AMERICAN ACADEMY OF
OTOLARYNGOLOGY–
HEAD AND NECK SURGERY

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Comments re: October 26, 2015, PCAST report to the President on *Aging America & Hearing Loss: Imperative of Improved Hearing Technologies.*

Drs. Holdren and Lander:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), please accept the following comments regarding the recently released report to the President on *Aging America & Hearing Loss: Imperative of Improved Hearing Technologies*.

As background, the AAO-HNS is the world's largest organization representing specialists who treat the ear, nose, and throat, and related structures of the head and neck. The Academy represents approximately 12,000 otolaryngologist—head and neck surgeons who diagnose and treat disorders of those areas. The medical disorders treated by our physicians are among the most common that afflict all American, 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.

Given the specific expertise of our Membership, we have been watching closely, and appreciate, the efforts of PCAST and other entities, such as the Institute of Medicine (IOM), to study, and hopefully mitigate, some of the ongoing issues faced by the nation's senior population in regards to the access and affordability of hearing aids, and their applicable services.

For ease of review, the following comments are organized in the context of the PCAST's formal recommendations. However, they may also reference, refute, and/or articulate concern regarding statements included

in the general PCAST analysis/report.

Open up the market for innovative hearing technologies:

PCAST Recommendation 1. *FDA should designate as a distinct category ("basic" hearing aids) non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss and adopt distinct rules for such devices.*

(a) FDA should approve this class of hearing aids for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser. FDA should also approve for OTC sale, both in stores and online, tests appropriate to the self-fitting and adjustment of these OTC devices by the end user. Such hearing treatments and tests meet the FDA requirements for OTC products, which are that consumers should be able to self-diagnose, self-treat, and self-monitor the condition.

(b) FDA should exempt this class of hearing aids from the QSR regulation in its present form and substitute compliance with standards for product quality and recordkeeping appropriate for the consumer-electronics industry, developed by an appropriate third-party organization and approved by FDA. Similar actions should be taken with respect to diagnostic hearing tests used to dispense and fit Class I hearing aids.

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 seniors. Although the AAO-HNS believes that providing access to a lower-cost or "basic" hearing aid could/would likely benefit a large portion of the senior population, we caution that specific action should first be taken to ensure that 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. **As such, we assert it is an overstatement to conclude that patients/consumers could or would be able to self-diagnose, self-treat, and self-monitor their particular 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 television, etc. volume used to compensate for the person's hearing loss.

Therefore, the AAO-HNS 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 a "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. In general, the PCAST report makes light of the potential *medical* issues associated with hearing loss. However, a large percentage of Medicare beneficiaries (the general population discussed in the PCAST report) have multiple and complex medical conditions. For example, according to a 2014 U.S. Department of Health and Human Services report[i], 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]

As such, any changes to current regulations regarding the availability and/or access to hearing aids must be accompanied by parallel efforts to ensure said changes aren't viewed by the public as a means to disregard the *medical* issues that *can* be associated with hearing loss. The PCAST report seeks to classify such occurrences as "extremely rare," by focusing on the incidence of patients who are diagnosed with acoustic neuroma. In reality, there is a broad range of medically-related issues associated with hearing loss. Furthermore, the Report (perhaps inadvertently) lumps together "sudden" and "unilateral" onset of hearing loss. These are two separate hearing-related issues. "Sudden" hearing loss (SHL) is defined as rapid-onset, occurring over a 72 hour period, of a subjective sensation of hearing impairment in one or both ears.[iii] The occurrence of SHL should be viewed as a medical emergency, requiring immediate evaluation by an MD/DO physician. By receiving prompt evaluation, diagnosis, and treatment of SHL by a physician, patients have a greater chance of recovery.

Ensuring patients/consumers continue to receive proper evaluations before purchase of a hearing-related device will also help mitigate the instances where such a device isn't actually needed. For example, the AAO-HNS generally disagrees with PCAST's assessment that "…ear-wax removal at a clinic or local drugstore…" is an adequate means for cerumen management. The AAO-HNS position statement regarding cerumen management states, "…removal requires mechanical or chemical manipulation of the external auditory canal and such manipulation may result in traumatic and/or inflammatory lesions to the external auditory canal, tympanic membrane, and/or middle ear conduction mechanism."[iv] The AAO-HNS believes mechanical and/or chemical manipulation of the external auditory canal in an effort to remove cerumen should only be performed by or under the supervision of a qualified physician (MD or DO). Allowing and advocating for the non-professional or personal management of cerumen may create complications for a patient/consumer that would have otherwise not required ANY additional treatment, service, or intervention.

