HLAA and ADA Address Questions from Members of Congress Regarding the OTC Hearing Aid Act

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The Hearing Loss Association of America (HLAA) and the Academy of Doctors of Audiology (ADA) have received numerous requests from members of Congress to provide information to members of Congress regarding the Over the Counter Hearing Aid Act of 2017. We are pleased to provide information and resources to provide Congress with concise and clear information, so that Members can make an informed decision regarding this important legislation.

Question: How will consumers be able to safely self-identify and navigate the OTC hearing aid system?
Answer:

1. *Effective Self-Identification Tools Are Now Available*. New tools allow consumers to self-identify "red flag" and other serious medical conditions of the ear. For example, the Consumer Ear Disease Risk Assessment (CEDRA), developed by Dr. David Zapala, is designed to effectively assist consumers in making informed decisions about the need for further medical evaluation. An upcoming article in the Journal of the American Medical Association (JAMA), attached, clearly demonstrates the effectiveness and reliability of the CEDRA tool in assisting consumers in self-identifying the need for a medical evaluation.

   Additionally, home hearing tests such as the FDA-approved iHEAR, as well as screening tools such as Jacoti Hearing Suite and the National Hearing Test, can be used by consumers to help determine if an OTC product may be suitable for their type and degree of hearing loss.

2. *The FDA and leading authoritative bodies have determined that a medical evaluation prior to the purchase of hearing aids does not improve outcomes.* The National Academies of Science, Engineering and Medicine (NASEM), in its landmark study, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*, concluded that, despite the fact that anecdotal evidence shows that the waiver is widely utilized, there is no pattern of negative outcomes to consumers. The Committee went on to recommend that the FDA eliminate the requirement for consumers to obtain a medical evaluation (or sign a waiver) prior to the purchase of hearing aids.[1]

   On December 7, 2016, the FDA announced that it was voluntarily stopping enforcement of the medical evaluation requirement because it has "little to no clinical benefit[2]."

[1] http://www.nap.edu/read/23446/chapter/2#5
[2] https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm532005.htm

3. *Hearing aids have been available direct to consumers for decades from mail order and online sources without the requirement of a hearing test or medical evaluation.* For example, Hearing Help Express, based in Illinois is currently marketing its online hearing aids for those with severe hearing loss: https://www.hearinghelpexpress.com/hearingaids. Its ability to do so has been tested in the courts. The courts upheld online hearing aid sales without professional intervention, in 2006, with the case: *Missouri Board of Examiners for Hearing Instrument Specialists v. Hearing Help Express, Inc.* The 8th District Court of Appeals overturned the Missouri (state) ban on online hearing aid sales without prior fitting or testing, noting that the existing FDA regulations (allowing for widespread use of the waiver for the required medical evaluation) preempted the state ban. The Court's opinion was as follows:

   "We conclude that the requirements of Mo. Stat. § 346.110(1) are in addition to the federal requirements applicable to the sale of hearing aids and that they directly relate to the safety of consumers and the effectiveness of the devices. The Missouri statute therefore "interfere[s] with the execution and accomplishment of the objectives of the FDA's hearing aid regulation," 45 Fed.Reg. at 67327, and must be deemed preempted by the MDA (Medical Devices Amendment)."[3]

   As consumers already have direct-to-consumer Internet access to hearing aids and similar unregulated technologies, the creation of a regulated OTC class will not increase existing risks to the public. It will actually improve transparency and allow consumers to make informed decisions about their hearing loss treatment options.

4. *OTC hearing aids will encourage more people to prioritize hearing health, including screening and testing.* Only 15 percent of adult consumers with hearing loss obtain hearing aids today. The single greatest barrier to hearing aid adoption is awareness. Hearing health is not prioritized to the same degree as vision and dental health are, among other health care providers or insurers, despite the high risks associated with untreated hearing loss. Most physicians do not include hearing screening or hearing testing in their annual, preventive care visits.

   What's more, Medicare, the largest payer of health care in the elderly, does not include a hearing screening or evaluation in the "Welcome to Medicare" evaluation that every new Medicare beneficiary has available to them when they enter the payment system. This lack of attention to prevention and early detection of hearing loss, by the broader health care community is a major barrier to the ultimate adoption of amplification and other treatments.

   The widespread introduction of OTC hearing aids will bring with it unprecedented opportunities to educate and inform consumers about the importance of hearing health and early intervention for hearing loss. As a result, more consumers will undoubtedly seek out both self-screening tools, and professional audiologic evaluations in an effort to optimize their hearing.

