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November 12, 2015

The President
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mr. President,

The Academy of Doctors of Audiology (ADA) applauds the President's Council of Advisors on Science and Technology (PCAST) for its focus on using technology to remove barriers to care for the millions of Americans with hearing loss. ADA members are audiologists who have spent their professional lives evaluating, managing and treating patients with hearing and balance disorders. ADA is cognizant of the significant health implications of untreated hearing and balance disorders, and ADA wholeheartedly agrees that hearing loss is a public health issue that requires prompt attention.

ADA believes that it is important to acknowledge that treatment for hearing loss can be complex and include anatomical, physiological, emotional, psychological, social and vocational issues that need to be addressed for any given patient. Moreover, clinical treatment for hearing loss is most often focused on improving communicative ability in patients with the hearing loss. That "treatment" goes well beyond the utilization of any device, be it a hearing aid, assistive listening device or personal sound amplification product. Functional improvement in communication, therefore, is often the primary goal for patients with hearing loss. As noted in the PCAST report, the emerging evidence of the relationship of hearing loss to cognitive function also illustrates the complexity of hearing loss and its associated comorbidities. ADA urges a stronger emphasis on evaluation and treatment beyond the device itself. The device is only a single component in a comprehensive plan of care, necessary for improving hearing, listening, and communication skills.

ADA offers the following positions on PCAST recommendations, along with rationales and additional recommendations:

The ADA position regarding PCAST recommendation #1: ADA supports the PCAST recommendation to create a *"class of hearing aids for over-the-counter sale, without the requirement for consultation with a credentialed dispenser."* Patients can already obtain these types of products over the counter or over the Internet without professional intervention.

Additional recommendations: ADA recommends that these over-the-counter (OTC) products be very specifically labeled and include a strong recommendation that a patient seek a comprehensive audiologic evaluation from an audiologist or physician prior to purchasing any device for the treatment of hearing loss, especially if the patient exhibits any of the warning signs of ear disease (tinnitus, dizziness, drainage, sudden hearing loss, asymmetry, foreign body in the ear, cerumen impaction, congenital or traumatic deformity of the ear). ADA also recommends labeling that is largely consistent with the PCAST recommendation that the device is a "non-surgical, air conduction hearing aid intended to address hearing loss."

It is important to note that children inappropriately treated with these devices are at risk for severe complications due to untreated ear disease. In addition, children inappropriately treated may be at risk for speech or language delays, poor school performance and/or cognitive delay. Over-amplification in the case of normal hearing can result in hearing loss caused by noise exposure from the device.

Rationale: There is no mechanism to ensure, consistent with PCAST recommendations, that only patients with "bilateral, gradual onset, mild-to-moderate, age-related hearing loss" will purchase and employ these devices. Consumers simply cannot make this type of determination without a comprehensive audiologic evaluation, at least at the onset of their communication difficulties.

An individual needs a comprehensive hearing evaluation, complete with an otoscopic evaluation, air and bone conduction testing, speech testing in both quiet and noise and a comprehensive case history to determine 1) the onset of the hearing loss, 2) the degree of hearing loss, 3) the type of hearing loss and 4) the etiology of the hearing loss. This level of evaluation cannot, currently, be accomplished via the internet. ADA believes that the role of the audiologist is important for successful patient outcomes along the hearing healthcare continuum of care.

Opposition to on-line self-diagnosis: ADA is opposed to on-line "testing" as it refers to a diagnostic evaluation. We are, however, very supportive of on-line hearing "screening" tools.

Rationale: True audiologic "testing," that allows audiologists to determine type, degree and possible etiology of hearing loss requires, at a minimum, a comprehensive case history, otoscopy, pure-tone air and bone conduction testing and speech recognition testing, in both quiet and in noise. On-line testing, at this juncture, is hampered by coupling/receiver issues (on the consumer side), the ambient noise effects of the room in which the consumer is seated and the patient understanding of the test requirements. ADA believes online evaluation tools should be utilized merely as screening tools to estimate degree of loss only.

