



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

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January 31, 2017

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted Electronically via

<https://www.regulations.gov/document?D=FDA-2016-D-3466-0002>

Re: Docket Number FDA-2016-D-3466; Immediately in Effect Guidance
Document: Conditions for Sale for Air Conduction Hearing Aids.

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) 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 in response to the December 12, 2016, FDA Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids.

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 regarding a potentially complex system, and cost. As stated in previous comments, the AAO-HNS supports continued efforts to mitigate these barriers. However, a preoccupation with

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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.

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 by adults/seniors. **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. For example, an individual living alone may personally evaluate his/her hearing loss as only mild or moderate, not realizing that another individual with normal hearing would not be able to tolerate the excessive volume (e.g. television) used to compensate for the person’s hearing loss.

Although the recent FDA guidance states that the agency will 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 over-the-counter (OTC), a patient will still benefit, and will certainly not be harmed, by receiving an appropriate evaluation of their actual hearing loss.

This point is particularly critical for patients who potentially suffer from one of the many *treatable* causes of hearing loss. Overall, the potential *medical* issues associated with hearing loss should not be made light of, especially given that a large percentage of Medicare beneficiaries (the core populations discussed in the PCAST and NAS reports) suffer from multiple and complex medical conditions. For example, per a 2014 U.S. Department of Health and Human Services reportⁱ, in 2012-2014, the most frequent occurring conditions among the senior population included: hypertension (71%), diagnosed arthritis (49%), heart disease (30%), cancer (24%), and diabetes (21%). Of the five aforementioned medical conditions, three have correlations to hearing loss. In addition, ototoxic and vestibulotoxic drugs can have a direct correlation with hearing loss; a factor exacerbated by advanced age (over 65).ⁱⁱ **In recognition of the complexities associated with hearing loss, the AAO-HNS is pleased that despite the ongoing analysis of various hearing-health services, the physician referral requirements currently in place for Medicare beneficiaries remain intact.**

And, as the hearing healthcare community moves toward “uncharted” territory regarding access and availability of various hearing-health related devices, **the AAO-HNS applauds the FDA for reiterating 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 FDA include examples 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;*
- (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 recognizes that the FDA intends to consider a regulatory framework for hearing aids that can be sold directly over-the-counter (OTC) to consumers, without the requirement for consultation with a credentialed dispenser. As part of this process, the AAO-HNS recommends that the FDA simultaneously reevaluate its guidance relating to Personal Sound Amplification Products (PSAPs). In many cases, patients/consumers may view PSAPs as a market-entry device. And, if they have a positive experience with a PSAP, but eventually believe they could benefit from greater hearing assistance, a patient/consumer may be more apt to transition to a standard hearing aid if medically necessary. Therefore, mitigating barriers for patients/consumers to obtain such devices could result in earlier detection of mild to moderate hearing losses with a subsequent increased utilization of the system overall—a desired outcome articulated by both PCAST and NAS.

We do, however, caution that steps must be taken, especially in terms of manufacturing, to ensure the safety of PSAPs and any other potential OTC hearing device. For example, there are currently variable manufacturing standards for PSAPs with reported instances of gain in the range of 140 dB. The AAO-HNS believes 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). As previously stated, **the AAO-HNS also believes that consumers will benefit from the inclusion information that outlines the “red flags” associated with ear disease in all PSAP and/or potential “basic” (OTC) hearing aid packaging.** The standardization of such packaging and inserts is a critical aspect of any effort to deregulate, on any level, PSAPs and/or a potential “basic” hearing aid device.

Finally, we stress that the above comments are framed in the context of a specific type (bilateral, gradual onset, mild-to-moderate age-related) of hearing loss and for specific patient populations (adults/seniors). We feel that any/all potential OTC hearing devices are inappropriate for individuals under the age of 18 and should NOT be available even if such products (OTC hearing aids and/or PSAPS) are approved for adults.

The AAO-HNS recognizes that the aforementioned recommendations are not equivalent to a thorough audiological evaluation and individual counseling during the rehabilitative process. However, for those with a mild to moderate sensorineural hearing loss, we feel these recommendations have the greatest chance to improve the penetration of available technology with minimal risk.

As these and other recommendations are evaluated, the AAO-HNS looks forward to working with the FDA, 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,

A handwritten signature in black ink that reads "James C. Denny III". The signature is written in a cursive style with a large, looped initial "J" and a distinct "III" at the end.

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

ⁱ https://aoa.acl.gov/Aging_Statistics/Profile/2015/docs/2015-Profile.pdf

ⁱⁱ <http://www.audiologist.org/ada-resource-library/diabetes-hearing-loss-resources>