AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

November 19, 2015

John P. Holdren, Co-Chair
Eric Lander, Co-Chair
President's Council of Advisors on Science and Technology
Executive Office of the President
1650 Pennsylvania Avenue, NW
Washington, DC 20504

Dear Messrs. Holdren and Lander:

On behalf of the American Speech-Language-Hearing Association (ASHA), we commend the President's Council of Advisors on Science and Technology (PCAST) for their interest in accessibility and affordability of hearing health care for millions of Americans with untreated hearing loss. The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 182,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students.

Our organization agrees that there is a significant need to improve access to and affordability of audiology services, and that the current pathway to care may be cumbersome and costly. The ASHA community supports greater access to services and devices to treat hearing loss.

We are, however, disappointed that the Council was tasked to evaluate only one aspect of hearing health care services—an amplification device. By focusing solely on a device, the Council has made an error in assuming that hearing is analogous to vision and has inadvertently dismissed the importance of an individualized treatment plan developed by an audiologist as best practices in hearing health care.

Hearing loss is a complex chronic health condition that requires consideration of the whole person, and often needs the expertise of several health professionals and/or a partnership between a primary health care provider and an audiologist. Hearing loss affects many body and brain systems and, when untreated, has been demonstrated to lead to other serious conditions, such as social isolation, depression, increased falls, and other comorbidities.

A common misconception that was evident in the PCAST report is that amplification alone will enable a person with hearing loss to hear and understand fully in the same manner that glasses can restore normal vision. A hearing aid alone is not enough to overcome a hearing disability. Treatment for hearing loss is more complex and requires a comprehensive assessment of the patient's needs in addition to a detailed evaluation of auditory function beyond the simple audiogram—areas of expertise that audiologists have specialized training to do. Much like consumers would not benefit from purchasing a prosthetic arm or leg without counseling and rehabilitation from physical and occupational therapists, consumers appreciate limited or no

benefit from over-the-counter (OTC) hearing aids absent counseling and rehabilitation from an audiologist.

Unfortunately, while the cost of the hearing aid may play a role in consumer access to hearing health care services, current federal and private health care policy also contributes to this limited access. Physicians do not typically include hearing evaluations in their annual preventative care visits, nor does Medicare include or cover an initial hearing test in their *Welcome to Medicare* evaluation. Medicare limits the coverage of audiology to diagnostic evaluation only, and specifically excludes services for hearing aid selection and fitting as well as counseling and rehabilitative services provided by an audiologist. This creates a situation in which consumers may not have the resources to receive evidence-based treatments needed for their hearing loss. It is imperative that all barriers, such as adequate reimbursement for professional hearing health care services, and not just the price of hearing aids, be considered before public policy is enacted.

We ask that you and your health, science, and technology advisors make a more comprehensive assessment of patient access to all hearing health care services, rather than simply focusing on the cost of a device. We urge recommendations that consider evidence-based hearing and health care practices that will improve access to affordable hearing health care.

The Council has made recommendations and has requested public feedback. Therefore, we respectfully submit the following comments on the PCAST recommendations related to amplification.

Recommendation 1—New Distinct Category of Hearing Aids for OTC Or Online Purchase: NONSUPPORT

ASHA has grave concerns about the recommendation for a new class of over-the-counter hearing aids for those with mild-to-moderate hearing loss. Such a recommendation could pose hearing risks to the consumer if the underlying cause is not properly tested and diagnosed by a hearing health care professional, and if the purchased device is not properly fitted for the consumer.

Currently, consumers can purchase hearing aids through the Internet and over-the-counter. We have heard from our members that consumers are coming to their offices with Internet and OTC devices with complaints, concerns, and questions related to programing and adjustments. **While we are not in favor of the recommendation**, should the FDA move forward with "basic hearing aids" as a new OTC category, we recommend that these devices be sold with an open platform. That would allow audiologists to view, adjust, repair, and/or modify the parameters as needed by the patient. Current software used to program or adjust hearing aids is proprietary to the manufacturer and—as noted in the report—places restrictions on the number of hearing aid brands available at any one location.

In addition, care must be taken to ensure that OTC devices intended to address hearing loss in adults with age-related, mild-to-moderate sensorineural hearing loss are registered as medical devices. Regulations must be in place to distinguish between hearing aids classified as medical devices and consumer electronics that augment hearing—known as personal sound amplification

products (PSAPS). As noted in the report, the line between PSAPs and hearing aids has become blurred and, at times, differentiated only by its advertised purpose.

The FDA must maintain consistency in its regulations regarding hearing aids to ensure that patients purchasing these devices have had the benefit of a comprehensive audiologic evaluation. The FDA must also develop guidelines to ensure consistency in what constitutes an online hearing test/screen versus a comprehensive audiologic evaluation. We express concerns regarding the advocacy for OTC or online hearing tests for self-diagnosis. Environmental noise may influence the estimates of hearing thresholds rendering unreliable or false results that can cause additional problems in programming any hearing aid.

Furthermore, consumers who purchase these devices should be made aware of the FDA "Red Flag" conditions and symptoms and be instructed to seek medical care should these symptoms present.