The ADA position regarding PCAST Recommendation #2: ADA supports the PCAST recommendation that the FDA should withdraw its draft guidance on Personal Sound Amplification Products (PSAPs) and ADA supports the PCAST recommendations on the appropriate use and labeling of PSAPs.

Additional recommendations: ADA recommends that PSAPs include a strong recommendation that a consumer, who intends to use the device to treat hearing loss, seek a comprehensive audiologic evaluation from an audiologist or physician prior to purchasing the device, especially if the patient exhibits any of the warning signs of ear disease (tinnitus, dizziness, drainage, sudden hearing loss,

asymmetry, foreign body in the ear, cerumen impaction, congenital or traumatic deformity of the ear). In addition, ADA believes that these products should indicate that they are not FDA-registered medical devices, specifically designed for the treatment of hearing loss.

ADA also encourages the development of industry standards that are approved by the American National Standards Institute (ANSI) that address, at a minimum, the following:

- Frequency response bandwidth
- Frequency response smoothness
- Distortion control limits
- Noise levels
- Short/long term acoustic output
- Tone control
- Battery life
- Latency
- Automatic level control
- Active noise suppression
- Speech optimization
- Feedback control
- Signal-to-noise enhancement
- Directionality

ADA offers a few points of clarification to the issues the PCAST raised regarding device costs. First, PCAST indicated "64% of people with the most serious hearing loss reported that they could not afford a hearing aid." Unfortunately, these recommended actions will not alleviate the device cost barrier for these individuals. Over-the-counter devices and PSAPs, while they show promise for assisting those mild to moderately hearing impaired, are audiologically inappropriate for individuals with moderate, severe or profound hearing losses. Higher degrees of hearing loss require greater audiological oversight, due to the acoustical limitations of the ear itself.

The ADA position regarding PCAST Recommendation #3 and #4: ADA supports the PCAST recommendations.

Rationale: The Health Insurance Accountability and Portability Act (HIPAA) of 1996 ensures that all patients have the right to have access to and a copy of their audiological evaluation report, including the audiogram itself and their recommended plan of care. This plan of care could include a hearing aid, PSAP, assistive listening device and/or rehabilitative recommendations. The audiology community encourages patient access to this information.

Further, ADA believes that all hearing aids should be dispensed in an open platform format. Hearing aid programs should be able to be viewed, adjusted and modified by any licensed provider. Currently, there are numerous dispensaries and franchise clinics in this country that dispense "locked" hearing aids to their patients. A locked device will prevent an outside provider from viewing, adjusting or modifying the program or settings of these devices. Most consumers are not notified of this at the time of purchase. There is no state in this country that prohibits this action or that requires a patient be notified of this fact prior to the purchase of the device. ADA finds this practice to be counter to the best interests of the patient.

ADA believes that all programmable hearing devices sold in the United States should be delivered to the consumer on an open platform, that programmable hearing aids be developed on a consistent platform (such as NOAH) and that the programming software be easily available, at no cost to the provider, from the manufacturer of the device. This will allow the consumer increased access to care, greater buying

power, greater flexibility and improved care portability between providers. ADA supports FTC actions that would alleviate this current issue for both consumers and providers.

ADA shares PCAST's concerns regarding achieving better access to affordable, quality amplification options. We also agree that there needs to be greater innovations, technologies and manufacturers in the marketplace. In ADA's view, the hearing aid industry is entirely too insular. There is a significant need for value-based alternatives for both providers and patients. Private sector audiologists currently pay manufacturers significantly more for hearing aids than public (VA, Medicaid etc.) or retail (Big Box) sector counterparts. This is why there has been a growth in these sectors while private sector growth has been stagnant. Until recently, there have been few products available to audiologists at price points below $300. ADA understands that the only way to reduce the costs of devices is through greater competition in the marketplace.

