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May 17, 2017

Federal Trade Commission
Office of the Secretary
Secretary Donald S. Clark
600 Pennsylvania Ave., NW
Washington, DC 20580

Re: Notice of Workshop and Requesting Public Comments; Hearing Health and Technology Workshop, Project No. P171200

Secretary Clark:

The Academy of Doctors of Audiology (ADA) extols efforts by the Federal Trade Commission (FTC) to examine competition, innovation, and consumer protection issues related to hearing health and technology. In support of that purpose, the ADA was pleased to participate in a panel discussion, during the FTC-hosted public workshop, *Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care*, held on April 18, 2017.

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.[1]

Inconsistent and incongruent state and federal laws and regulations serve to unduly limit competition, restrict consumer choice, and impede access to care. Today, even the most astute and determined consumers are often stymied by the lack of reliable information about the cost and quality of hearing technologies and services.

The cost of treating hearing loss is an irrefutable barrier for many Americans. Several prominent national organizations and federal governmental bodies, including the FTC, have sought to address the prohibitive cost of hearing care over the past few years. The FTC's commitment to ensure that consumers have access to truthful and non-misleading information about hearing health products and services is commendable.

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

To that end, the ADA appreciates the opportunity to provide supplemental information in response to questions put forth by FTC for public comment.

1. **What information about hearing technology and related health care services is available to consumers who may be shopping for these goods and services? How useful do they find this information?**

There is a glut of information about hearing technology and related health care services available to consumers—unfortunately there is also an overabundance of conflicting and misleading information in the marketplace.

According to, *Hearing Healthcare for Adults: Priorities for Improving Access and Affordability*, published by the National Academies of Sciences, Engineering and Medicine (NASEM), "The hearing health care system is largely unknown to or difficult to penetrate by the general public. Routes for accessing hearing health care go through both business-driven and health care-driven pathways for individuals to gain access to the services and technologies best suited to meet their needs."[2]

Patients rely heavily on the advice of their primary care physician when it comes to selecting a hearing health care provider—and the American Association of Family Physicians (AAFP) recommends that primary care physicians screen persons older than 60 years for hearing loss during periodic health exams.[3] However, studies show that as many as 85 percent of patients report that their primary care provider has neither asked about, nor assessed their hearing.

Consumers, who suspect they have hearing loss, respond to advertisements, solicit feedback from friends and family, search internet resources, and seek physician referrals in order to identify a hearing health care provider. Research indicates considerable confusion among consumers about the qualifications and services provided by audiologists versus hearing aid dealers.

Some unprincipled hearing aid dealers deceive the public by using inflated titles and credentials to create the perception that they are bona fide health care professionals, rather than salespeople or technicians. There is likewise a pattern of unscrupulous behavior among hearing aid dealers who use the word *audiology* in their company names, when their businesses do not employ audiologists. This practice has become so prevalent that the term "fraudiology" has been coined, and is widely used to describe attempts to lure unsuspecting customers by falsely advertising that there is an audiologist on staff, and available to treat patients

Hearing aid dealers who mislead consumers are not a new phenomenon—nor are they news to the FTC. The 1977 FTC report, *United States of America Before Federal Trade Commission Report of the Presiding Officer on Proposed Trade Regulation Rule for the Hearing Aid Industry [16 c. F. R. Part 4 4 0] [public record 215-44]*, offers a retrospective look at this challenge.

[2] Hearing Health Care for Adults: Priorities for Improving Access and Affordability, Blazer et.al, 2016, p.29
[3] http://www.aafp.org/afp/2012/0615/p1150.html

Evidence presented to the FTC four decades ago, noted that "*Salesmen and salesman-trainees are generally taught not to present themselves as salespersons but rather as experts on hearing, hearing loss, hearing aids, and other corrective measures. They will many times introduce themselves using a title that states or implies professional status and impressive rank: such titles are many and varied but among those most commonly used are "hearing aid specialist," "hearing aid audiologist," "hearing aid counselor," "hearing aid consultant," and "certified hearing aid audiologist."*[4]

