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Statement of the Academy of Doctors of Audiology Supporting the Over-the-Counter Hearing Aid Act of 2017

Introduction

The Academy of Doctors of Audiology (ADA) supports H.R. 1652/S.670, the Over-the-Counter Hearing Aid Act of 2017, and commends Representatives Blackburn and Kennedy, and Senators Grassley and Warren for their foresight in introducing this legislation, which if enacted, will remove unnecessary and burdensome barriers to hearing care for millions of Americans.

Congress should enact this legislation to allow adult consumers with mild-to-moderate hearing loss to purchase some types of hearing aids over the counter (OTC), and eliminate the requirement that adult consumers obtain a medical evaluation or sign a waiver in order to acquire these hearing aids. This landmark legislation will also direct the U.S. Food and Drug Administration (FDA) to issue regulations containing safety and labeling requirements for this new category of OTC hearing aids, and to update FDA draft guidance on Personal Sound Amplification Products (PSAPs).

The Over-the-Counter Hearing Aid Act is consistent with ADA's longstanding position that the FDA should implement recommendations from the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering, and Medicine (NASEM), which have both independently suggested establishing a regulatory framework that permits OTC hearing aid sales and abolishes medical clearance requirements for adults, in order to improve access to life-changing hearing technologies for consumers nationwide.

Hearing Health Care Challenges in the United States

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.[1] 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.

[1] https://www.cdc.gov/mmwr/volumes/66/wr/mm6605e3.htm

Unclear pathways to care, inconsistent and incongruent state and federal laws and regulations, and ambiguous classifications regarding emerging amplification and assistive technologies, create confusion and impede access to care for many Americans. Therefore, Congress' commitment to work with the FDA to streamline and modernize hearing aid regulations is both warranted and welcomed.

Hearing technology has advanced significantly over the past several years, and today's hearing aids are more sophisticated, user-friendly, and powerful than ever before. Unfortunately, hearing aid usage rates have not improved over the same time period; far too many Americans live with hearing loss and treatment is too expensive. Only about 14 percent of the 37 million Americans with hearing loss actually use a hearing aid – and one major reason for this treatment gap is cost. Prices for different types and models of hearing aids can vary, but the average cost of a device, with services, is about $2,400. Most people need two hearing aids, one for each ear, and devices typically need to be replaced every five years. Several prominent national organizations and federal governmental bodies, including Congress,[2] have sought to address the high cost of hearing care over the past few years through administrative and legislative efforts, designed to make hearing aids and/or associated hearing health care services more affordable and accessible.[3]

According to the Better Hearing Institute, the consumer-facing arm of the Hearing Industries Association, 33% of individuals with hearing loss have incomes of less than $30,000 per year and 68% of those with hearing loss cite financial constraints as a core reason they do not use hearing aids.[4]

Access to care is another key barrier to treatment for hard of hearing adults. The 10.8 million U.S. adults who currently use hearing aids only account for 26% of those who could benefit from hearing amplification.[5] 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[6]. 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.

In ADA's estimation, 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, even among other health care providers, 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

[2] https://www.healthypeople.gov/2020/topics-objectives/topic/hearing-and-other-sensory-or-communication-disorders, https://www.nidcd.nih.gov/workshops/accessible-and-affordable-hearing-health-care/2009, https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf, http://www.nap.edu/catalog/23446/hearing-health-care-for-adults-priorities-for-improving-access-and, https://www.consumer.ftc.gov/articles/0168-buying-hearing-aid

[3] 114th Congress: Hearing Aid Assistance Tax Credit Act (H.R. 1882/S. 315), Medicare Hearing Coverage Act (H.R. 1653), Help Extend Auditory Relief Act (H.R. 2748), Audiology Patient Choice Act (H.R. 2519), Medicare Audiology Services Enhancement Act (H.R. 1116) http://www.nap.edu/catalog/23446/hearing-health-care-for-adults-priorities-for-improving-access-and, https://www.consumer.ftc.gov/articles/0168-buying-hearing-aid 114th Congress: Hearing Aid Assistance Tax Credit Act (H.R. 1882/S. 315), Medicare Hearing Coverage Act (H.R. 1653), Help Extend Auditory Relief Act (H.R. 2748), Audiology Patient Choice Act (H.R. 2519), Medicare Audiology Services Enhancement Act (H.R. 1116)

