



**AMERICAN ACADEMY OF
OTOLARYNGOLOGY—
HEAD AND NECK SURGERY**

April 6, 2017

2016-2017 ACADEMY BOARD OF DIRECTORS

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Ave., NW
Suite CC-5610 (Annex B)
Washington, DC 20580

Submitted Electronically via
<https://ftcpublic.commentworks.com/ftc/hearinghealthtechworkshop/>

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

Dear Secretary Clark:

Hearing loss is one of the most common issues faced by individuals as they age, and unfortunately, many adults fail to seek appropriate intervention when symptoms of hearing loss first appear. Given the growing body of evidence indicating that hearing loss can have a profound impact on the social, functional, and psychological well-being of a person, stakeholders from across the hearing healthcare community have engaged with applicable governing/regulatory bodies (PCAST, FDA, NAS, Congress) over the past two years to put forth recommendations meant to broaden the availability and accessibility of hearing healthcare for adults. The American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) has participated in this process and looks forward to assisting in continued efforts to ensure hearing healthcare services in the United States are widely accessible, affordable, and safe. To help achieve this goal, we respectfully offer the following comments for consideration as part of the April 18, 2017 Federal Trade Commission Workshop entitled “Hearing Health and Technology, Project No. P171200.”

As background, the AAO-HNS is the world’s largest medical organization representing specialists who treat the ear, nose, and throat, and related structures of the head and neck. The Academy represents approximately 11,000 otolaryngologist—head and neck surgeons in the United States who diagnose and treat disorders of those areas. The medical disorders treated by our physicians are among the most common that afflict all Americans, young and old. They include chronic ear infection, sinusitis, snoring and sleep apnea, hearing loss, allergies and hay fever, swallowing disorders, nosebleeds, hoarseness, dizziness, and head and neck cancer. And, in the context of the hearing healthcare “debate,” otolaryngologist—head and neck surgeons are the only healthcare providers with the breadth of training and expertise to treat *all aspects* of hearing loss.

The AAO-HNS recognizes the continued momentum in the United States and worldwide to increase the utilization of hearing healthcare services, particularly the adoption of technology designed to improve the hearing of those with mild-to-moderate hearing loss. We also acknowledge that to achieve this goal, structural changes regarding access to, and the delivery of, hearing healthcare services will be necessary.

There are many reasons why those with hearing loss are not participants in the current system, including, but not limited to: failure to realize the problem, denial of the problem, perceptions

OFFICERS

Gregory W. Randolph, MD
President
Boston, MA
Gavin Setzen, MD
President-Elect
Albany, NY
Scott P. Stringer, MD
Secretary/Treasurer
Jackson, MS
James C. Denny III, MD
Executive Vice President and CEO
Alexandria, VA

IMMEDIATE PAST PRESIDENT
Sujana S. Chandrasekhar, MD
New York, NY

AT-LARGE DIRECTORS

Peter J. Abramson, MD
Atlanta, GA
Carol R. Bradford, MD
Ann Arbor, MI
Sonya Malekzadeh, MD
Washington, DC
Karen T. Pitman, MD
Towson, MD
Seth R. Schwartz, MD
Seattle, WA
Michael D. Seidman, MD
Celebration, FL
Timothy L. Smith, MD
Portland, OR
Jay S. Youngerman, MD
Plainview, NY

BOARD OF GOVERNORS

Stacey L. Ishman, MD
Chair
Cincinnati, OH
Sanjay R. Parikh, MD
Chair-Elect
Seattle, WA
David R. Edelstein, MD
Past Chair
New York, NY

SPECIALTY SOCIETY ADVISORY COUNCIL

Dennis H. Kraus, MD
Chair
New York, NY
Pete S. Batra, MD
Chair-Elect
Chicago, IL

COORDINATORS

Jane T. Dillon, MD, MBA
Socioeconomic Affairs
Rolling Meadows, IL
Robert R. Lorenz, MD, MBA
Practice Affairs
Cleveland, OH

EX-OFFICIO

Susan D. McCammon, MD
Chair, Ethics Committee
Galveston, TX

regarding a potentially complex system, and cost. The AAO-HNS continues to support efforts to mitigate these barriers. **However, a preoccupation with increased utilization (by easing entry and reducing costs) must not overshadow the equally important need to ensure the quality and safety of hearing healthcare services and/or devices.**

The AAO-HNS appreciates the Federal Trade Commission's (FTC) efforts to ensure appropriate patient safety protections are maintained as hearing-related technologies and/or devices continue to evolve and respectively submits the following comments for consideration.