Specifically, the FTC's Presiding Officer, G. Martin Shepherd found, *"There is substantial evidence that sellers, through their approach, titles, business names, advertisements, and office manners do often attempt to be recognized by the public as hearing care professionals, rather than as hearing aid sellers."*

Finally, Mr. Shepherd concluded in the report that *"such other words implying expertise as "professional," "otometrist," and "audioprosthologist," are currently being used to some extent by dealers is just cause for serious concern."*

Since the 1977 FTC report, many states have prohibited the use of the title "audioprosthologist" by hearing aid dealers, for the very reasons that Mr. Shepherd raised. While the profession of audiology has evolved from a master's level to a clinical doctoring profession over the past 40 years, the elementary training, education, and qualifications required to become a hearing aid dealer have not changed. And, the pattern of attempts by hearing aid salespeople to misrepresent their qualifications for profit continue unabated.

Just as consumers find difficulty differentiating among providers, they also struggle to acquire credible information about hearing technology and associated products. According to a 2013 Pew Research Center study, more than 70 percent of internet users seek health information online annually, and approximately 20 percent of internet users have consulted online reviews of particular drugs or medical treatments, doctors or other providers, and hospitals or medical facilities.[5]

A Google search for hearing aids brings up more than 14 million results. While there are some excellent first-page results from the Mayo Clinic and the National Institute on Deafness and Other Communication Disorders (NIDCD), many of the highest-ranking results are associated with entities who cloak their bias[6] in an effort to steer consumers toward their affiliated hearing aid products and retailers. Only the most discerning consumers are able to consistently obtain impartial hearing technology reviews and objective information about hearing health care online.

The ADA is pleased that the President's Council of Advisors on Science and Technology (PCAST), NASEM, the U.S. Food and Drug Administration (FDA), the FTC, members of Congress, and other agencies have intensified efforts to ensure accessible, affordable hearing health care--and to improve publicly available information on hearing health for consumers.

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[4] https://www.ftc.gov/system/files/documents/reports/report-presiding-officer-proposed-trade-regulation-rule-hearing-aid-industry/r511006_-_report_of_the_presiding_officer_on_the_proposed_trade_regulation_rule_for_the_hearing_aid.pdf (p.p. 62, 129, 149)

[5] http://www.pewinternet.org/2013/01/15/health-online-2013/

[6] https://www.hearingtracker.com/blog/hearing-aid-reviews-real-consumer-feedback/

The ADA believes that increased transparency and choice in the hearing aid market, will reduce frustration, confusion and anxiety among consumers, and increase hearing aid adoption among the millions of Americans who could benefit from treatment, but who have thus far been unable to successfully navigate the hearing health care system in order to obtain it.

2. How are hearing aids and other forms of hearing technology commonly distributed and sold? To what extent are new sellers of hearing devices, as well as new methods of distribution and sales, affecting the range of goods, services, and prices available to consumers?

Together, audiologists and hearing aid dealers are responsible for the delivery of 90 percent of the hearing aids dispensed to consumers. Physicians dispense a limited number of hearing aids, and a small percentage of hearing aids are sold over the Internet and through mail order.

More than 95 percent of hearing aids sold worldwide are manufactured by six companies, collectively known as *The Big 6*. Most private label brands, including Costco's "Kirkland" brand, are also manufactured by Big 6 firms. In addition to manufacturing the vast majority of hearing instruments dispensed to consumers, the Big 6 also operate extensive vertical channels that include hearing aid retail clinics and franchises, management networks, buying groups, and third party administrators. These enterprises cement Big 6 market shares, limit provider choice, and deter competition.

All of the Big 6 companies offer hearing technologies, of similar quality and features, in similar price ranges. Despite the fact that hearing aid adoption rates among hearing impaired consumers hover at around 26 percent[7], there is seemingly no market incentive for Big 6 manufacturers to aggressively compete against each other for new customers, or to increase unit sales volume by lowering prices or increasing advertising. Current market dynamics allow legacy manufacturers to achieve excellent profits through high unit prices, low penetration (fewer units), and virtually no threat from new competitors.

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. However, hearing aid usage rates have not improved over the same time period. One major reason for this treatment gap is cost.

