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Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue
Washington, DC 20580

RE: Comments in Response to the April 18 Workshop: Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care

Dear FTC Commissioners and Staff:

On behalf of the American Academy of Audiology (the Academy), I am pleased to submit these written comments to the Federal Trade Commission (FTC) on topics associated with the delivery of hearing care in the U.S. The Academy recognizes that the role of the FTC is to ensure a vibrant marketplace and that consumers are educated regarding their rights and responsibilities. As such, the Academy would like to address three specific topics: (1) The role of the audiologist in the delivery of hearing care; (2) the impact of bundling versus unbundling of technologies and services within the marketplace; and (3) consumer protection issues regarding access and decisions about technologies.

The role of the audiologist in the provision of hearing care

Hearing loss is the third most common health problem encountered in the U.S. The most common form of non-medically remediable hearing loss involves change in function of the sensory end organ of the ear, and is most commonly characterized as a "sensory" form of hearing loss. Sensory hearing loss is generally progressive and is not treatable by medical or surgical intervention. The most common form of treatment for sensory loss is hearing aids.

Sensory loss may also lead to changes in function of the nerve that connects the ear to the brain (neural loss) or changes in brain functioning itself (central loss). From the consumer's perspective, the perception of hearing loss, communicative impairment, or functional limitations result from the cumulative effects of all types of hearing loss. The typical consumer is unable to differentiate the contribution of sensory, neural, or central loss to the perceived problems. The purpose of an audiological evaluation is to identify the extent of any hearing loss, the contributions of the various parts of the auditory system to the perceived complaint, the extent to

which the hearing loss is treatable, and a treatment plan. Assessment procedures include a comprehensive history and physical examination of the ear; a measure of perceived communication handicap; a pure tone audiogram and performance on various speech measures; assessment of tympanic membrane function; evaluation of specific cellular functions within the inner ear; assessment of the reflex arc that begins at the ear, transverses the brainstem and results in contractions of muscles within the middle ear; and assessment of central auditory function using various behavioral and electrophysiologic procedures, including auditory brainstem and cortical evoked response procedures. The purpose of an audiologic evaluation is to: (1) determine if a hearing loss exists; (2) if so, what type and degree; (3) identify underlying causes of the hearing loss; (4) determine the extent to which the loss impacts communication or function; and (5) provide direction for the development of a treatment plan. The procedures specified in most state licensing laws for non-audiologist individuals who sell hearing aids limit testing to those procedures used to select and fit a hearing aid, most commonly the pure tone audiogram and speech measures. As such, the purpose of a hearing test, as utilized by dispensers, and the assessment procedures utilized by audiologists, serve two very different purposes.

Emerging evidence suggests that sensory hearing loss can lead to reorganization of the auditory areas of the brain within three months of onset of the loss.[1] This brain reorganization may explain, in part, why different outcomes occur with similar sensory hearing losses. It may also suggest that delays in seeking treatment for hearing loss or for perceived communication impairment may lead to more significant long-term consequences for patients. While the evidence does not yet exist as to whether these changes in brain function that result from hearing loss can be reversed through treatment plans, the necessity to take into account brain function during the development of treatment plans is emerging. Thus, the role of the audiologist includes differentiation between the contributions of sensory loss and brain function to the perceived communication impairment of the patient.

This differentiation of function can only be achieved through the specialized assessment procedures included in a comprehensive audiologic assessment. Beyond the assessment, comorbidities such as tinnitus, vertigo, and imbalance may also be related to ear and brain function. Unlike hearing instrument specialists whose primary function is to sell hearing aids, the audiologist's scope of practice includes assessing and differentiating these patient factors, particularly as they relate to underlying causes. [2]Audiologists earn doctoral degrees from one of 75 academic programs in the United States, including some of the leading academic institutions (e.g. Vanderbilt University, Washington University St. Louis, University of North Carolina Chapel Hill, etc.) Academic training provides audiologists with the

[1] Glick H and Sharma A: Cross modal plasticity in developmental and age-related hearing loss; Clinical implications. Hearing Research. 343 (2017) 191-201
[2] Audiology Scope of Practice: http://www.audiology.org/publications-resources/document-library/scope-practice

knowledge, skills, and competencies to function in high-level patient care activities. Audiologists practice in community clinics, adult and pediatric hospitals (including VA hospitals – the largest employer of audiologists in the U.S.), otolaryngology practices, school systems, universities, and private practices. They are licensed in all 50 states as independent providers of hearing care services.