[4] http://www.hearingaidtaxcredit.org/faqs.cfm

[5] http://hearinghealthmatters.org/hearingeconomics/2015/assessing-the-validity-of-marketrak-ix-adoption-rates/

[6] http://www.pewresearch.org/fact-tank/2010/12/29/baby-boomers-retire/

them when they enter the payment system.[7] 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 OTC Hearing Aid Act Offers a Responsible Solution for Millions of Americans

The ADA believes that a widespread commitment to prevention and early diagnosis could have a significant impact on the social stigma associated with hearing loss. Enactment of the Over the Counter Hearing Aid Act, and the widespread availability of OTC hearing aids for use by those with mild-to-moderate hearing loss will help integrate the importance of evaluation and treatment into the health care landscape, and individuals will begin to see hearing health as a greater health care concern.

Safety and Efficacy

The ADA is pleased that the Over the Counter Hearing Aid Act mandates the Health and Human Services Secretary, in conjunction with the FDA to complete the following:

> (A) include requirements that provide reasonable assurances of the safety and efficacy of over-the-counter hearing aids;
> (B) include requirements that establish or adopt output limits appropriate for over-the-counter hearing aids;
> (C) include requirements for appropriate labeling of the over-the-counter hearing aids, including how consumers may report adverse events, any conditions or contraindications, and any advisements to consult promptly with a licensed physician; and
> (D) describe the requirements under which the sale of over-the-counter hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

The OTC Hearing Aid Act will not de-regulate hearing aids. Rather, it will re-regulate them in a way that standardizes safety, efficacy, consumer protection and access for all Americans. The availability of FDA-registered OTC hearing devices will allow consumers to make better informed decisions about their treatment options, and will also facilitate increased competition, enhance quality and improve transparency in the purchase of direct-to-consumer hearing amplification products. Opening the market to FDA-regulated OTC hearing aids is a responsible means of providing consumers, with mild-to-moderate hearing loss, with more affordable, more efficient access to care than exists now.

The ADA recommends that over-the-counter (OTC) hearing aids be very specifically labeled and include a strong recommendation that a patient seek a comprehensive audiologic evaluation from an audiologist or physician prior to purchasing any device for the treatment of hearing loss, especially if the patient exhibits any of the warning signs of ear disease (tinnitus, dizziness, drainage from the ear, sudden hearing loss, asymmetric hearing, foreign body in the ear, cerumen impaction, pain, congenital or traumatic deformity of the ear).

[7] 1 Chapter 16. (2008). In Medicare Benefit Policy Manual (pp. 1-28). Marblehead, MA. Retrieved October 29, 2015 from http://www.cms.gov/. 2 Chapter 15. (2008). In Medicare Benefit Policy Manual. Retrieved October 29, 2015, from www.cms.gov. 3 Your Medicare Coverage. (n.d.). Retrieved October 29, 2015, from https://www.medicare.gov/coverage/preventive-visit-and-yearly-wellness-exams.html

With regard to amplification gain and output, appropriate safety measures should be undertaken for all amplification devices including hearing aids, smart phones, headphones, hearables, assistive listening devices (ALDs), and PSAPs. The ADA is pleased that the legislation includes requirements that establish or adopt appropriate output limits for OTC hearing aids.

ADA suggests that one potential mechanism for ensuring that OTC hearing aid products are confined to use by the intended consumers (those with mild-to-moderate hearing loss), is to implement amplification gain and output threshold specifications that stay within the ranges that will only provide a meaningful benefit to those with mild-to-moderate hearing loss.

While a comprehensive evaluation and treatment by an audiologist remains the recommended standard of care, it is not the chosen pathway to care for every consumer. There is a preponderance of data available today that demonstrates that, when it comes to hearing loss, the risk of non-treatment may be greater than the risk of self-treatment.[8] Untreated hearing loss is associated with serious health risks, such as depression, dementia, and social isolation. Seniors with untreated hearing loss are also at a higher risk of falls – the leading cause of fatal injury among older adults. The tremendous co-morbidities and maladies associated with hearing loss are well documented,[9] as are the benefits of amplification in improving quality of life and mitigating serious health conditions.[10] Therefore, the public will be best served if the FDA allows hearing devices to be available to consumers over the counter, just as they are already available over the Internet.