Alternative technologies such as personal sound amplification products (PSAPs) and smart phone applications, though not regulated for use to treat hearing loss, are often prescribed by audiologists and/or utilized by consumers for that purpose. These disruptive technologies, some of which have been available for many years, provide convenient, low-cost amplification alternatives for consumers, but, because they are unregulated, they can potentially pose additional risks. New sellers are poised to have a significant impact on the range of goods, services, and prices available to consumers if traditional market channel barriers, including regulations, are appropriately modified to accommodate new methods of distribution, including the direct-to-consumer delivery of technologies and tele-audiology services.

There is a tremendous unmet need for value-based alternatives for both providers and patients. Independent audiology practices currently pay significantly more for hearing aids than their public sector

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

(VA, Medicaid etc.) or retail sector (Big Box) counterparts. In the ADA's view, the only way to lower the costs of devices is through greater competition in the marketplace.

Historically, audiologists and hearing aid dealers have packaged hearing technology and hearing services into a bundle, and the consumer paid one up-front price for hearing aid technology and ongoing care. Today, many audiology practices are moving towards "unbundled" pricing models, which allow patients to pay as they go, rather than purchasing recurring services that may not be utilized. While transparency can be achieved in either bundled or unbundled models of care, the value of professional audiologic evaluation and treatment services seems to be more readily recognized by the patient when services are decoupled from hearing technology products. Regardless of the model, the ADA recommends that providers offer itemized pricing for services and technologies, and pricing structures that are straight forward and easy for consumers to understand.

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 one-quarter of hearing impaired adults who could benefit from hearing amplification.[8] There are fewer than 25,000 providers who dispense hearing aids (including audiologists, physicians, and hearing aid dealers). 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.[9] The number of providers is not growing—but the number of consumers who will need hearing aids is growing dramatically.

Aging consumers will push up demand and reduce supply for all types of health care, and particularly hearing health care. 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.[10]

Every member of the hearing health care team must practice at the full extent of their license, if hearing health care providers are to be able to effectively serve older adults. Unfortunately, audiology services under Medicare (Part B) are arbitrarily constrained, creating an unnecessary barrier to care that channels beneficiaries to a limited number of legacy providers, and requires patients to undergo an expensive, time-consuming, multi-step, and multi-stop process to obtain coverage for diagnostic and treatment services.

In order to obtain coverage, Medicare Part B currently requires patients to acquire a physician order prior to seeking Medicare-covered services from an audiologist, even though there is no order requirement per statute, and even though audiologists are already responsible for medical necessity. Further, Medicare Part B only recognizes/reimburses audiologists for diagnostic services, notwithstanding the fact that audiologists are licensed and trained, in every U.S. state and territory, to provide a wide-range of Medicare-covered treatment services.

[8] http://hearinghealthmatters.org/hearingeconomics/2015/assessing-the-validity-of-marketrak-ix-adoption-rates/
[9] http://www.pewresearch.org/fact-tank/2010/12/29/baby-boomers-retire/
[10] https://www.cdc.gov/mmwr/volumes/66/wr/mm6605e3.htm

Other federal agencies recognize that a mandatory visit to a physician's office, for adult patients who suspect that they have a hearing problem, has proven to inflate the cost of care without improving outcomes. Federal programs, including, but not limited to, the Veteran's Administration (VA), the Federal Health Benefit Plan (FEHBP), and many Medicaid programs allow patients to seek treatment directly from audiologists, without a physician order. The U.S. Food and Drug Administration (FDA) also recently took action to remove the medical evaluation requirement for adult patients seeking hearing aids, because it provides, "little to no clinical benefit."[11]

Most private insurers, including most Medicare Advantage plans, by virtue of their coverage policies, encourage patients to seek direct care from audiologists, and allow audiologists to be reimbursed for *all* of the covered services that they are licensed to provide (both diagnostic and treatment services). Audiologists are subjectively excluded from the appropriate classification under Medicare Part B, creating an artificial market advantage for other providers.