Beyond the aforementioned medically-related concerns, we agree with the PCAST's assertions in its report that the costs associated with hearing aids remain prohibitive for a large population that could benefit from receiving some form of assistive hearing device. In addition, we agree that 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 surgeon, 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 those reasons that 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 screening.

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.

PCAST Recommendation 2. *FDA should withdraw its draft guidance of November 7, 2013 on Personal Sound Amplification Products (PSAPs). PSAPs should be broadly defined as devices for discretionary consumer use that are intended to augment, improve, or extend the sense of hearing in individuals. PSAP manufacturers should continue to be able to make truthful claims about their use in normal settings. FDA should not require language in PSAP labeling or advertising that excludes their use by individuals with age-related hearing loss no worse than mild-to-moderate.*

The AAO-HNS agrees with PCAST's recommendation that the FDA withdraw its draft guidance regarding 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. In addition, 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. **However, the AAO-HNS also believes that consumers would benefit from the inclusion of or information on the "red flags"[v] 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.**

<u>Increase opportunities for consumer choice</u>

PCAST Recommendation 3. *Analogously to its "Eyeglass Rule," FTC should require audiologists and hearing-aid dispensers who perform standard diagnostic hearing tests and hearing aid fittings to provide the customer with a copy of their audiogram and the programmable audio profile for a hearing aid at no additional cost and in a form that can be used by other dispensers and by hearing-aid vendors. Also analogously, the availability of a hearing test and fitting must not be conditioned on any agreement to purchase goods or additional services from the provider of the test.*

As previously stated, the AAO-HNS supports continuing to require consumers/patients to receive a medical evaluation and appropriate hearing test 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.)

PCAST Recommendation 4. *Similarly in effect to its "Contact Lens Rule," FTC should define a process by which patients may authorize hearing-aid vendors (in-state or out-of-state) to obtain a copy of their hearing test results and programmable audio profile from any audiologist or hearing-aid dispenser who performs such a test, and it should require that the testers furnish such results at no additional cost. While FTC has the authority to issue new regulations of this sort, action can be accelerated and strengthened by legislative direction. We urge the Administration to work with Congress to initiate bipartisan legislation that would instruct FTC to issue a rule for hearing aids and PSAPs similar to the eyeglass and contact lens rules.*

The AAO-HNS agrees with PCAST's recommendation regarding the portability of hearing test/audiogram results. **And, theoretically, the AAO-HNS would support legislation instructing the FTC to issue a rule for hearing aids and PSAPs similar to the eyeglass and contact lens rules.** However, and with all legislative matters, the AAO-HNS strongly feels that the "devil is in the details." Any future legislation proposed to address/mitigate the issues discussed in the PCAST report would require careful analysis by the AAO-HNS. The inclusion of provisions regarding the requirement of appropriate hearing evaluation/testing would be critical.

Summary

The AAO-HNS appreciates PCAST's analysis of the barriers faced by older Americans in terms of hearing loss and access to appropriate hearing-created services and/or devices. The PCAST report offers several tangible recommendations to help mitigate these issues for a potentially large portion of the older population. While more extensively elaborated above, the AAO-HNS reiterates its support for the following:

- **The availability of a "basic" and/or OTC hearing aid, intended for patients/consumers categorized to benefit from non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss. In order to identify individuals who actually fall into this category, the AAO-HNS stresses the importance of retaining requirements for a medical evaluation by a physician and appropriate (high-quality and standardized) hearing test.**

- **The withdrawal of draft FDA guidance and concurrent deregulation of PSAPs, thereby increasing the availability of basic or market-entry assistive hearing devices. Said devices should, however, include standardized information regarding the "red flag" warnings associated with ear disease.**

- **The availability of portable hearing test/audiogram results following the provision of a medical evaluation and standardized hearing test. Such flexibility**

will encourage consumer choice and hopefully spur technological advances and natural downward market changes regarding the cost of various hearing-related devices.

- **The potential for future legislation relating to the portability of hearing test/audiogram results and access to various hearing-related devices.**

The AAO-HNS looks forward to working with PCAST and other relevant stakeholders regarding efforts to mitigate the barriers associated with access to appropriate hearing-healthcare devices (and services) in the United States. If you have any questions or would like additional information regarding these comments, please contact legfederal@entnet.org.

Sincerely,

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

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[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.entnet.org/sites/default/files/SHL-talking-points-physicians.pdf
[iv] AAO-HNS Position Statement: Medical Role in Cerumen Management. http://www.entnet.org/?q=node/926
[v] AAO-HNS Position Statement: Red Flags-Warning of Ear Disease http://www.entnet.org/?q=node/912