There are promising new tools being developed that offer promise for consumers 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.[11] 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.

State consumer protection laws offer specific recourse and information to consumers regarding the requirements for the sale and return of hearing aids. Existing product liability laws and regulations for the manufacture of hearing aids offer sufficient protections for consumers, in terms of product safety.

Exclusion of Children

The Over the Counter Hearing Aid Act specifically and appropriately excludes children. OTC hearing aids are not designed for or indicated for use in children. Children inappropriately treated with these devices are at risk for severe complications due to untreated ear disease. In addition, children inappropriately treated may be at risk for speech or language delays, poor school performance and/or cognitive delay.

Regulatory precautions should be taken to ensure that OTC hearing aids do not fall into the hands of children; however, there is no evidence that indicates any demand for adult hearing aids for use in children, and there is no reason to believe that adult hearing aids would be purchased OTC by or for children.

Low income families have far more options available to address hearing loss in children than adults. The Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Program provides a national mandate for hearing

[8] http://www.ncbi.nlm.nih.gov/books/NBK233884/ , http://ncpssmfoundation.org/Portals/0/hearing-loss.pdf

[9] http://www.ncbi.nlm.nih.gov/pubmed/24588528

[10] http://www.betterhearing.org/sites/default/files/quality_of_life.pdf, http://www.ncbi.nlm.nih.gov/pubmed/26480972

[11] https://phhp-slhs.sites.medinfo.ufl.edu/files/2012/11/UF-IOM-DISEASE-RISK-PRESENTATION-.pdf

aid coverage for children under 21[12]. EPSDT is the child health component under Medicaid (42 U.S.C. 1396a(a)(10)(A); 1396d(a)(4)(B); 1396d(r)). EPSDT services are mandated for children from birth through age 21. A state must provide to Medicaid beneficiaries under age 21 hearing services, including appropriate screening, diagnostic, and treatment, including hearing aids. Specifically, EPSDT covers the following medically necessary audiological services for children who are at risk for hearing impairment: Audiological assessments; Hearing aid evaluation; and Medically necessary hearing aid services, including hearing aids and hearing aid accessories and services. These hearing services must be provided periodically at intervals that meet reasonable standards of medical practice. Medicaid coverage requirements will go a long way to ensure that families would not seek OTC hearing aid options to try to treat children.

Just as with OTC medications and other FDA-regulated OTC products, OTC hearing device warning labels should include information detailing contra-indications for use in children. FDA warning labels are shown to be largely effective in deterring the use of OTC products in children when they pose dangers. The ADA acknowledges that there have been instances where OTC products were used by, and caused harm to, children. For example, Reye's Syndrome, a rare but serious condition in children, has been linked to aspirin use. Even so, the benefits of selling aspirin over the counter far outweigh the potential risks to children. Similarly, the low potential for contra-indicated OTC hearing aid use by children presents a low risk, which does not outweigh the potential benefits of OTC hearing aids for the millions of American adults with hearing loss who would achieve clinical and functional benefits from their use.

Consistency, Clarity and Continuity in Rulemaking

The ADA stipulates that there are risks with self-treatment by adults who suspect that they have hearing loss, including overlooking conditions that warrant medical intervention. However, the ADA contends that in the current regulatory environment, those risks are already being taken by consumers with either limited information--or worse yet, misinformation. The Over the Counter Hearing Aid Act will bring about much needed consistency, clarity and continuity for the sale of hearing aids to adults across the United States.

Hearing aids have been widely purchased over the internet and through the mail for decades without government interference. 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)."*[13]

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. Audiologists will continue to play a critical role in a system that includes OTC hearing aids.

[12] http://www.hearingloss.org/content/medicaid-regulations

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

Many audiologists will elect to offer these products through their practices, just as they currently offer traditional hearing aids. Many consumers will seek audiology services after purchasing OTC devices, regardless of whether they purchase them online, over-the-counter, or at the audiologist's office.

In addition to creating a consistent regulatory framework for the direct-to-consumer purchase of hearing aids, the Over the Counter Hearing Aid Act will also permanently remove archaic medical evaluation requirements, which channel consumers towards a narrow set of providers, and pose undue interference in clinical practice. Existing FDA regulations for the requirement for a medical evaluation prior to the purchase of a hearing aid, or the use of a waiver for adults to opt-out of the evaluation[14], was first promulgated in 1977 and can be found in Section 21 CFR 801.421.