Even if Medicare Part B is modernized, the current provider-driven model will not be able to keep up with the demand for hearing healthcare services in the years to come. The introduction of OTC hearing aid options for adult consumers with mild-to-moderate hearing loss would ease pressure on provider-reliant networks, allowing audiologists and other providers to focus on providing specialized treatment for more complex cases.

3. How are innovations in hearing technology – including hearing aids, personal sound amplification products (PSAPs), and other devices and platforms – changing the competitive landscape and expanding the range of viable options to ameliorate hearing loss? What other innovations and developments are on the horizon?

Innovations in hearing technology will undoubtedly change the competitive landscape in years to come. Traditional hearing aid manufacturers, consumer electronics companies, app developers, and hearing science and medical researchers are already shaping the future of hearing health care. One example of a particularly exciting innovation in hearing technology was recently introduced by a company called Ear Lens, which has developed a hearing aid that incorporates a lens surgically which rests on the ear drum and uses light to activate the user's natural hearing system.

In addition to advancements in amplification devices (hardware) such as the ability to stream audio signals, reduce noise and feedback, and increase battery life, there have also been tremendous advancements in software technology, which allow for remote or self-programming and adjustments. Many PSAPs are technologically equivalent to hearing aids, and offer many of the same features. Smart phone applications now offer a robust array of amplification options that are free, fast, user-friendly, and of good quality.

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

There have also been recent innovations in online and app-based hearing test kits, which have made tremendous advancements in efficacy. At least one, iHEAR, has already been FDA-approved for home use. Medical and pharmaceutical innovations under development will also unquestionably help prevent and mitigate hearing loss in the years to come.

One of the most important not-so-recent advancements in technology is the use of tele-audiology. Tele-audiology involves the use of telecommunication and information technology to provide clinical audiology services remotely. Using tele-audiology, an audiologist in Michigan can assess and treat a patient anywhere in the country, or around the world.

The U.S. Veterans Administration has pioneered the practice of tele-audiology, beginning with pilot studies that commenced in 2009. Today, tele-audiology is being used by the VA quite effectively to conduct assessments and provide a full range of rehabilitative services, including remote hearing aid programming and fitting, and aural rehabilitation and counseling services. The VA tele-audiology program provided more than 15,000 tele-audiology encounters in FY 2014, making tele-audiology one of its top 15 telehealth programs.

VA audiologists, as federal employees, are not stymied by state licensure laws, which hinder audiologists in other practice settings from effectively delivering tele-audiology services across state lines. The ADA noted with pleasure, FTC's 2016 comments to the Delaware Board of Speech/Language Pathologists, Audiologists and Hearing Aid Dispensers encouraging regulatory practices that remove existing restrictions on clinical services performed using telecommunication tools to improve access, consumer choice and competition.[12]

4. **To what extent are hearing aids, PSAPs, or "hearables" interoperable with different adjustment or programming tools, as well as other technologies and communication systems? What standard setting efforts are underway and how might standard setting further competition and innovation (or fail to do so)?**

The FDA sets standards for hearing aid manufacturing and labeling to help ensure safety and efficacy for these products. The Consumer Technology Association (CTA) has recently developed voluntary standards for personal sound amplification products (PSAPs) for the same purpose. The Federal Communications Commission (FCC) sets standards that ensure hearing aid compatibility with telephones.

Hearing aids with telecoils are often used with other electronic communication products. Standards related to hearing aid telecoils and induction loops allow consumers, using different brands and types of hearing aids, to connect to loop systems manufactured by multiple manufacturers, ensuring consistent compatibility and reliability. Hearing aids, assistive technologies, PSAPs and hearables are also frequently connected to Bluetooth and assistive technologies.

[12] https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-delaware-board-speech/language-pathologists-audiologists-hearing-aid-dispensers-regarding-its-proposed-revisions-its/161130_ftc_dealers_final_.pdf

The ADA believes that all programmable hearing devices sold in the United States should be delivered to the consumer on an open platform, that programmable hearing aids should be developed on a consistent platform (e.g. NOAH), and that the programming software be readily available, at no-cost to the provider, from the manufacturer of the device. This will allow the consumer increased access to care, greater buying power, greater flexibility, enhanced interoperability, and improved portability of care.