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

Technical information/specifications for various hearing devices is widely available to consumers. For example, standard packaging and vendor websites would likely include information regarding a device's battery requirements, how to turn the device on/off, and other basic details. However, information about the various causes and/or ranges of hearing loss (and applicable services) is generally harder to find and less "consumer friendly." Information regarding the intricacies of hearing loss and/or hearing-related services can be found via the National Institute on Deafness and Other Communication Disorders (NIDCD), the World Health Organization (WHO), and other health-related professional organizations like the AAO-HNS. Despite the *availability* of this information, there remains a gap in its actual usability for the average consumer. One of the main reasons for this gap relates to a consumer's ability to recognize the type and severity of their hearing loss. There is also little information available to an average consumer outlining the potentially treatable causes of hearing loss.

In recognition of this fact, the AAO-HNS continues to recommend the standardization of packaging inserts for all assistive hearing devices using consumer-friendly language, particularly regarding potentially treatable causes of hearing loss.

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?

In the United States, hearing aids were historically sold by hearing aid specialists, audiologists, and in physician offices, typically as a bundled service (e.g. batteries, adjustments, etc.). However, recent changes in the marketplace have broadened the access points to include "big box" stores (who typically employ an audiologist), insurance companies, and via online sales. However, the availability of devices via these "vendors" may vary based on state law. Consumers can also purchase additional "non-medical" hearing-related devices (PSAPs, pocket-talker, game ear, etc.) from other retailers, such as a sporting goods store, magazines, and international sources.

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?



In general, the range of assistive hearing devices available to consumers has not changed, but there has been substantial progress in integrating these hearing aids with television, phones, and a variety of audio and video appliances. In addition, considerable advancement and/or innovation has been achieved in hearing testing/screening, especially via personal devices including smart phones, tablets, watches, and Bluetooth. The accuracy of at-home or personal hearing testing/screening, completed via online and/or “app-based” programs, has increased dramatically, with some even providing results that include word discrimination. The availability of these improved testing/screening mechanisms will likely result in an increased number of individuals with recognized hearing loss. As such, many of these individuals may seek assistance and/or intervention for their hearing loss at an earlier stage. Overall, these advancements in screening, paired with the potential availability of an over-the-counter (OTC) or “basic” hearing aid, should positively impact the overall demographic group of adults with mild-to-moderate hearing loss. Early intervention of this initial hearing loss may also help to slow its advancement.

Other positive developments in the assistive hearing device space include: better battery life for various hearing aids, improved cleaning capabilities for persons with limited dexterity, and the ability of a consumer to create at-home/personalized molds for standard amplification devices like PSAPs. Personal molds for hearing devices are particularly important because they can increase the usage, effectiveness, and comfort associated with a device by mitigating potential infection, irritation, and pain.

While these notable innovations have helped to advance hearing healthcare, it is also critical to manage consumer expectations regarding the performance of their hearing device. Even with the assistance of these new technologies, amplification can only accomplish so much, and in many cases, could cause, mask, or accelerate noise-induced hearing loss. Consumers must be properly informed via package inserts and other means (e.g. advertising) about the limitations of these devices. They do not “fix” or eliminate a person’s hearing loss, and the underlying cause of the hearing loss will likely worsen over time. The human body is the limit as no current technology can replicate a healthy ear.

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

Today, many assistive hearing devices include several programming or adjustment tools that are interoperable with other devices such as smart phones, Bluetooth, and hearing loop systems.