Bundling versus unbundling in the delivery of technologies and services

A small percentage of hearing losses in adults are amenable to medical or surgical treatment. For those persons with non-medically or non-surgically treatable hearing loss, the treatment may include developing alternative communication strategies, counseling of both the patient and their significant others, acquisition of assistive listening devices, provision of amplification devices, or some combination of the above. As was highlighted at the recent FTC Workshop two individuals with identical hearing losses may have completely different communication needs; therefore, decisions regarding treatment plans are based on individual patient characteristics, including lifestyle variations, employment status, and/or socialization requirements.[3] The manner in which treatment is delivered will vary based on the patient's access to hearing care services, physical characteristics such as dexterity and cognitive function, and the family support status of the patient. Thus, the complexity of the characteristics of the patient, beyond the hearing loss, will dictate the scope of a treatment plan.

When amplification is included as part of the overall treatment plan, the amplification services, by necessity, include comprehensive and long-term follow-up services to assure the patient is appropriately fit as well as achieving the required benefit. This includes adjustment of the devices over time as the brain acclimatizes to the changed auditory input. In this regard the treatment plan may also include counseling regarding expectations of benefit; development and implementation of an instructional plan for increasing communicative competence; coordination of care with other providers in the cases of existing comorbidities; and measurement of progress and outcomes associated with the devices. In addition, decisions regarding alternative options for overcoming functional limitations (e.g. FM systems, direct audio input, streaming capabilities, cochlear implants, etc.) are also included in the post fitting services for amplification.

Within the audiology delivery system, the costs of the treatment services, particularly if those services include amplification devices, may be "bundled" together as a single price. In addition to the scope of the treatment services, the bundled price also will include costs for warranties, replacement guarantees, batteries for the devices, cleaning kits, ear molds (if necessary), and some

[3] FTC Workshop "Now Hear This" https://www.ftc.gov/news-events/events-calendar/2017/04/now-hear-competition-innovation-consumer-protection-issues

predetermined length of time during which office visits are provided at no charge. Thus bundled pricing includes both the device and services associated with the treatment plan. This process is strikingly similar to the manner in which surgical procedures are conducted, charged, and reimbursed. In addition to the surgical procedure itself, the surgeon's charge also includes a pre-determined post-operative time period during which the office visits and physician encounters are provided as part of the necessary follow-up to the surgery. Patients may return as often as necessary during this time to receive care as the office visit charges are bundled with the surgical charge. While all patients generally return once or twice, there may be those that have smooth recoveries that do not need additional care, and those that have difficult recoveries that may need additional care from the surgeon. Similarly, when individuals receive hearing aids, they are generally provided with follow-up care for some pre-determined length of time, and the number of encounters with the audiology providers will vary depending on the needs of the patient.

However, the exception to bundled charges for audiology services is that the initial diagnostic services are generally not included in a bundled pricing structure. Diagnostic services provided by audiologists are usually reimbursed by third party payers, including Medicare. This is not the case for the non-audiologist hearing instrument dispenser as they often include the hearing test in the bundled price, or often provide "free" hearing tests. (As participating providers with Medicare, audiologists must charge Medicare beneficiaries the same fee as any other patient, and therefore do not offer free hearing tests.)

Bundled pricing generally includes the following advantages to the consumer:

- Inclusion of post-fitting services for a predetermined length of time, often a year or more
- No charge for follow-up services, particularly if the patient requires a greater than average number of office visits
- Cleaning and in-office repairs at no charge
- Long term loss and damage warranties.
- Batteries and accessories (e.g. wax guards) provided at no charge
- Semi-annual checks of hearing aids and reprogramming of hearing aids at no charge
- Some insurance companies require bundling of the device and services

Some audiology practices choose to unbundle the price of amplification devices from the associated services. In this scenario, the devices and accessories (e.g. care kit, batteries, ear molds, etc.) are priced independent of the diagnostic services, the delivery fee for the hearing aids, long-term warranties, and the long-term post-fitting follow-up services. The unbundled model (also called "pay-as-you-go" model) has the following advantages:

- Allows the consumer to readily differentiate the cost of the device, accessories and services
- Provides the consumer with the opportunity to be selective in choosing the level of services
- Reduces the price differential between low, mid-range and high level technologies as the costs of the services are fixed, regardless of the technologies
- Allows consumers to purchase devices through other platforms and then receive only the service components from the audiologist

The Academy believes that pricing for amplification devices, accessories, and associated services should be transparent to the patient, and has published guidance, educational materials, and a number of resources to support unbundling, most recently in our statement on Affordability and Accessibility of Hearing Care.[4] Many of our members acknowledge the benefits of unbundling; however, challenges to universal adoption remain. For example, there is a lack of consistency among payers leading to some services being reimbursed by insurance and others not. Feedback from the audiology community suggests that some patients are able to access their benefits more fully when services are bundled. The Academy is working to convene a meeting of major private payers to address this issue. The Academy urges the FTC to consider some of these challenges and recognize that market forces, including payer policies and consumer preferences, can affect the audiologist's decision to bundle or unbundle his/her services. We would the welcome the opportunity to work with the FTC to address these challenges in order to assure transparency in pricing of hearing care services.

