC hearing aids and fail to receive appropriate care; thereby, not achieving the sufficient benefit from OTC hearing aids.

ASHA supports efforts by Congressman Gus Bilirakis related to Medicare coverage of professional services provided by an audiologist, and is working with him and his staff for reintroduction of this legislation in this Congress. We urge the Subcommittee to consider and pass this legislation, which would allow Medicare beneficiaries to receive coverage of these important hearing health care services.

We respectfully request that the Subcommittee move cautiously forward. Hearing loss is permanent, and over-amplification can cause further damage to the ear and greater degrees of hearing loss. Conversely, under-amplification may cause the consumer to become frustrated and leave their hearing problems untreated. Therefore, inappropriately chosen OTC hearing aids present a significant health risk to individuals. By limiting the legislation to mild hearing loss and requiring data collection on consumer safety and complaints, the U.S. Food and Drug Administration (FDA) can

better assess both the positive and negative implications of a “do-it-yourself” model for hearing health care.

Background

Hearing loss is a medical condition that can be categorized by which part of the auditory system is damaged. There are three types of hearing loss: conductive, sensorineural and mixed. Some conductive loss can be corrected by medical or surgical intervention and include such conditions as a build-up of wax in the ear, ear infections, or a perforated eardrum. Sensorineural hearing loss involves damage to the inner ear or a nerve pathway from the inner ear to the brain. This type of hearing loss cannot be medically or surgically corrected, and is the most common type of permanent hearing loss. Sensorineural loss can occur through aging, illness, head trauma, or exposure to loud noise. An individual can experience both conductive and sensorineural hearing loss at the same time, which is referred to as mixed hearing loss.

Individuals cannot self-diagnose the cause or the magnitude of their hearing loss nor can they self-treat the hearing disability that results from hearing loss. Access to devices used to treat moderate to profound hearing loss should remain under FDA regulation, and access to necessary professional services should not be eliminated for these individuals through a “do-it-yourself” OTC option. Individualized treatment and counseling are necessary to most effectively address the multi-faceted and disabling effects of this chronic health condition. Given that hearing loss is a medical condition with the potential for other health implications, it stands to reason that medical devices that are intended to treat moderate to profound hearing loss should be made available only after an evaluation and consultation with an audiologist.

Hearing aids are not analogous to OTC reading glasses. They are more analogous to contact lenses. Much like an individual would not place contacts in their eyes without the appropriate prescription, one should not use hearing aids without first understanding the magnitude of their hearing loss and, particularly, the difficulties related to understanding speech in background noise, which can only be addressed through a professional audiologic evaluation. Those in favor of OTC hearing aids believe that a device alone can ameliorate hearing loss. This is far from the truth. A device alone cannot and does not address the hearing health care needs of a consumer. Without professional involvement, consumers run the risk of either exacerbating their condition with over-amplification or becoming frustrated with the device due to under-amplification, which may result in a decision to not seek further professional care for their hearing loss. Both pose serious health and safety risks to the consumer.

While the legislation being considered is intended for adults, there are no safeguards in the legislation to ensure that children do not have access to OTC hearing aids. **It is imperative that OTC hearing aids should not be permitted for children.** Children treated with these devices are at risk for severe complications due to untreated ear disease; inadequate amplification **leading to severe, permanent, and disabling language impairment**; as well as additional hearing loss due to inappropriate levels of amplification. The effects of hearing loss on children are far greater than those of adults.

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 191,500 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students. For more information, contact Ingrida Lusic, ASHA's director of federal and political advocacy, at ilusic@asha.org.