The regulations state:

(1) Except as provided in paragraph (a) (2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.[15]

(2) Waiver to the medical evaluation requirements. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement.[16]

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.[17]

Anecdotal evidence also indicates that use of the waiver is widely utilized. The ADA is unaware of any *credible* research demonstrating that the medical evaluation requirement actually leads to the identification and treatment of medical conditions that would not otherwise be identified appropriately by the consumer.

On June 2, 2016, the NASEM released a landmark report, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*, which affirms this recommendation. The NASEM Committee stated, *"In examining the Food and Drug Administration's (FDA's) requirements for physician evaluation prior to obtaining hearing aids, the committee finds no evidence that the required medical evaluation or waiver of that evaluation provides any clinically meaningful benefit. In weighing the rareness of the medical conditions, the incidence of hearing loss in adults, the widespread need for hearing health care, and the wide use of the medical waiver, the committee recommends removing this regulation to serve consumers' best interests."*[18]

Evidence suggests that more than 90 percent of adults with hearing loss have sensorineural hearing loss that is not due to a medically and surgically treatable condition.[19] It should also be noted that hearing loss is

[14] Code of Federal Regulations Title 21: Chapter 1, Subchapter H, Section 501 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=801&showfr=1&subpartnode=21:8.0.1.1.2.7

[15] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=801.421

[16] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=801.421

[17] https://archive.org/stream/hearingaidmarket00unit/hearingaidmarket00unit_djvu.txt

[18] http://www.nap.edu/read/23446/chapter/2#5

[19] http://audiology-web.s3.amazonaws.com/migrated/SafetyofAudiologyDirAcc.pdf_5386cdbf06edb4.53934137.pdf

identified through diagnostic audiologic testing, not through a medical evaluation.

The FDA agrees that the medical evaluation requirement should be removed. As of December 7, 2016, the FDA has voluntarily ceased enforcement of the medical evaluation requirement, for adults over 18 years of age, because "it offers little or no meaningful clinical benefit."[20] Unfortunately there are still many state laws that contain medical clearance requirements, which mirror the FDA regulation. Congress should, therefore, take immediate action to eliminate the medical evaluation requirements (including the use of a waiver) for adults pursuing amplification devices across the 50 states and U.S. territories by enacting the Over the Counter Hearing Aid Act.

PSAP Guidance

The Over the Counter Hearing Aid Act will direct the Secretary to update and finalize the draft guidance of the Department of Health and Human Services entitled, ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (PSAPs).'' This is important since it is no longer possible to distinguish unregulated and regulated hearing devices by intended use. Nor is it always possible to use technological features or performance to differentiate hearing aids from non-regulated products such as PSAPs.

The FDA states, *"A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing. Hearing aids are usually programmed to address an individual's degree of hearing loss across sound frequencies to improve speech intelligibility. Additionally, hearing aids may be coupled acoustically or wirelessly to external electronic products such as televisions, MP3 players, and telephones. A hearing health professional (such as an audiologist or a hearing aid dispenser) is usually required to program and optimize the performance of hearing aids with these more complex features.*

In contrast, a Personal Sound Amplification Product or PSAP is a wearable electronic product that is not intended to compensate for impaired hearing, but rather is intended for non-hearing impaired consumers to amplify sounds in certain environments, such as for hunting or other recreational activities. PSAPs typically are simpler sound amplification devices with fewer features and less functionality than hearing aids, although some of the technology and functionality of hearing aids and PSAPs may be similar."[21]

Contrary to the FDA's statement, many of today's PSAPs are technologically equivalent to hearing aids.[22] Further, technologies will undoubtedly continue to emerge and advance for both classifications of devices. Attempts to categorize or differentiate these products merely by technological features are counterproductive.

The purposeful allowance of an OTC category of hearing devices, for adults, will streamline regulations in a manner that encourages all hearing device manufacturers to register and market their products transparently and responsibly, therefore increasing consumer choice and aligning the products' intended and actual uses. The availability of OTC hearing devices will allow the public to make better informed decisions about their treatment options, and will also likely lower the cost of hearing aids for the hearing impaired.