We would like to emphasize, again, that prices for treatment and/or amplification devices cover the spectrum of care from development of a treatment plan through long-term patient care management. A unique piece of the pricing is that the patient has ongoing access to audiologic care that leads to maximizing the experience with the product.

Consumer protection in the hearing care delivery system

The Over-the-Counter Hearing Aid Act recently introduced in Congress would mandate that devices be available for persons with mild-to-moderate hearing loss; however, research demonstrates that patients can neither self-identify the presence of a hearing loss nor differentiate the degree of hearing loss (e.g. mild, moderate,

[4] American Academy of Audiology Statement on Accessibility and Affordability of Hearing Care: http://www.audiology.org/publications/accessibility-and-affordability-hearing-care-adult-consumers

severe, etc.). The recent study by Humes, et al. (2017) confirms this perspective[5]. This dichotomy of perspective suggests three questions:

(1) How will a consumer be able to differentiate their degree of hearing loss without first obtaining an audiogram?
(2) How will the FDA enforce a rule that does not mandate an audiologic assessment prior to obtaining a device?
(3) How will the FTC, with its limited resources, be able to enforce advertising and marketing claims for this expanded category of amplification devices?

The ability to differentiate between types and degrees of hearing loss, understanding the unique communication needs of each person with hearing loss, and the contribution of individual characteristics of each patient has been found to be crucial to assuring the best treatment outcomes for each patient. While the Academy recognizes that some patients may be helped with personal sound amplification products (PSAPs), others with an OTC type hearing aid, and still others with traditional amplification products, the inability to identify whether they have actual hearing loss or the degree of that loss would suggest that some consumers will be not be able to select the appropriate technology based on perceptions alone. The necessity of providing guidance to patients regarding the appropriate technology would suggest that obtaining a comprehensive audiological evaluation prior to making any decision regarding specific technologies may be in the best interest of the patient. Therefore, the Academy recommends that patients considering the use of a technology to overcome communication or functional limitations would be best served if they obtained a comprehensive audiologic assessment prior to acquiring any technology. In this manner, consumers can be informed as to their hearing status and the possible solutions for their unique concerns.

Because consumers cannot differentiate the degree or type of hearing loss in the absence of a comprehensive audiological evaluation, it is likely that individuals with either no hearing loss or with severe or profound hearing losses might obtain and utilize technologies not intended for their hearing status (i.e. they do not have mild to moderate hearing losses.) The FDA would be unable to identify or determine whether PSAPs would be used for hearing loss, nor would they be able to identify those persons with more substantial losses who also obtain and utilize OTC hearing aids.

Similarly, opening the market to direct-to-consumer hearing aid devices could result in unsubstantiated claims regarding the target population, expected outcomes, or potential benefits. The Academy believes that the development of guidelines

[5] Humes et al. (2017). The effects of service-delivery model and purchase price on hearing-aid outcomes in older adults: a randomized double-blind placebo-controlled clinical trial. *Am J Audiol*. 2017;26(1):53-79

regarding advertising and marketing of OTC devices or PSAPS will be critical to protect consumers from misleading or inappropriate claims and to assist the FTC in addressing deceptive advertising practices.

Summary

The recent actions of the National Academy of Sciences, Engineering and Medicine (NASEM), the FDA, PCAST, and Congress have focused on the accessibility and affordability of hearing care. These actions have primarily focused on the cost of hearing aids without a concomitant focus on the issues of making hearing care more accessible. In this regard, issues of accessibility are seemingly tied to the cost structure of amplification devices with the expectation that lowering the cost of these devices, or allowing those devices to be sold over-the-counter, will lead to an increase in accessibility by the consumer.

The Academy supports efforts to increase the consumer's access to quality hearing care and to self-direct that care to the extent possible. Self-direction of care, however, assumes that the consumer can make informed decisions regarding the appropriate course of action in accessing that care. As such, the Academy recommends that the FTC develop strategies to educate consumers regarding their roles and responsibilities in accessing various hearing care options. As part of this education, the Academy supports the concept that informed decisions regarding hearing care begins with a comprehensive audiological evaluation that would allow the consumer to differentiate treatment options, including accessing amplification devices online or OTC.

The Academy stands ready to work with the FTC in assuring appropriate regulations are developed to protect the consumer as hearing health technology evolves, and to ensuring consumers have access to the expertise that can assist them in making decisions regarding their hearing care. We appreciate the opportunity to provide this information to the FTC and look forward to working with you on this matter. If the Academy can provide any additional assistance or information, please contact Kate Thomas, senior director of advocacy and reimbursement at 703-226-1029 or kthomas@audiology.org.

Sincerely yours,

Ian Windmill, PhD
President, American Academy of Audiology