

By Barbara Kelley



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Ringling in the New Year with Good News

Barbara Kelley is executive director of HLAA and can be reached at bkelly@hearingloss.org. Follow Barbara on Twitter @BKelley_HLAA

While almost everyone typically slows down as we enter the holiday season, HLAA, other organizations and federal agencies were hard at work for people with hearing loss. Here is what happened and why.

On December 1, 2016, Senate Bill S.9 was introduced by Senators Elizabeth Warren (D-Mass.) and Chuck Grassley (R-Iowa) to provide for the regulation of over-the-counter (OTC) hearing aids. The “Over-the-Counter Hearing Aid Act of 2016” would make certain types of hearing aids available over the counter and remove many of the barriers for consumers who could benefit from hearing aids.

HLAA is a supporter of the bill, along with AARP, the Consumer Technology Association (CTA), Bose Corporation, and the Gerontological Society of America (GSA). Senators Warren and Grassley have plans to reintroduce the legislation in the new 2017 Congress. All reports point to solid bipartisan support. You can find the full text of the bill on hearingloss.org.

Why Over-the-Counter Hearing Aids?

HLAA is the only consumer-group sponsor of the National Academies of Sciences, Engineering, and Medicine (NAS) study and resulting report *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. The NAS report outlined 12 recommendations that would make hearing health care more affordable and accessible for consumers.

HLAA has come out in support of all the recommendations contained in the report, and Recommendation 7 specifically states, “The Food and Drug Administration [FDA] should establish a new category of over-the-counter (OTC) wearable hearing devices.”

The Warren-Grassley bill is one step toward making hearing devices more affordable and accessible.

While the Warren-Grassley bill uses the term “hearing aids,” the final name and definition of what qualifies as an OTC device is determined by the FDA. Whether they are called OTC hearing aids, OTC wearable hearing devices or something else, they would be only for adults with mild-to-moderate hearing loss. If the bill passes, or if the FDA creates this new category before a bill passes, HLAA will work with industry and the FDA to ensure these products are safe and effective; are clearly labeled with information important to consumers, including realistic expectations and whether or not they meet voluntary industry standards; have clear return policies; ensure that the devices are compatible with other technologies and hearing assistive technology; and outline any red flags that point to the need to see a physician before purchase.

HLAA will further work to ensure consumers are educated about these and all hearing amplification devices. This aligns with both Recommendation 11 of the NAS report to “Improve publicly available information on hearing health” and HLAA’s mission to “Open the world of communication to people with hearing loss by providing information, education, support and advocacy.”

HLAA has long valued the expertise and care that audiologists and hearing instrument specialists provide to people seeking help for their hearing loss. We expect many people will continue seeking the skill and expertise of a hearing professional. HLAA’s hope is that the availability of these OTC devices will intrigue people who would not otherwise get this help. These devices could even end up being

purchased through an audiologist or hearing aid specialist. Further, once people have tried an OTC device they might look to upgrade to traditional hearing aids through the care of an audiologist.

To give consumers access to the entire spectrum of hearing assistive devices, we hope to see audiologists turn to transparent pricing that unbundles the cost of the hearing aid from the cost of services. We would also like audiologists to incorporate open programming systems, allowing them to adjust any type of hearing aid, anytime.

When only 20 percent of people who need hearing aids purchase them, something must change. Quality OTC devices were not even possible 20 years ago, but with the technology available today, and the greater innovation that is sure to come, it is possible to build a more affordable, better quality, basic hearing device. We believe the hearing health care industry is at a crossroads; we must seize this opportunity to ensure that people who want to do something about their hearing loss are not prevented from doing so due to cost or accessibility.

HLAA's goal is to see more people seek help for any degree of hearing loss. HLAA supports the availability of OTC devices as a first step that consumers with mild-to-moderate hearing loss can take to address their hearing loss earlier and more conveniently. We believe audiologists still provide the gold standard of care for people with hearing loss and that complex fittings should be performed only by a hearing professional. However, giving consumers a choice to use less expensive and more readily-available devices will be a huge step toward greater awareness about the need for good hearing health care and greater

adoption of hearing aids and hearing technology.

December 7, 2016

Not only was December 7 the 75th Commemoration of Pearl Harbor, the day that lives in infamy in the history of our country, it was the marking of another historic move made by the FDA.

At the NAS open meeting in Washington, DC, Eric Mann, M.D., Ph.D., otolaryngologist and clinical deputy director for the FDA, announced that the FDA does not intend to enforce the requirement that individuals 18 years and older receive a medical evaluation or sign a waiver prior to purchasing most hearing aids. The announcement is in direct response to Recommendation 3 of the NAS report to "Remove the [FDA's] regulation for medical evaluation of waiver." We applaud the FDA's decision to remove this requirement and believe it is a step forward to remove barriers and make hearing health care for consumers more affordable and accessible.

In making the announcement, Dr. Mann also said that the FDA is considering another of the report's recommendations which would create a new category for over-the-counter hearing devices.

A New Day and Age

When HLAA began 37 years ago, these moves to put the person with hearing loss at the center of care was not in the collective thinking of our culture. Times have changed. Technology has exploded. Remember when computers and cell phones were used only by people who could afford them or understood how to use them? These devices were disruptive innovations that changed the market on who could afford and use them.

The time has come for hearing aids to join the list of market disruptors.

In addition, patients now play a greater role in their health care. How many of us go to the doctor equipped with information and suggesting remedies to our physicians to consider because we know what is best for us? The team approach should be the same way for hearing health care. People with hearing loss deserve choices and solid information to make decisions along with their health care providers.

There's More to Hearing Loss Than Getting a Hearing Aid or Cochlear Implant

HLAA is in this for the long haul. The NAS report substantiates what we have been working for—adherence to the Americans with Disabilities Act and other legislation, better acoustics in buildings, assistive listening systems in public places, insurance and Medicare coverage for hearing aids and auditory rehabilitation, more information about hearing loss available to the general public, and ensuring that primary care providers screen for and discuss hearing loss.

What Can You Do?

Stick with us. Tell your friends and family to join HLAA. When our membership grows, so does our influence. When our staff meets with legislators, industry and policy makers, my experience is that HLAA is highly regarded and what we say on behalf of our members really matters. I am proud of our work and our membership. Thank you. These are exciting times. **HLM**