



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

June 30, 2016

Robert Califf, MD
Commissioner
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-2015-N-4602-0003>

Re: Docket No. FDA-2015-N-4602 for “Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop; Request for Comments.”

Dear Commissioner Califf:

Hearing loss is one of the most common issues faced by individuals as they age. Despite this, far too few adults seek appropriate intervention when symptoms of hearing loss first appear. In an effort to mitigate this issue, stakeholders from across the hearing healthcare community have engaged with applicable governing/regulatory bodies (PCAST, FDA, IOM) over the last year to put forth recommendations to potentially ease barriers associated with the availability and accessibility of hearing healthcare for adults. The American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) has participated in the aforementioned process, and provided oral testimony at the FDA workshop entitled “Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids” on April 21, 2016. As follow-up, we respectfully offer the following comments to reiterate our position pertaining to potential changes regarding the delivery of hearing healthcare services in the United States.

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.

The AAO-HNS recognizes there is significant momentum both in the United States and worldwide to increase the utilization of hearing healthcare services,

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particularly the adoption of technology designed to improve the hearing of those with significant 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 significant 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. While the AAO-HNS agrees that efforts must be made to overcome these barriers, we must move forward with careful consideration and analysis relating to what can be done to significantly increase utilization (by easing entry and reducing costs) while retaining necessary protections for patients.

To this end, the AAO-HNS is generally supportive of 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.

Therefore, the AAO-HNS strongly recommends the retention 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 could seek purchase of 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. 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 IOM reports) suffer from multiple and complex medical conditions. For example, according to a 2014 U.S. Department of Health and Human Services reportⁱ, in 2011-2013, the most frequent occurring conditions among the senior population included: hypertension (71%), diagnosed arthritis (49%), heart disease (31%), cancer (25%), 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 was pleased that the recent IOM report did NOT recommend removing the physician referral requirements currently in place for Medicare beneficiaries.**

Retention of a medical evaluation requirement for Medicare patients should not be seen as a limiting aspect of the hearing healthcare delivery system. **The AAO-HNS emphasizes that primary care and/or most specialty physicians (MD/DOs) are able to provide an *initial* medical examination of the ear, and if necessary, a subsequent referral for audiological/hearing aid services.** According to the Agency for Healthcare Research and Quality (AHRQ), there were approximately 209,000 practicing primary care physicians in the United Statesⁱⁱⁱ, in addition to the approximately 11,000 otolaryngologists.



Finally, the AAO-HNS recognizes for a variety of reasons, hearing aids (and their associated costs) have not necessarily benefited from the vast technological advances that have occurred since hearing aids (in various forms) entered the market. **It is in this context that the AAO-HNS urges interested parties to differentiate between the “access” issues associated with the cost of hearing aids, versus alleged “access” issues to qualified hearing-healthcare professionals** (e.g. otolaryngologist—head and neck surgeons, primary care physicians, audiologists, etc.) which tend to offer hearing aid services in the same urban and rural areas. While patients/consumers will undoubtedly benefit from the creation of additional pathways for hearing loss treatment or mitigation (e.g. PSAP, “basic” hearing aid, or other “hearable” device), it remains critically important that the same patients/consumers are, from the first step (evaluation), pointed in the right direction. If not, the effort is done in vain. **It is for these reasons the AAO-HNS supports efforts to pragmatically deregulate the availability of various assistive hearing devices, while still retaining requirements for a patient to receive the appropriate medical evaluation and hearing testing.**

Ideally, commonsense efforts to deregulate and thereby increase access to “basic” hearing devices and “hearables” will spur additional technological innovations – naturally driving costs down, much like what has been seen in regards to smart phones. **To that end, the AAO-HNS generally agrees with PCAST’s recommendation that the FDA withdraw its draft guidance regarding 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 IOM.

We do, however, caution that steps must be taken, especially in terms of manufacturing, to ensure the safety of PSAPs. 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 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 also believes that consumers would benefit from the inclusion of or information on the “red flags”^{iv} 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.**

However, and as previously stated, the AAO-HNS supports continuing to require consumers/patients to receive a medical evaluation and appropriate hearing test, to rule out anatomic and/or other **correctable causes of hearing loss**, prior to the purchase of any potential OTC “basic” hearing aid device. After having received such an evaluation, the AAO-HNS sees no reason why a patient/consumer should not be able to “shop around” for their own most cost-effective solution. Based on a standard evaluation, a skilled otolaryngologist—head and neck surgeon or audiologist should be able to assist, and make recommendations regarding, the best course of action for the patient—even if that means directing them to a high-quality PSAP. Conversely, the same dialogue will also enable the hearing healthcare provider to fully explain why a PSAP (or other applicable device) may



not be appropriate, or helpful, for a person’s particular hearing loss. Ultimately though, the decision to purchase any hearing-related device would be left to the patient/consumer, and in whatever setting they chose (clinic/office, online, etc.). In addition, the same “at-home” or entry-level technology a consumer/patient used to identify or screen for an initial hearing loss could be used to perform serial exams aimed at detecting any further decline, which could then trigger a more complete exam by the appropriate hearing healthcare professional.

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). The AAO-HNS recognizes over half of the pediatric patients in the United States are covered by Medicaid, which in most states includes hearing aid benefits. We feel that any/all potential OTC hearing devices are inappropriate for this age group and should NOT be available even if such products (OTC hearing aids and/or PSAPS) are approved for adults.

The AAO-HNS recognizes that our recommendations are not equivalent to a thorough audiological evaluation and individual counseling during the rehabilitative process. However, and 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 to these patients with minimal risk. We must be willing to move from the “perfect” to the “safe.”

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

Sincerely,

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

ⁱ http://www.aoa.acl.gov/Aging_Statistics/Profile/2014/docs/2014-Profile.pdf

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

ⁱⁱⁱ <http://www.ahrq.gov/research/findings/factsheets/primary/pcwork1/index.html>

^{iv} AAO-HNS Position Statement: Red Flags-Warning of Ear Disease <http://www.entnet.org/?q=node/912>