[20] https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm532005.htm

[21] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm373461.htm

[22] http://hearinghealthmatters.org/hearinprivatepractice/2015/boundary-areas-between-psaps-and-hearing-aids-part-1/

Additional Considerations for Congress to Ensure Access to Audiology Services Under Medicare

Treatment for hearing loss can be complex and include anatomical, physiological, emotional, psychological, social, and vocational issues that need to be addressed for any given patient. Moreover, clinical treatment for hearing loss is most often focused on improving patients' communicative ability. That "treatment" goes well beyond the utilization of any device, be it a hearing aid, an assistive listening device (ALD), a PSAP, or a smart phone application. Functional improvement in communication is the primary goal for patients with hearing loss.

Providing consumers with mild-to-moderate hearing loss with streamlined access to OTC hearing aids is a step forward, but it alone does not complete the journey to better outcomes for patients. Efforts in Congress to improve access to audiology services for Medicare patients are underway — and will be integral to widespread patient success with OTC hearing aids. Many older adults, in particular, will require audiologic care for successful treatment. We are pleased to report that the Audiology Patient Choice Act will be reintroduced in the 115th Congress by Representative Tom Rice (R-SC).

The Audiology Patient Choice Act will modernize existing Medicare regulations that undermine access and affordability for many older Americans. For example, Medicare Part B patients are currently required to obtain a medical order before Medicare will cover an audiologic evaluation from a licensed audiologist. There is absolutely no sound rationale for this approach now that the medical evaluation requirement has been voluntarily removed by the FDA, because it offers no benefit to the patient.

Medicare Part B patients are also shuffled back and forth between providers in an inefficient process, because audiologists are only recognized under Medicare Part B as diagnosticians, despite the fact that they are licensed to provide Medicare-covered rehabilitative services. The Audiology Patient Choice Act, if enacted, will alleviate many of these barriers within the Medicare system, and allow Medicare Part B beneficiaries to have the same access to audiology care as Medicare Advantage beneficiaries and most Americans do.

Technological advances have made it possible for audiologists to utilize telehealth for hearing screening, hearing aid counseling and aural rehabilitation and some hearing aid fitting, orientation and follow-up services. Unfortunately, licensure and reimbursement models have not kept pace with this technology. The success of the Over the Counter Hearing Aid Act will be greatly fortified if Congress also takes action to enact the Audiology Patient Choice Act to ensure that consumers have access to comprehensive diagnostic and rehabilitative audiology services.

Conclusion

According to statistics compiled by the National Institute on Deafness and Other Communication Disorders (NIDCD), 37.5 million American adults, aged 18 and older, report some form of hearing loss. However, only 30% of adults aged 70 and older and 16% of adults aged 20 to 69 who could benefit from wearing hearing aids have ever used them.[23]

Lack of awareness, among consumers and the medical community, regarding the importance of protecting and optimizing hearing over a lifetime, is well documented, as are associated co-morbidities and the substantial risks of non-treatment of hearing disorders.

[23] https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing

Most consumers wait 7-10 years to seek treatment after they discover that they have a hearing loss. For many it is cost, for others access—and still more don't recognize the importance of optimizing their hearing over their lifetimes.

The regulatory environment has struggled to keep pace with rapid advances in hearing amplification technology. Creating an OTC hearing device market will foster competition, broaden consumer choice, improve affordability, and accelerate future innovation. OTC products will also provide an additional entry point that may guide consumers into the hearing healthcare system sooner, so that they can get the help that they need.

The ADA and its members seek expanded access for consumers to audiology services. We strive to accomplish this goal through the advancement of practitioner excellence and high ethical standards in the provision of quality audiologic care. The Over-the Counter Hearing Aid Act will help to facilitate these objectives and is consistent with the ADA's mission and philosophy. ADA further encourages Congress to consider a holistic approach to hearing healthcare that will also ensure streamlined access to audiology services.

In summary, the removal of the medical clearance requirement and the availability of a regulated OTC hearing devices, which include appropriate labeling and safety measures, will expand access to quality hearing health products and services, reduce duplicative costs, and remove unnecessary, non-beneficial barriers to care. For this reason, the ADA is pleased to support the Over the Counter Hearing Aid Act.

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