S.670/H.R.1652, Over the Counter Hearing Aid Act

We would like to thank the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) for providing an open forum to discuss S.670/H.R.1652, the Over-the-Counter (OTC) Hearing Aid Act, and to balance consumer health and safety issues with consumer interests in greater competition and innovation. As clinical audiologists, who can relate to both sides of the issue, this is both exciting and concerning. We are aware of the need for prompt attention to the significant health implications of untreated hearing disorders. It is encouraging to know that there is sincere concern and efforts to help the hearing impaired population but also concerning that the newly proposed do-it-yourself (DIY) hearing aid delivery system could result in negative unintended outcomes for consumers.

Evidence shows that the vast majority of individuals perceiving a hearing loss present other red flag conditions that require medical attention and that would go undetected with an OTC approach. As licensed (laws established to protect the public) practitioners, we adhere to best practices. Hearing loss is a medical condition with many different causes. We understand and manage a complex health condition every day. We not only evaluate and treat tinnitus, hearing loss and balance problems, we help patients manage a variety of other medical problems. Patient medications are reviewed to determine if they are contributing to the hearing loss or balance problem. Referrals are made to cardiology when we diagnose a low frequency hearing loss. Dermatology referrals are made for skin lesions on the ear (3rd most common location for skin cancers). Otolaryngology referrals are made for ear diseases which may require medical surgery or treatment that can cure their hearing loss. Psychology referrals are made for depression caused by tinnitus (perception of noise or ringing in the ear) or aging. Internal Medicine referrals are made for depression, cognitive function impairment, and pulsatile tinnitus just to name a few.

A hearing aid is a widget and the success they have comes from the provider who adheres to best practices (MarkeTrak IX). Treatment goes well beyond the utilization of the device. Any technology that goes in our bodies warrants extra care. These hearing devices need cleaning, reprogramming, repairing, and wireless pairing to ensure the patient is receiving appropriate benefit thus improving patient satisfaction.

There is no evidenced-based research to support consumers self-diagnosing and self-treating hearing loss. Recent studies have shown that the majority of people are not able to appropriately self-diagnose their degree and type of hearing loss. As a result, consumers will risk missing or delaying medical intervention or will purchase hearing devices that are not appropriate for their loss. Very often we see patients that come to us because they have a hearing problem and it turns out that they have excessive wax buildup in their ears. Once we clean the patient's ears their hearing returns to normal. A consumer, in this case, would have most likely chosen to purchase an inappropriate OTC hearing aid. We know that subsequently this consumer would have been dissatisfied with the OTC hearing aid performance and choose not to wear it, driving down both consumer satisfaction and successful adoption.

Consumers already have access to low-cost hearing aids. Personal Sound Amplification Products (PSAPs) have been on the market for several years and have not significantly improved consumer adoption. Internationally, in Japan and South Korea, it has been proven that the PSAP/OTC DIY model has failed and that the deregulation of hearing aids has led to lower consumer satisfaction and lower adoption rates (Hearing Industry Association (HIA), 2016). Provider dispensed care extends the life of the product by offering preventative maintenance and appropriate device reprogramming as the consumer's hearing loss progresses compared to the DIY approach where the consumer purchases cheap PSAPs/OTCs more frequently thus spending more money over a long period of time.

We agree with HIA's statement that if an OTC hearing aid category is created, consumers are free to mis-diagnose, mis-treat, and mis-manage their care on their own. These OTC products must be very specifically labeled to include strong recommendations and warning labels. They should NOT be utilized by children. If a hearing loss is detected the consumer should seek a comprehensive hearing evaluation by a licensed professional. The OTC devices should have limitations in gain and output. In addition, any online or self-hearing assessment tool should NOT be considered a hearing "test" but be utilized merely as a screening tool to estimate the degree of hearing loss. We ask that strong provisions are put in place to minimize the impact on patient safety and outcomes.

Thank you for your consideration. Feel free to contact us if you have any questions or need further information.

Melissa Segev, Au.D.
Annapolis, MD

Briana Holtan, Au.D.
Baltimore, MD