



Statement for the Record re: H.R. 1652
To the U.S. House of Representatives Committee on Energy and Commerce
Health Subcommittee Hearing Regarding
“Examining Improvements to the Regulation of Medical Technologies”
Tuesday, May 2, 2017

The American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) thanks the Subcommittee on Health for the opportunity to submit a statement for the record regarding H.R. 1652, the “Over-the-Counter Hearing Aid Act of 2017.”

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. If enacted, H.R. 1652 would help provide a new pathway for consumers to access assistive hearing devices by establishing a new category of “basic” or “over-the-counter” (OTC) hearing aids for adults with mild-to-moderate hearing loss. **The AAO-HNS supports the concept of OTC hearing aids for adults with mild-to-moderate hearing loss**, but respectively urges members of the Committee to consider the following comments/recommendations prior to advancing H.R. 1652 as a standalone bill and/or including it in any comprehensive piece of legislation.

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 medical 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 regarding a potentially complex system, and cost. **The AAO-HNS supports continued efforts to mitigate these barriers. However, a preoccupation with increased utilization and broader access (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.**

As such, the AAO-HNS continues to support the concept of denoting a “basic” category of hearing aids, which would be more easily available for purchase OTC by adults/seniors.

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Although the AAO-HNS believes providing access to a lower-cost or “basic” hearing aid could/would likely benefit a large portion of the adult (especially senior) population, **we caution that specific action should first be taken to ensure a particular individual/patient’s condition actually falls into the category where non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss would be of value.** Although we find ourselves in a period of disruptive technology that has made it possible for many patients to participate in self-screening, early detection, and monitoring of many diseases, **we assert it is an overstatement to conclude that all patients/consumers could or would be able to self-diagnose, self-treat, and self-monitor their hearing loss.**

Although the Food and Drug Administration (FDA) announced in December 2016 that it would no longer enforce the requirement for a medical evaluation/waiver prior to purchasing a hearing aid (for adults), **the AAO-HNS stands by its recommendation regarding the benefits of a medical evaluation by a physician, followed by a standardized hearing test (via a hearing health professional or appropriate online/technological source), BEFORE an individual purchases any type of basic hearing aid or other FDA-regulated assistive hearing device.** Even if the resulting end-product is purchased OTC, a patient will still benefit, and will certainly not be harmed, by receiving an appropriate evaluation of their actual hearing loss.

Therefore, the AAO-HNS urges lawmakers to consider amending H.R. 1652 to include the following provisions, before it is advanced on its own, or via a broader legislative package:

- i. **Requirement for medical evaluation/hearing screening.** This initial step will ensure an individual’s hearing loss falls into the category where non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss would be of value.
- ii. **Requirements relating to the standardization of OTC hearing aid packaging and inserts.** Ensuring consumers receive consistent information and adequate protections regarding any OTC hearing device is critical. Per its December 2016 guidance, the FDA agrees that the inclusion of the following notice should remain a requirement for all prospective hearing aid device packaging:

“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.”

The AAO-HNS also recommends that lawmakers instruct the FDA to revise the above-stated notice to also include “medically treatable conditions” associated with hearing loss. 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.

In addition, all package inserts should also notify consumers of the FDA “Red Flag” warnings for ear disease. These 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;*
 - (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.*
- iii. **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.

Finally, we emphasize that the above comments/recommendations are framed in the context of a specific type of hearing loss (bilateral, gradual onset, mild-to-moderate, age-related) and for specific patient populations (adults/seniors). **We strongly believe any/all potential OTC hearing devices are inappropriate for individuals under the age of 18.**

Again, we thank the Subcommittee for its interest in creating a new pathway for adults with mild-to-moderate hearing loss to access assistive devices, and appreciate the consideration of the above-stated recommendations. The AAO-HNS looks forward to working the Committee, the bill’s authors, as well as others in the hearing health community, to ensure safe, timely, and affordable access to hearing healthcare services. If you have any questions or would like additional information, please contact the AAO-HNS Legislative Advocacy team at legfederal@entnet.org.