446 East High Street, Suite 10
Lexington, KY 40507
866-493-5544
www.AuDiologist.org

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD, 20832
Docket Number: FDA-2015-N-4602

RE: Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids

To Whom It May Concern:

The Academy of Doctors of Audiology (ADA) commends recent efforts by the Food and Drug Administration (FDA) to *"better understand how the agency can appropriately balance patient safety while encouraging advancements in hearing aid technology and access to these devices in the United States."*[1]

To that end, the ADA was pleased to deliver a presentation during the FDA-hosted public workshop, *Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids*, held on April 21, 2016.

- ADA Presentation Slides April 21, 2016
- FDA Workshop Webcast
- Transcript

The ADA appreciates the opportunity to provide the enclosed supplemental comments that support recommendations to modernize the FDA regulations and improve access to safe, effective, and affordable hearing health care.

According to statistics compiled by the National Institute on Deafness and Other Communication Disorders (NIDCD), 37.5 million adults aged 18 and older in America report some form of hearing loss. However, only 30 percent of adults aged 70 and older and 16 percent of adults aged 20 to 69 who could benefit from wearing hearing aids have ever used them.[2]

[1] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm480239.htm
[2] https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing

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.

The cost of treating hearing loss is an irrefutable barrier for many. Several prominent national organizations and federal governmental bodies[3] have sought to address the high cost of hearing care over the past few years. Additionally, there are currently at least five pieces of legislation in the U.S. Congress, which were introduced for the purpose of making hearing aids and/or associated hearing health care more affordable and accessible.[4]

Unclear pathways to care, due to ill-defined professional roles, inconsistent and incongruent state and federal laws and regulations, and ambiguous definitions with regard to emerging technologies, further impede access to care for many Americans. Therefore, the FDA's commitment to streamline and modernize hearing aid regulations is both warranted and welcomed.

The ADA and its members are dedicated to fostering expanded access 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 ADA's mission aligns with the FDA's stated desire to ensure to preserve patient safety and accelerate innovation. With these objectives in mind, the ADA offers the following recommendations to the FDA:

Recommendation 1: ***Eliminate the medical evaluation requirements for adults, including the use of a waiver, as currently required by the Food and Drug Administration. We believe this important change will result in increased access and reduced costs, without sacrificing successful outcomes or patient safety.***

The Food and Drug Administration 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[5], 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.[6]

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[3] 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

[4] 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

[4] 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)

[5] 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

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

(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.[7]

The regulations require that the labeling for hearing aids include the following statements:
Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.[8]

Relevant History:
The FDA first developed regulations for the sale of hearing aids in 1977, in reaction to U.S. Senate hearings, which exposed rampant marauding by unscrupulous hearing aid dealers who preyed on elderly consumers. When the FDA first developed regulations for hearing aids, the necessity of a medical evaluation seemed appropriate, as there was the assumption that hearing aid dealers were not reliably identifying underlying disease, or the necessity to seek medical counsel or intervention in certain situations.

Audiologists began routinely dispensing hearing aids during the 1980s, as the audiology profession continued to evolve. During the 1990s, audiology transitioned from a master's-level profession, to a clinical doctoring profession, with the Au.D. as its distinctive designator. Today, a doctorate degree is the first professional degree conferred for clinical audiology practice and is required for new licensees in all 50 states and the District of Columbia. Thus, the need for separate medical clearance is no longer necessary as audiologists are trained in identifying underlying causes of hearing loss that require medical attention. Furthermore, over the past 40 years, state licensure laws and state consumer protection laws have been enacted and strengthened for audiologists and other hearing aid dispensers.

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 Food and Drug Administration, 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.[9]

[7] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=801.421
[8] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=801.420
[9] https://archive.org/stream/hearingaidmarket00unit/hearingaidmarket00unit_djvu.txt

Although the FDA took meaningful steps towards eliminating the medical clearance requirements during the 1990s, proposed rulemaking to eliminate the medical clearance requirement was never enacted, and the proposed change was abandoned in 2001.[10]

Rationale for Change:

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 patient. There is no evidence that the required medical evaluation, as a condition of purchasing a hearing aid, improves the outcome for patients seeking hearing health care. The FDA should, therefore, take immediate action to eliminate the medical evaluation requirements for adults pursuing amplification devices, including the use of a waiver.