As the availability of various hearing aid devices, especially PSAPs and/or OTC hearing aids, expand, the AAO-HNS strongly recommends strict standards for the manufacturing of these devices. For example, there are currently variable manufacturing standards for PSAPs with reported instances of gain in the range of 140 dB. The AAO-HNS asserts there should be PSAP/OTC manufacturing standards that would limit the maximum gain level for each device. Assuming such manufacturing standards/protections were in place, the AAO-HNS supports the assertion that PSAP manufacturers should have the opportunity to market their products as capable (in general terms) of providing hearing assistance in a variety of settings. In addition, any entry-level hearing aid should also maintain production standards to ensure a predictable clinical response without causing injury due to over-amplification (e.g. maximum gain level

for any OTC hearing aid). The AAO-HNS emphasizes that louder is not better, and regulating maximum gain levels for assistive hearing devices will help ensure consumers are accessing safe devices, which will not cause further hearing loss.

The establishment of maximum gain standards is a concept that could also be broadened to other devices to protect consumers from hearing loss. For example, most smart phones and/or tablets allow users to increase volume without any information about decibel impact on hearing loss. Given the known sophistication of these devices, relatively easy programming changes could be mandated to provide consumers with a numeric decibel reading as volume is increased. In addition to the numeric decibel values, a “caution” notice should appear once a certain volume threshold is surpassed. There are conflicting studies on what level this should be. To help avoid confusion by consumers, the AAO-HNS would recommend 85 dB, as this is the threshold the public is familiar with for workplace noise exposure limits. Although consumers could still listen beyond the “safe” range, they would at least be better informed of volume ranges associated with noise-induced hearing loss.

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?

As stated, the manufacturing of all assistive hearing devices should be standardized to ensure consumer safety and satisfaction. Standardization requirements must also extend to device packaging and/or applicable insert materials.

In its recent guidance, the Food and Drug Administration (FDA) reiterated the importance and continued enforcement of existing labeling requirements for hearing aids. Per the FDA guidance, the provision of the following notice remains a requirement for prospective hearing aid users:

“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 the medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.”

In addition, the AAO-HNS recommends the inclusion of “medically treatable conditions” within the above-stated notice. Specifically, conditions that need medical management to prevent further hearing loss and possibly eliminate the need for a hearing aid. Such conditions include: cerumen (wax) impaction; infection; perforation of the ear drum; Meniere’s disease; tumors of the ear; otosclerosis; and sudden sensorineural hearing loss.

Further, the AAO-HNS views the continued inclusion of “Red Flag” warnings for ear disease as a critical packaging component for all current and/or future hearing-related devices. As stated in the FDA guidance, the warning conditions include:

- (i) *Visible congenital or traumatic deformity of the ear;*
- (ii) *History of active drainage from the ear within the previous 90 days;*
- (iii) *History of sudden or rapidly progressive hearing loss within the previous 90 days;*



AMERICAN ACADEMY OF
OTOLARYNGOLOGY-
HEAD AND NECK SURGERY

- (iv) *Acute or chronic dizziness;*
- (v) *Unilateral hearing loss of sudden or recent onset within the previous 90 days;*
- (vi) *Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz;*
- (vii) *Visible evidence of significant cerumen accumulation or a foreign body in the ear canal; and*
- (viii) *Pain or discomfort in the ear.*

The AAO-HNS also supports the establishment of a structured mechanism for at least five years of data collection. The potential availability of OTC hearing aid devices represents a substantial shift in the paradigm for hearing healthcare. As such, the AAO-HNS supports a simultaneous effort to collect data to assist in the analysis of consumer/patient and provider satisfaction and usage. Such data will help mitigate issues regarding any future or “next generation” hearing-related devices.

As these and other recommendations are evaluated, the AAO-HNS looks forward to working with the FTC, and other stakeholders, to ensure safe, timely, and affordable access to hearing healthcare services. If you have any questions or would like additional information, please contact legfederal@entnet.org.

Sincerely,

U

U

James C. Denny III, MD
Executive Vice President/CEO