[3] http://caselaw.findlaw.com/us-8th-circuit/1432490.html

Question: Why does making OTC hearing aids available to those with perceived mild-to-moderate hearing loss pose no increased safety risk compared with allowing them for a perceived mild loss only?
Answer:

1. *OTC hearing aid safety risk does not increase with the severity of hearing loss.* The degree of hearing loss is not an indicator of the type of hearing loss, or whether or not it requires medical intervention. From a medical and surgical perspective, if OTC hearing aids are safe for mild loss, they are equally safe for mild-to-moderate hearing loss.[4]

2. *From a clinical perspective, there is no difference between a hearing aid for mild hearing loss and a hearing aid for moderate hearing loss.* Hearing loss is on a continuum and there is no exact point where the perception of mild hearing loss ends, and where moderate begins. By the same token, the same hearing aids are typically used to treat mild and moderate hearing loss using various adjustments. There are also differing scales and thresholds for what is considered mild and moderate hearing loss.[5]

3. *Evidence supports the safety and efficacy of OTC hearing aids for mild-to-moderate hearing loss.* As renowned otolaryngologist, epidemiologist and gerontologist, Dr. Frank Lin, noted in his testimony to Congress on May 2, 2017, evidence supports the use of OTC hearing aids by consumers with mild-to-moderate hearing loss. The most compelling scientific study to date, consisting of a definitive NIH-funded randomized controlled trial, by Larry Humes et al.[6] demonstrated that consumers can self-fit OTC hearing aids—and that these hearing aids provide benefits to consumers with mild-to-moderate hearing loss.

   According to Dr. Lin, "There is absolutely no medical reason or rationale to consider limiting the intended use of OTC hearing aids (and hence the FDA performance standards of these devices) to only those individuals with a mild hearing loss."

   The U.S. Food & Drug Administration (FDA), which is arguably one of the most risk-averse agencies within the federal government, has affirmed its ability to regulate OTC hearing aids to ensure their safety and efficacy for consumers with mild-to-moderate hearing loss. Dr. Jeffrey Shuren provided testimony to the Energy & Commerce Health Sub Committee on May 2nd, indicating that the FDA has no concerns with the OTC Hearing Aid Act or the FDA's ability to execute its requirements should it be enacted.[7]

4. *Retailers already market and sell FDA-registered hearing aids directly to consumers, even consumers with perceived severe hearing loss, and they have been doing so for decades over the internet and through the mail (as noted with the Hearing Help Express reference above).*

   Yet, the outspoken opponents of the introduction of OTC hearing aids for those with mild-to-moderate hearing loss, have not fought against online hearing aid sales with the same fervor. Could it be because online retailers make up such a small percentage of total hearing aid sales (and thus only represent a small *competitive* threat to the manufacturers and providers who now

[4] Frank Lin, M.D., oral testimony to Energy & Commerce Health Sub Committee on May 2, 2017.
[5] http://www.asha.org/public/hearing/Degree-of-Hearing-Loss/, http://www.hear-it.org/Defining-hearing-loss
[6] Humes, L. E. et al. The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial. American journal of audiology 26, 53-79, 2017.
[7] Jeffrey Shuren, M.D., director, Center for Devices and Radiological Health, Food & Drug Administration, oral testimony to the Energy & Commerce Health Sub Committee on May 2, 2017

raise concern over allowing those with moderate hearing loss to benefit from provisions in the OTC Hearing Aid Act)?

ADA and HLAA contend that concerns raised about the use of OTC hearing aids by those with moderate hearing loss are not about concerns for patient outcomes, the concerns are about changing the present closed market to an open market competitive system, and with it the possibility of a threat to the stream of income to those who benefit most from this system s it now exists. The opposition in effect is willing to sacrifice innovation and patient choice to protect the status quo. The May 30th Washington Insider piece sums it up well: http://www.businessinsider.com/washington-is-broken-even-without-trump-2017-5

Question: Why is there no need to further study the issue of OTC Hearing Aids before moving forward with enacting the legislation?
Answer:

1. *The evidence supporting the introduction of OTC hearing aids into the market place is well documented.* Audiologist and researchers, Dr. Gail Gudmundsen and Dr. Mead Killion submitted citizen's petitions to the FDA in 2003—nearly 15 years ago, requesting that it take identical actions to those now included in the legislation.[8] The issues surrounding risks and benefits of OTC hearing aids have been widely debated since that time. Meanwhile, technological advances in hearing aids and accessories have dramatically improved their efficacy and reliability.