ADA agrees that audiologists and other hearing healthcare providers should offer transparent pricing, and ADA is supportive of itemized and other transparent pricing models. As the PCAST suggests, itemization (unbundling) may have a positive impact on hearing aid affordability—but only if consumers are well informed regarding the expectations and costs associated with professional audiologic treatment services.

ADA has long encouraged providers to offer patients access to every amplification and treatment option available including hearing aids, assistive listening devices, FM systems and rehabilitation programs, whether delivered over-the-counter or through the provider. However, consumers must understand that audiologists, while committed and passionate about evaluating and treating hearing impaired individuals, cannot provide patients with services and care at no charge.

There are important components of diagnosis and treatment, which simply cannot be mirrored using a self-service model of care. Aspects of care such as otoscopy (to examine the condition of the ear canal and tympanic membrane/eardrum), device insertion and removal, battery removal and placement, device cleaning, moisture prevention, feedback management and counseling will not be available from direct-to-consumer enterprises. Consumers who utilize over-the-counter products may find that they need to seek subsequent services from audiologists in order to optimize product features and prevent health complications—and consumers should be prepared to pay for this professional care when required.

Other Barriers Must Be Addressed for Optimal Care

ADA recognizes that there is a significant need to improve access and affordability for older adults seeking professional hearing health care services. The pathway to evaluation and treatment of hearing loss is rather convoluted, unnecessarily cumbersome, and sometimes costly for the patient. Today, Medicare Part B, does not align with best practices in patient care.

There is an extreme lack of third-party coverage for the evaluation (when the testing is for the sole purpose of obtaining amplification) and treatment (amplification, assistive listening devices and/or aural rehabilitation) in this country. Increased access to third-party reimbursement for these items and services is yet another barrier to adoption. Medicare does not cover routine hearing care or hearing

screenings.[1] Hearing testing is only covered when medically ordered and necessary. Medicare does not pay for testing when "the type and severity of the current hearing, tinnitus, or balance status needed to determine the appropriate medical or surgical treatment is known to the physician before the test or the test was ordered for the specific purpose of fitting or modifying a hearing aid."[2] In approximately 60-70% of the cases in this country, it is true that the hearing impaired patient must bear the entire cost of the hearing aid, its related items and services and any necessary rehabilitation. ADA believes that adoption would increase, if we follow the data available from Great Britain, where hearing aids are a covered benefit within their socialized healthcare system, to approximately 40% (from our current 20%) if third-party reimbursement were more readily available.

Further, Medicare patients are currently required to obtain a medical order before Medicare will cover an audiologic evaluation from a licensed audiologist. These patients are then shuffled back and forth between providers in an inefficient process. Recently, Representative Lynn Jenkins, introduced legislation, The Audiology Patient Choice Act (HR 2519), which, if enacted, will alleviate many of these barriers within the Medicare system.

Technology advances have made it possible for audiologists to utilize telehealth for hearing screening, hearing aid counseling and aural rehabilitation and some hearing aid fitting, orientation and follow-up services. Unfortunately, licensure and reimbursement models have not kept pace with this technology. Telehealth services are not reimbursed for audiology. Home-based care is another avenue that many audiologists are interested in pursuing to improve patient access. Reimbursement issues make this type of care unavailable or costly to the patient. Medicare only covers audiologic care provided in the home in very limited situations.

Awareness is a Key Barrier:

As the primary providers of hearing and balance healthcare in this country, audiologists are on the frontlines, attempting to mitigate barriers to care for patients. While ADA agrees that cost and access are significant barriers to adoption, ADA does not view them as the largest barrier to treatment. There are already phone applications, hearing aids and PSAPs that are easily available to consumers via retail (OTC), internet and mail order outlets. Even though these products are available at costs ranging from $0-$1000 each, consumer adoption has not been greatly improved.

In ADA's view, awareness, both from the individual and the health care community, is the single, largest barrier to hearing aid adoption. Hearing health is not prioritized to the same degree as vision and dental health is, even among other health care providers, despite the high risks associated with untreated hearing loss. Most physicians do not include hearing screening or hearing testing in their annual, preventive care visits. What's more, Medicare, the largest payer of health care in the elderly, does not include a hearing screening or evaluation in the "Welcome to Medicare" evaluation that every new Medicare beneficiary has available to them when they enter the payment system.[3] Recently, the Centers for Disease Control (CDC) omitted hearing loss from a study on disabilities.