On June 2, 2016, the National Academies of Sciences Engineering and Medicine (NASEM), formerly known as the Institute of Medicine (IOM), released a landmark report, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability (NASEM Report)*, 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."*[11]

The NASEM Report specifically included the following recommendation:
"The Food and Drug Administration should remove the regulation that an adult seeking hearing aids be required to first have a medical evaluation or sign a waiver of that evaluation and should ensure consumers receive information about the medical conditions that could cause hearing loss through continued inclusion of that information in hearing aid user instructional brochures."[12]

Evidence suggests that more than 90 percent of older individuals with hearing loss have sensorineural hearing loss not due to a medically and surgically treatable condition.[13] It should also be noted that hearing loss is identified through diagnostic audiologic testing, not through a medical evaluation.

At a minimum, given audiologists' education, training and qualifications, the regulation should be amended to allow a medical *or audiologic* evaluation by a physician *or an audiologist*. Audiologists are wholly qualified to refer to medical physicians, when needed. The rate of reported malpractice by audiologists is significantly lower than that of medical doctors. Professional and medical liability insurance rates for audiologists are among the lowest of any professional doctoring profession. Rates are determined by the level of risk associated with a particular health care discipline (including frequency and severity of claims).[14]

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[10] http://hearinghealthmatters.org/hearingeconomics/2011/regulation-of-hearing-aids-in-the-us-part-6-its-a-long-story/
[11] http://www.nap.edu/read/23446/chapter/2#5
[12] http://www.nap.edu/read/23446/chapter/2#6
[13] http://audiology-web.s3.amazonaws.com/migrated/SafetyofAudiologyDirAcc.pdf_5386cdbf06edb4.53934137.pdf
[14] 2003 Annual Report, National Practitioner Data Bank, US DHHS

Medical clearance serves as an anti-competitive instrument that unduly forces consumers towards care from narrow set of providers, and costs the patient and society a tremendous amount of money and time in unnecessary duplicative services. The elimination of the current requirement of a medical evaluation by a physician should serve to improve access *and* reduce costs. Models of hearing care suggest that both the time and cost involved of accessing physicians for the purpose of obtaining the medical evaluation can be obstacles to patients.

Bratt, et al.[15] diagramed the additional burdens, in terms of time and costs, by requiring a patient to seek a medical evaluation as part of the hearing care process. The direct costs to the patient, and the indirect costs to a third party payer, increase with any additional steps in the process. Porter[16] noted that the value of medical care is based on the outcomes relative to the costs, with costs referring to the total costs over the full cycle of care for a patient's condition, not the cost of individual services. Thus, the value of hearing care, including amplification, is related to the total of all costs to the patients, including the cost associated with the medical evaluation. These additional costs serve to reduce the perceived value of hearing care to the patient.

Arguments citing patient safety as the rationale for retaining the regulatory requirement for a medical evaluation have no merit. Under the existing medical evaluation requirements, it is far easier for a patient to purchase a hearing aid online than it is for them to purchase it through a licensed audiologist.

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 FDA regulations preempted the state ban. The opinion of the court is 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)."[17]

In summary, there is no evidence that the medical clearance requirement offers any benefit to the consumer. The regulation imposes an unnecessary barrier to care for the consumer and poses undue interference in clinical practice. Anecdotal evidence indicates that use of the waiver is widely utilized. Therefore, the ADA respectfully requests that the FDA remove the medical evaluation requirement at its earliest opportunity.

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[15] Bratt GW, Freeman B, Hall JW, and Windmill IM: The audiologists as entry point to health care: Models and perspectives. Seminars in Hearing, 17:227-234, 1996.
[16] Porter ME: What is value in health care? N Engl J Med. 2010 Dec 23;363(26):2477- 81.
[17] http://caselaw.findlaw.com/us-8th-circuit/1432490.html

Recommendation 2: ***The ADA recommends that the FDA purposefully allow Class I hearing aids and/or another similar FDA-regulated hearing technology, whose intended use is compensating for impaired hearing, to be available for over-the-counter sale to adults, without the requirement for consultation with a credentialed or licensed dispenser.***

The FDA regulations define a hearing aid as *"any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing."*[18]

(a) *Identification.* A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400).

(b) *Classification.* (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9.[19]

The ADA recognizes that 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 personal sound amplification product (PSAP), or a smart phone application. Functional improvement in communication, therefore, is often the primary goal for patients with hearing loss.

For these reasons, the ADA recommends that over-the-counter (OTC) products 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). The ADA also recommends labeling that states that the device is a "non-surgical, air conduction hearing aid intended to address mild to moderate hearing loss."

With regard to amplification gain and output, appropriate safety measures should be undertaken for *all* amplification devices including hearing aids, smart phones, headphones, hearables, ALDs, and PSAPs. The ADA strongly recommends that all amplification devices be required to adhere to defined maximum output thresholds.

