

March 31, 2017

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

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

Dear FTC Commissioners and Staff:

The American Academy of Audiology (the “Academy”) is the world's largest professional organization of, by, and for audiologists, representing over 12,000 members. The Academy is pleased to be an active participant in the upcoming workshop hosted by the FTC: Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care.

In the January 4 announcement of the April workshop, the FTC noted that the workshop will center on:

- Consumer Information and Search Costs
- Innovation in Hearing Technology and Treatment
- Innovation in Hearing Health Care Delivery
- The Benefits and Costs of Regulation

The Academy would like to bring to your attention to two issue statements that we released on January 26th, as we believe these to be relevant to this workshop and the four topics for consideration.

Our statement, *Accessibility and Affordability of Hearing Care for Adult Consumers*,¹ is a comprehensive consumer-focused issue statement centered on the accessibility of appropriate hearing care, recognizing that individuals have the right to self-direct their hearing care, noting that there are ways to help self-manage hearing loss, and recognizing that cost concerns for ideal hearing care may prevent appropriate treatment. The Academy understands that consumers may face challenges in accessing information on hearing care, especially as hearing care describes a broad range of services and devices. Many options are available for treatment or management of hearing loss, as well as services or technologies to mitigate hearing loss and its accompanying communicative impairment. With an aging population and an ever-broadening array of potentially confusing options for those with hearing loss, consumers need access to consumer-friendly information that would allow for comparisons between services, devices, and products. The Academy would recommend the following points for consideration:

¹ “Accessibility and Affordability of Hearing Care for Adult Consumers.” January 26, 2017.
<http://www.audiology.org/publications/accessibility-and-affordability-hearing-care-adult-consumers>

- A common language and terminology to be used across hearing healthcare venues and providers that the consumer can easily understand;
- A clear differentiation of the cost of services from the cost of products when purchasing hearing devices;
- Regulatory or statutory requirements that allow direct and cost-effective access to audiologic services;
- Increasing access to audiology services through the support for telehealth initiatives that allow consumers in underserved markets to receive hearing care services.

The Academy's second issue statement focuses exclusively on the availability of over-the-counter (OTC) hearing aids². This issue statement provided specific guidelines that the Academy would recommend for OTC devices should they become approved by law. The Academy strongly believes that this statement, along with the other, should help guide the discussion for the workshop on hearing health and technology.

The increased need for hearing services among the aging population, coupled with advancements in technology, have understandably prompted the FTC, the U.S. Food and Drug Administration (FDA,) and Congress to focus on expanding consumer options with regard to accessing hearing health services and technology. Recognizing the possibility that OTC devices may soon be made more readily available, the Academy wants to ensure that consumers are protected as they engage in their self-directed hearing care. The Academy believes that to ensure ideal outcomes for the consumer, OTC devices should meet specific standards and be labeled in a clear manner. Specific provisions the Academy would like to see, should OTC devices become available to consumers, include:

- Devices should be defined in a manner so as to avoid confusion with hearing aids that are FDA regulated as medical devices and intended for use by both adults and children who experience losses of greater than a mild degree, or have losses other than sensory type;
- The devices should be labeled as intended for use by adults with mild hearing loss and mild communicative impairments;
- The devices are labeled as intended for use by adults over the age of 18;
- The red flag warning signs must be included with all labeling for products intended to manage hearing loss or communication deficits, and that indications for referral for an audiologic or otologic evaluation are noted;
- The labeling should include language that specifies that the device is not intended to replace the advice of a licensed audiologist;
- The labeling should note that the devices are not intended to treat tinnitus, inner ear dizziness, or pain in the ears.

² "Over-the-Counter (OTC) Hearing Devices. January 26, 2017.

<http://www.audiology.org/publications/over-counter-otc-hearing-devices>

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The Academy appreciates the efforts by the FTC to host this workshop and engage stakeholders. We look forward to being an active participant in the discussions that we anticipate will take place well beyond April 18th.

In a changing technological environment, the Academy recognizes that many existing models of hearing health-care will continue to evolve. Accessibility to high quality care at affordable prices in the hearing health world is a critical issue and, to this end, the Academy strongly supports the upcoming FTC workshop. We are committed to continuing our work with the FTC and the FDA to ensure that consumers with all levels of hearing loss are able to access appropriate patient-centered treatments and technology to ensure that optimal results are achieved. If you would like any additional comments from the Academy prior to the upcoming workshop, please contact Kathryn Werner, Vice President of Public Affairs at _____ or _____

Sincerely,



Ian Windmill, PhD

President, American Academy of Audiology