Currently, there are numerous dispensaries and franchise clinics in this country that sell "locked" hearing aids to their patients. A locked hearing aid will prevent an outside provider from viewing, adjusting, or modifying the program or settings of the device. Most consumers are not notified in writing that they are purchasing a locked device at the time of purchase. This practice does not serve the best interests of the patient. Establishing a uniform, open platform standard will increase competition, consumer choice, and opportunities for informed decision making.

5. **To what extent might existing federal and state regulations be modified or streamlined to better accommodate new technologies and business models, consistent with promoting competition and innovation while meeting legitimate consumer protection objectives?**

Several existing federal and state regulations and statutes should be added, modified, streamlined, or more intensely enforced. The ADA makes the following recommendations:

1. Truth in Advertising laws should be evaluated, fortified, and better enforced, so that consumers are not mislead about the hearing health products and services that they are purchasing. These laws should also be carefully applied to ensure manufacturers of non-regulated hearing technologies can make truthful claims about their products.
2. The Audiology Patient Choice Act, H.R. 2276, should be enacted by Congress to amend Title XVIII of the Social Security Act to allow Medicare Part B patients to have direct access to audiology services, to allow audiologists to be reimbursed for the Medicare-covered services that they are licensed to provide, and to correctly classify audiologists with providers of similar education and training, thus removing unnecessary and costly, anti-competitive constraints for patients and providers.
3. State statutes and regulations that govern telemedicine and audiology licensure should be evaluated and amended, as needed to allow for licensure portability for audiologists and the interstate practice of tele-audiology.
4. The Over the Counter Hearing Aid Act, S.670/H.R. 1652 should be enacted by Congress to increase competition and lower hearing aid prices by allowing adult consumers with mild-to-moderate hearing loss to purchase some types of hearing aids over the counter (OTC), to permanently eliminate the requirement that adult consumers obtain a medical evaluation or sign a waiver in order to purchase a hearing aid, and to instruct the FDA to finalize PSAP guidance to clarify ambiguity around alternative hearing technologies.
5. The FTC should identify opportunities to apply concepts from the FTC "eyeglass rule" to hearing care. The Health Insurance Accountability and Portability Act (HIPAA) of 1996 ensures that all patients have the right to have access to and a copy of their audiological evaluation report, including the audiogram itself and their recommended plan of care. This plan of care could

include a hearing aid, PSAP, assistive listening device (ALD), and/or rehabilitative recommendations. The audiology community encourages patient access to this information. Hearing health care providers should deliver this information without extra cost and providers should be prohibited from conditioning the availability of an examination on the requirement that patients agree to purchase additional goods or services.

6. The FTC should prohibit the sale of "locked" hearing aid devices, to consumers, or at a minimum, require sellers to notify consumers, in writing, that they are purchasing a device that uses proprietary software, or that will in any way restrict consumers from choosing providers outside the franchise or network.

The regulatory environment has struggled to keep pace with rapid advances in hearing amplification technologies and hearing health care delivery models. The ADA applauds FTC efforts to examine the hearing aid industry, and to identify ways in which enhanced competition and innovation might increase the availability and adoption of hearing aids by consumers who need them.

The ADA recognizes the importance of balancing consumer health and safety issues with consumer interests, and the ADA and its members are dedicated to the advancement of practitioner excellence and high ethical standards in the provision of quality audiologic care. Hearing loss has significant social, emotional, and physical consequences for consumers. It has been linked to cognitive decline, increased risk of falls, and other comorbidities such as diabetes and heart disease. For these reasons alone, it is imperative that we change existing paradigms and practices so that an increasing number of consumers, who will benefit from hearing technology and services, are able to get them.

As such, the ADA will continue to advocate for safe, effective, and efficient pathways to care that foster competition, broaden consumer choice, improve affordability, and accelerate future innovation. We look forward to working with the FTC and other agencies to facilitate these efforts. Please contact me or the ADA executive director, Stephanie Czuhajewski at sczuhajewski@audiologist.org if we can be of service.

Respectfully,

Angela Morris, Au.D., President