[18] 21 CFR 801.420

[19] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=874.3300

Rationale for Change:
Class I medical devices do not require premarket approval and are in the same general classification with tongue depressors, surgical tools, and other low risk devices and equipment. Consumers can already directly purchase FDA-regulated hearing aids online as discussed on page five (5). Technologically similar, unregulated products are also readily available over the counter or over the Internet without professional intervention or regulation.

The Spring 2016 issue of Hearing Health Magazine[20] illustrates the dilemmas faced by consumers and hearing health care professionals in the current regulatory climate. PSAP utilization is being discussed and advocated routinely in hearing health and consumer forums, proving the validity and regularity of downstream and off-label usage of non-regulated OTC devices in treating hearing loss.

The FDA states, *"To clearly distinguish between PSAPs and hearing aids, the FDA relies on the intended use of each product to determine whether it is a medical device or an electronic product. The intended use may be established by labeling or promotional materials. Labeling or promotional materials that make claims, or include language that suggests the use of a PSAP for hearing impaired consumers, establish an intended use for the electronic product as a medical device, which would therefore be subject to the regulatory requirements for a hearing aid, as described in this guidance."*[21]

Turning just a few pages in the same issue of Hearing Health Magazine (p. 23[22] and p. 27[23]), brings the reader to carefully crafted PSAP advertisements. While these advertisements may technically comply with the FDA regulations, they are clearly intended, by their placement and position, to reach hearing health care providers and hearing impaired consumers.

With regard to amplification technology, "intended use" represents a line in the sand that has been washed away by the tides of innovation. It is no longer possible to distinguish unregulated and regulated 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.*

[20] https://view.publitas.com/p222-4764/hearing-health-spring-2016-issue/page/20-21
[21] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm373461.htm
[22] https://view.publitas.com/p222-4764/hearing-health-spring-2016-issue/page/22-23
[23] https://view.publitas.com/p222-4764/hearing-health-spring-2016-issue/page/26-27

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."[24]

Contrary to the FDA's statement, many of today's PSAPs are technologically equivalent to hearing aids.[25] 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. Hopefully, it will also make products more affordable and accessible to the hearing impaired.

The ADA stipulates that there are risks with self-treatment, including overlooking conditions that warrant medical intervention. However, we contend that in the current regulatory environment, those risks are already being taken with either limited information--or worse yet, misinformation.

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.[26] There are tremendous co-morbidities and maladies associated with hearing loss[27] and more data is being published daily. The benefits of amplification in improving quality of life and mitigating serious health conditions are also well documented.[28] 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.

The ADA recommendations to allow OTC hearing device sales are consistent with both NASEM's 2016 recommendations and recommendations provided by the President's Council of Advisors on Science and Technology (PCAST) in October 2015.[29]

The NASEM Report specifically states, *"The committee identified the need for FDA to create a category of OTC wearable hearing devices intended for use by individuals with mild or moderate hearing loss. These devices would need to meet specific safety and quality standards and labeling specifications. This regulatory approach would be similar to FDA's regulatory approach of creating separate device classification regulations for prescription eyeglasses and reading glasses (a parallel drawn here specifically*

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

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

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

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

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

[29] https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf

to the regulatory approach and not the performance of the devices). A category of OTC wearable hearing devices could provide an additional, easy-to-access option with the potential for lower cost to meet the hearing needs of adults with mild or moderate hearing loss."[30]

In summary, 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. As consumers already have OTC/Internet access to hearing aids and similar unregulated technologies, the creation of a regulated OTC class will not increase existing risks to the public.

Conclusion

The ADA applauds the FDA for its leadership in re-evaluating the existing regulatory environment for the manufacture and sale of hearing aids. The effort to fulfill the FDA's purpose to facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S should be noted.

The removal of the medical clearance requirement and the availability of a regulated OTC hearing device, which includes appropriate gain and output thresholds and labeling that encourages an audiologic evaluation prior to purchase, will expand access to quality hearing health products and services, reduce duplicative costs, and remove unnecessary, non-beneficial barriers to care.

It would be selfish for the ADA to advocate for maintenance of the status quo, given the information available. The ADA recognizes the need to improve adoption and treatment rates for the 37.5 million Americans with hearing loss, without sacrificing patient safety or efficacy. Our mission is consistent with the principles and objectives outlined by the FDA, and we are committed to working with the FDA to achieve these common goals.

Sincerely,

Rita Chaiken, Au.D., President

[30] http://www.nap.edu/read/23446/chapter/2#9