

November 15, 2015

Mr. Barack Obama, President of the United States
and
President's Council of Advisors on Science and Technology
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mr. President and Members of the Council:

The American Academy of Audiology (Academy) appreciates the opportunity to respond and provide input to the recent report of the President's Council of Advisors on Science and Technology (PCAST), focusing on the accessibility and affordability of hearing care for the millions of Americans with untreated hearing loss. We acknowledge and agree that there is a significant need to improve access and reduce the cost of hearing care for older adults. Both the PCAST report and the concurrent work of the Institute of Medicine's Committee on the Accessibility and Affordability of Hearing Care in Adults are welcomed reviews of the current state of hearing health care in America.

Unlike vision and corrective lenses, there is no treatment that "corrects" the types of hearing losses described in the body of the PCAST report. In fact, the treatment of hearing loss most often focuses on the functional changes associated with the loss. In this regard, treatment for hearing loss may be as simple as counseling, or extend to the provision of sensory aids such as cochlear implants or hearing aids, or may require some degree of therapeutic intervention. While vision loss and hearing loss can both be classified as sensory impairments, they cannot be related in terms of evaluation, treatment, impact, or outcomes.

Within the body of the PCAST report is the note that the average price of a hearing aid in 2014 is \$2,363 per unit (page 1), but that the Veteran's Administration (VA) can purchase hearing aids for approximately \$400 per unit. It is true that the VA, due to its volume buying power, can command a lower price for the device than the private sector. This also explains why retailers such as Costco can command lower costs. The private sector, particularly individual practices, does not receive the same level of discounts from the manufacturers that volume buyers command. Immediately then, the price to the patient is higher in the private sector simply due to the cost of goods.

In the private sector, the charge for the device and the charge for the *services* are often bundled together. This is not unlike the charges for a surgery where the cost for follow-up services, the "global" period, is bundled into the charge for the surgery by the physician. Similarly for hearing aid products, the global period includes all services, but generally extends for a year or more. The private sector, unlike the VA, must factor in the cost of the service associated with the dispensing of the devices, including the communication evaluation, selection, fitting, verification, and validation of the devices, the accessories (such as batteries and ear molds), and the follow-up services. Thus it is unfair to compare the wholesale cost of a hearing aid at the VA with the cost of dispensing a device in the private sector. Nonetheless, we do believe this bundling of charges for the device and the services has contributed to the public perception that the cost of a hearing aid is high.

Response to Specific Recommendations

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 on-line, 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 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.

Response

In several places in the report, PCAST relates hearing aids to consumer electronics. The audiology community has never considered a hearing aid to be a consumer electronic device. In fact, its regulation by the FDA as a “Class I medical device” clearly differentiates the hearing aid from other consumer electronic devices such as televisions, smart phones or tablets. Thus, our perspective is that the creation of a class of hearing aid as an over-the-counter consumer electronic would further confuse the consumer. We would recommend that should this category of device be created, that it not be labeled as a hearing aid. Conversely, the consumer should be able to differentiate an over-the-counter device from the devices available to treat more complex or substantial hearing losses.

We also recommend that the FTC should require that all OTC devices be sold with an open platform format that will allow any audiologist to view, adjust, repair, or modify the parameters as needed by the patient. Currently, software used to program or adjust hearing aids is proprietary to the manufacturer and, as noted in the PCAST report, places restrictions on the number of hearing aid brands available at any one location. To assure that additional barriers of having to identify local audiologists who may or may not have access to proprietary software associated with an OTC device, an open platform would allow greater access to professional care when needed.

The American Academy of Audiology also recommends to the FDA that any OTC device be labeled with the recommendation that it is in the best interest of the patient to seek a comprehensive audiological evaluation prior to obtaining any device for the treatment of hearing loss. The labeling should also include a listing of the red-flag conditions that might signal the presence of ear disease. We recommend the labeling includes the fact that these products are intended to address hearing loss in adults with typical, age-related, mild-to-moderate sensorineural hearing loss. We strongly recommend that the labeling include warnings that these products should not be used by children.

We are concerned about the use of online hearing tests and the current potential for such procedures to under- or overestimate the degree of hearing loss. Consumers would be best served by having a comprehensive audiological evaluation, at least at the onset of their communication difficulties and to rule out ear disease. Due to these factors, we believe that it would be inappropriate to refer to any online or in-store test as a “hearing evaluation” or a “diagnostic” procedure. Comprehensive audiological testing results in a determination of the type, degree, possible etiology of hearing loss, and a determination of the impact of the hearing loss, and requires, at a

minimum, a battery of procedures conducted in controlled environments. We would support, however, online tests that provide *screening* procedures of sufficient degree to determine that a hearing loss falls inside or outside the mild-moderate hearing loss category.

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.*

Response

Similar to our comments in Recommendation 1 earlier, PSAPs should be labeled with indications, uses, and warnings. In addition, we recommend that the FDA require labeling that indicates these devices are not specifically designed for the treatment of hearing loss. We recommend that PSAPs include a recommendation that consumers seek a comprehensive audiologic evaluation from an audiologist or physician prior to purchasing the device, particularly if they intend to use the device “off-label,” for treatment of hearing loss. We also recommend that the devices be labeled with warnings regarding the red-flag conditions. We strongly recommend that the devices include warnings that they should not be used for children.