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[1] Chapter 16. (2008). In Medicare Benefit Policy Manual (pp. 1-28). Marblehead, MA. Retrieved October 29, 2015 from http://www.cms.gov/.

[2] Chapter 15. (2008). In Medicare Benefit Policy Manual. Retrieved October 29, 2015, from www.cms.gov.

[3] Your Medicare Coverage. (n.d.). Retrieved October 29, 2015, from https://www.medicare.gov/coverage/preventive-visit-and-yearly-wellness-exams.html

This lack of attention to prevention and early detection by the broader health care community are major barriers to the ultimate adoption of amplification and other treatments. ADA believes that a widespread commitment to prevention and early diagnosis could have a significant impact on the social stigma associated with hearing loss. If the importance of evaluation and treatment of hearing loss become more integrated into the healthcare landscape, individuals will begin to see it as a greater healthcare concern.

Conclusion

ADA supports the PCAST recommendations to encourage greater competition and innovation within the hearing healthcare environment.

To date, the designations and labeling requirements assigned to different technologies have led to concern and confusion in the dispensing community. There have been questions, with very little clarification or guidance from governmental or regulatory agencies, as to whether or not a licensed audiologist can legally dispense a (PSAP) to a patient with a documented hearing loss. There have been additional questions as to how the sale of a device not classified by the Food and Drug Administration (FDA) as a hearing aid can be dispensed and allow the licensed audiologist to still comply with consumer protection, dispensing laws designed to govern "hearing aids."

The messages from industry, state licensure boards, and the FDA have been inconsistent and confusing. ADA recognizes that, currently in many cases, the only real difference between a "hearing aid" and a "personal sound amplification product" is the FDA 510K paperwork. These are just a few of the challenges that providers experience in attempting to deliver alternative technologies to patients.

Supplemental recommendations:

Recommendation #1: ADA recommends that the Administration urge the CDC to prioritize hearing loss as a major public health concern, which warrants routine screenings to help ensure early detection and treatment of hearing loss.

Recommendation #2: ADA recommends the following regulatory changes at the Centers for Medicare and Medicaid Services (CMS), which govern Medicare. This includes, but is not limited to:

- 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 that audiologists, to ensure Medicare coverage, receive a medical order prior to testing medically necessary audiologic and vestibular evaluations.
- Elimination of the Medicare requirement that audiologists are a "diagnostic only" profession so audiologists can be reimbursed for medically necessary audiologic treatment, including but not limited to, aural rehabilitation, that currently can be provided by and reimbursed to other, less educated providers.
- Inclusion of coverage for routine, prevention audiologic evaluations on a periodic basis (every two to four years), regardless of medical necessity (it could possibly be for the sole purpose of obtaining amplification).

In summary, ADA is pleased to see greater governmental recognition of hearing loss as a public health issue and a greater focus on the needs of the hearing impaired, specifically as it relates to hearing technology. It is critically important that the same level of attention and emphasis be directed towards ensuring patient access to high quality audiologic care.

Professional evaluation and treatment services are the recommended standard of care and vital to remediating a patient's hearing, listening and communication difficulties. Hearing optimization cannot be achieved through a device alone. Consumers are best served by undergoing a comprehensive evaluation prior to purchasing any device, regardless of whether the device is purchased over the counter or via a licensed provider.

ADA looks forward to a continued dialogue on these important issues and would be pleased to assist in efforts to expand consumer access to safe, efficient and effective hearing healthcare services, which promote patient safety and positive outcomes. Please contact me or Stephanie Czuhajewski at sczuhajewski@audiologist.org or 866-493-5544 if you need additional information. Thank you again for your consideration.

Respectfully,

Kimberly M. Cavitt, Au.D., President