   Consumers have also evolved—health care consumers today are tech savvy and accustomed to driving their care decisions. They view their relationship with health care providers as very much a partnership as opposed to having a plan of care dictated to them by a physician-custodian.

   Independent bodies, such as the President's Council of Advisors on Science and Technology (PCAST) and NASEM (formerly known as the Institute of Medicine), have spent years now studying the issue to come up with objective recommendations. The National Institute of Health has funded at least two studies, released in 2017 that show both the safety and efficacy of OTC hearing aids for the treatment of mild-to-moderate hearing loss, but also just as importantly, the ability of consumers to self-identify conditions that warrant medical intervention.

2. *Direct-to-consumer hearing aids and amplification products have a longstanding history in the marketplace, without credible evidence of harm.* Consumers already have access to direct-to-consumer hearing aids and other technologically similar amplification products—and they are making decisions about these products today without the type of transparent information that the OTC Hearing Aid Act will require.

   The OTC Hearing Aid Act will not de-regulate hearing aids sold over the counter—it will direct the FDA to modify existing regulations to ensure that these products can be delivered safely to consumers. The bill will require explicit labeling and mechanisms for consumer reporting for adverse effects, and will further ensure that OTC hearing aids are consistently dispensed across the nation, so that consumers, providers and manufacturers are clear, and so that there are no state regulatory or statutory barriers to access, which may be designed to funnel consumers to a narrow set of legacy providers, unnecessarily.

[8] http://leader.pubs.asha.org/article.aspx?articleid=2292324; https://www.fda.gov/ohrms/dockets/dailys/03/aug03/081203/03p-0362-cp00001-vol1.pdf; https://www.fda.gov/ohrms/dockets/dailys/03/aug03/081203/03p-0363-cp00001-vol1.pdf

3. *The FDA has considered removing the medical evaluation requirement for the past quarter century.* As early as 1993, it became clear that the medical clearance requirement was simply not functioning as the FDA intended. In his 1993 testimony to the U.S. Senate, Dr. David Kessler, then Director of the FDA, reported that the medical waiver provision was used far more extensively than expected and did not fulfill its original mission. He further noted that an audiological evaluation would suffice and testified that state licensure ensures competency and that consistent training should replace medical clearance.

   The American Academy of Audiology (AAA), the Academy of Doctors of Audiology (ADA), and the American Speech-Language Hearing Association (ASHA), the three leading national professional societies representing audiologists, have all advocated for the removal of the medical evaluation requirement for the past 25 years.

4. *Every delay has consequences, and the risk of non-treatment of hearing loss may be significantly higher than the risk of self-treatment.* While the support for OTC hearing aids has reached a new high as more solid evidence has emerged about the safety and efficacy of an OTC hearing aid model, perhaps some of the most compelling evidence for OTC hearing aids are the studies that show the significant risks associated with untreated hearing loss, including increased risks of depression, dementia, and falls—the leading cause of traumatic injury and death for older adults.

   According to a recent report from the Centers for Disease Control (CDC), hearing loss is the third-most common chronic physical condition among adults in the United States after hypertension and arthritis, and is twice as likely as diabetes or cancer.[9] Hearing loss is associated with low employment rates, lower worker productivity, and high health care costs. In addition, adults with hearing loss are more likely to have low income and be unemployed or underemployed than adults with normal hearing.

5. *There are not enough hearing health care providers to meet the need, and time is of the essence if we are to provide alternative models of care to meet demand.* The 10.8 million U.S. adults who currently use hearing aids only account for 26% of those who could benefit from hearing amplification. There are fewer than 25,000 providers who dispense hearing aids (including audiologists, physicians and hearing aid specialists). Practically speaking, there are an average of 1,700 hearing impaired consumers for every single licensed dispenser today—and there will be 10,000 consumers turning 65 years old each and every day from now until 2030.[10] The number of providers is not growing—but the number of consumers who will need hearing aids is growing dramatically. The current provider-driven model will not be able to keep up with the demand for hearing healthcare services in the years to come. Introducing OTC hearing aid options for consumers with mild-to-moderate hearing loss will ease pressure on provider-reliant networks, allowing audiologists to focus on providing specialized treatment for complex cases.

[9] https://www.cdc.gov/mmwr/volumes/66/wr/mm6605e3.htm
[10] http://www.pewresearch.org/fact-tank/2010/12/29/baby-boomers-retire/