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.*

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.*

Response

The American Academy of Audiology supports these recommendations as they are essentially consistent with current requirements of the Health Insurance Accountability and Portability Act (HIPAA) of 1996. HIPAA ensures that all patients have access to their medical records, including their audiogram and plan of care. The audiology community routinely provides this information to all patients currently. We do note, however, that the comments for allowing access to “...programmable audio profile...” suggests that there is a common methodology for reporting such information. Currently there is no such common methodology across practices or manufacturers of devices.

Additional Recommendations

The American Academy of Audiology supports the concepts of greater access and lowered costs for patients with hearing loss. The recommendations put forth in this report are noted to provide a few simple actions on the

part of federal government that could enhance the pace of innovation and rapidly decrease costs. The report also notes the complexity of this issue. As such, the American Academy of Audiology offers these additional recommendations that can be undertaken by the federal government to improve access to hearing care and to reduce the costs to the consumer.

Recommendation #1: Reclassify hearing loss as a chronic health condition.

The American Academy of Audiology recommends that the Centers for Disease Control and other appropriate federal agencies be directed to consider and classify hearing loss as a major public health condition and as a chronic medical condition. The expanding population of adults older than age 65, coupled with longer lives, will result in an expansion of the number of persons with hearing loss in the decades to come.

The U.S. Department of Health and Human Services (HHS) defines chronic illnesses as conditions “that last a year or more and require ongoing medical attention and/or limit the activities of daily living.” As the most common forms of hearing loss in adulthood are persistent, permanent, and progressive and impose functional limitations, hearing loss meets the HHS definitions of a chronic health condition. Defining slowly progressive hearing loss in the adult population as a chronic medical condition will allow Medicare and other third-party payers the latitude to provide reimbursement for services related to the condition, including treatment services, even if the devices are not covered.

Recommendation #2: Require insurance coverage for hearing care services.

The PCAST report identified the lack of insurance coverage for hearing care services as one of the barriers to hearing care. As was indicated in the report, Medicare does not provide coverage for hearing aids, nor does it provide coverage for the services associated with obtaining amplification devices. As such, the full cost for the devices and the services are borne by the patient. Directing Medicare and other payers to reimburse for the services associated with the provision of hearing aids would allow greater access to the devices, even if the cost of the devices was borne by the patient.

The American Academy of Audiology also recommends the following regulatory changes at the Centers for Medicare and Medicaid Services, specifically with regards to Medicare:

- Inclusion of an acoustic hearing screening and subsequent audiologic evaluation if the patient fails the initial screening, in the Welcome to Medicare examination.
- Elimination of the Medicare requirement that requires audiologists, to ensure Medicare coverage, receives a physician order prior to testing medically necessary audiologic and vestibular evaluations.
- Inclusion of coverage for routine audiologic evaluations on a periodic basis (every two-to-four years), to monitor hearing status.

Recommendation #3: Eliminate FDA medical evaluation requirement.

The American Academy of Audiology recommends that the FDA be directed to eliminate the requirement for the medical clearance/waiver for adults (anyone 18 years of age or older). This requirement has been inconsistently implemented and poorly enforced to date. There is no evidence that the medical evaluation requirement has led to improved hearing care, as most patients tend to waive the requirement. In fact, this requirement increases costs by requiring a medical evaluation and decreases access by requiring multiple visits to multiple providers. If over-the-counter options become available,

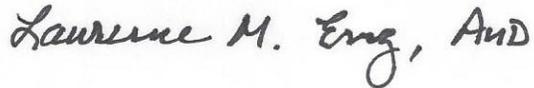
this requirement becomes moot and it would put an additional burden on the licensed provider that would not exist in the retail arenas; thus, creating additional access issues when the patient seeks care from a licensed provider.

Summary

The American Academy of Audiology supports the concept that providers offer patients access to every treatment or amplification option available, whether it is a hearing aid, personal sound amplification product, assistive listening device, FM system, or rehabilitation program. In this regard, we recognize the importance of the work of PCAST to raise awareness of hearing loss as a public health concern and to assist in aligning federal agencies with the goal of improving access and lowering costs. The American Academy of Audiology supports the PCAST recommendations to encourage greater competition and innovation within the hearing health-care environment. To date, the designations and labeling requirements assigned to different technologies has led to confusion in the dispensing community, and thus in the public as well. While we support many of the recommendations of the PCAST, we also believe that additional recommendations from the federal government would enable greater access and reduce the cost to the consumer of the services.

Please do not hesitate to call on us should you have any questions or concerns about our response or recommendations. We stand ready to work with the President's Council of Advisors on Science and Technology to improve access and reduce the cost of hearing care to the more than 30 million Americans with hearing loss.

Sincerely,

A handwritten signature in black ink that reads "Lawrence M. Eng, AuD". The signature is written in a cursive style with a large initial 'L' and 'E'.

Larry Eng, AuD, Board Certified in Audiology
President
American Academy of Audiology