It is imperative that OTC hearing aids should not be permitted for children. Children treated with these devices are at risk for severe complications due to untreated ear disease, inadequate amplification **leading to severe, permanent, and disabling language impairment**, as well as additional hearing loss because of inappropriate levels of amplification. We acknowledge that the scope of the report excludes children and adults with severe hearing loss. But, our concern is focused on the possibility of a parent purchasing a hearing aid for a child simply because it is available OTC at a lower cost due to absence of professional services. We must emphasize that childhood hearing loss is not the same as adult hearing loss for many reasons.

Recommendation 2—Rescind FDA Guidance on PSAPs: OPPOSE

Personal sound amplification products (PSAPs) are consumer electronic devices that are not regulated by the FDA. Too often advertisements blur the line between hearing aids, which are classified as medical devices, and PSAPs, which are consumer electronic devices. FDA guidance on PSAPs serves to assist the consumer in making informed decisions about their health care purchases. We would also urge the FDA to include encouragement for consumers to seek a comprehensive audiologic evaluation if they are intending to use the PSAP to treat hearing loss, and that consumer electronic devices are not classified for that use.

Recommendations 3/4—Provision of a Copy of the Audiogram to Patients: SUPPORT

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 ensures that all patients have the right to access and copy of their audiologic evaluation report—including the audiogram itself—and the recommended plan of care. This plan of care could include specific hearing aids and rehabilitation recommendations as individually appropriate.

Additional Comments and Recommendations

Below, we provide you and your advisors with clarification of three specific issues raised in the "findings" section of the PCAST recommendations. Clarification is needed for the misconceptions of 1) the comparison of eye glasses to hearing aids; 2) the Veterans Health

Administration's cost of hearing health care benefits provided; and 3) the practice of bundling the costs of services and device(s).

1) Over-the-counter eye glasses (readers) are commonly used as an example of how medical devices can be effectively distributed at a lower cost by allowing consumers to purchase them over-the-counter. Hearing aids and eye glasses are not analogous. Even the most advanced hearing aids cannot restore hearing to 100% in the same way that some glasses can restore vision to 20/20. In addition, the individual needs time to adjust to the sound provided by a hearing aid, whereas eyes adjust immediately to glasses. Consumers may need to revisit an audiologist several times to adjust the hearing aid to accommodate specific needs. Even though a hearing aid can provide substantial benefit, it will not restore normal hearing function.

2) We raise significant concern about the Council's assertion that hearing aid prices can be lower in the private marketplace, citing the Veterans' Health Administration's ability to purchase hearing aids through a negotiated volume-discounted rate. The report notes the average price of a hearing aid in 2014 to be $2,363 (page 1), compared to the Veteran's Administration purchasing power of approximately $400 per unit. This creates the impression that the mark-up on hearing aids in the private sector is nearly 600%. This would not be an accurate conclusion.

   It is true that the VA, due to its volume buying power, can command a lower price than the private sector. This also explains why Costco and other big box distributors can negotiate lower costs. The private sector, particularly individual practices, do not receive the same level of discounts from the manufacturers that volume buyers command. Consequently, the price to the patient is higher in the private sector simply due to the cost of goods. Furthermore, within the VA system, **the cost of evaluating hearing, selecting, ordering, fitting, and verifying hearing aids as well as providing follow-up services is paid through federal budget allocations** to the Department of Veteran's Affairs from Congress. In other words, the federal government subsidizes the actual costs associated with dispensing a hearing aid. As a result, the true cost of providing hearing aids in the VA system is substantially higher than $400 when the cost for the services are included.

   In contrast, the historical delivery model for amplification in the private sector includes both the device and the associated services. While we acknowledge that the cost to the patient in the private sector is higher than within the government sector, the difference in actual costs, when factoring in volume purchasing and **government subsidization**, become very small.

3) We acknowledge the challenges of the current practice of bundling the cost of a device with professional services and support the need for transparency in this area. If the cost of professional services were recognized and reimbursed (such as they are in the example of the VA provided above) by public and private health plans, this practice would no longer be necessary. Additionally, we request that the PCAST consider adding these recommendations to their report:

- Centers for Disease Control (CDC): Recommend that the CDC and other appropriate federal agencies be directed to classify hearing loss as a chronic medical condition. Defining progressive hearing loss in the adult population as a chronic medical condition would give Medicare and other third-party payers the latitude to provide reimbursement for professional hearing health care services, including treatment and rehabilitation.
- Coverage of hearing health care services: There is scant coverage by third-party payers of comprehensive audiologic services. Increased access to third-party reimbursement for these devices and services would remove a barrier to hearing health care. We ask that the President's Council encourage the Centers for Medicare & Medicaid Services (CMS) and Congress to work toward ensuring full coverage of audiologic diagnostic and treatment services under Medicare.
- Understand the difference of volume purchases from hearing aid manufactures. Private practice audiologists cannot generate the same volume of sales as the Veterans Health Administration or big box stores, such as Costco. Therefore, their costs are higher in terms of what they must invest in purchasing hearing aids from manufacturers. PCAST should consider recommendations that allow private practitioners to form co-ops that could afford those similar price points as the VA and Costco.

Thank you for the opportunity to provide feedback on this important report. ASHA stands ready to provide additional information and feedback on this significant issue. Please feel free to contact Ingrida Lusis, ASHA's director of federal and political advocacy, at ilusis@asha.org or 202-624-5951, should you require additional information.

Sincerely,

Judith L. Page

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2015 ASHA President