

July 16, 2021

The Honorable Xavier Becerra
Secretary of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Secretary:

In light of comments included with the Executive Order (EO) on Promoting Competition in the American Economy issued by President Biden on July 9, the American Academy of Audiology (the Academy) is reaching out to your agency to offer additional insights relative to the availability of over-the-counter (OTC) hearing aids. We noted with dismay that the EO fact sheet dismisses the role of the audiologist as the primary hearing healthcare specialist as part of the equation for effective use of OTC devices. While we certainly support efforts to lower costs and improve access to hearing aids, we have grave concerns about the oversimplification of hearing loss and treatment in the advancement of OTC devices.

Representing the interests of approximately 14,000 audiologists nationwide, the Academy is dedicated to providing quality hearing and balance care services through professional development, education, research, and increased public awareness of hearing and balance disorders. Audiologists are doctorally-prepared professionals whose scope of practice includes auditory and vestibular diagnosis and treatment services, as well as neurological monitoring.

While the EO implies that the OTC hearing aid category cuts back on the need for the expertise of an audiologist, the reverse is true. It is important to understand that hearing loss is more complex than a lack of volume; thus, management of hearing loss is best after a comprehensive hearing assessment conducted by an audiologist. This may include a lifestyle assessment to gauge the impact of hearing difficulties on quality of life and activities of daily living, followed by a number of tests targeted at understanding the individual's sensitivity to sounds of various pitches, ability to understand complex sound patterns such as speech in quiet or in noise, and physiologic evaluations of various structures in the auditory pathway. The audiologist uses this information to not only identify how the structures of the ear have been impacted; to treat hearing difficulties optimally, the audiologist must gain a deeper understanding of the individual's lifestyle needs and learned preferences for sound presentation. The audiologist can then develop comprehensive treatment recommendations that may include device selection and optimization, as well as supportive counseling and guidance through a customized hearing rehabilitation plan. Audiologists are highly educated to determine the cause of hearing loss, refer for medical intervention when necessary, and implement an effective management plan, which often is more than simply increasing the volume through a device.

According to the U.S. Dept. of Health & Human Services' NIH/NIDCD, approx. 28.8 million U.S. adults could benefit from hearing aids. The Academy is hopeful that many of these consumers suffering from hearing loss will seek the assistance of an audiologist and, when deemed to be appropriate, will either try over-the-counter hearing aids and/or consider devices that are recommended, prescribed, and verified by an audiologist. The OTC devices may offer a lower cost treatment option, but the consumer should have the benefit first of a professional diagnosis before making an investment into a treatment option that may not be appropriate or meet their needs. Hearing, and the ear-brain interface responsible for decoding complex sounds such as speech, is complex. For some individuals with hearing difficulties, the issue is that some sounds are too soft to be processed; in this case, they may benefit from a relatively simple amplification device that offers a boost to the specific pitches they are experiencing difficulty hearing. For others, there is also difficulty in processing complex speech sounds even when loud enough, especially in challenging listening environments. These individuals

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may require more advanced technology options or other types of hearing habilitation support. The recommended technology option and hearing habilitation program will depend on the type and degree of hearing loss, as well as the lifestyle needs of the individual. Self-determination of a hearing loss as “mild” or “moderate,” the range for use of OTC devices, is subjective; the consumer needs the guidance of an audiologist for a diagnosis, the best treatment option, and how to utilize a device.

The Academy urges the HHS to recognize the critical role of the audiologist in helping consumers to navigate the various options and determine the type of device that would be most appropriate to treat their diagnosed degree of hearing loss. Further, for those who purchase an OTC device, the professional adjustment, verification and support can improve benefit. It is through involvement of an audiologist that consumers will achieve the best possible outcomes with OTC hearing aids and avoid the risks of under- or untreated hearing loss. We would be happy to provide additional information and stand ready to work with your agency to advance effective solutions for hearing and balance problems.

Sincerely,

A handwritten signature in black ink that reads "Angela Shoup". The signature is written in a cursive, flowing style.

Angela Shoup, PhD, FAAA, FNAP
President, American Academy of Audiology

cc: Kristin Avery, White House Liaison, HHS
Elizabeth Jurinka, Special Assistant to the President, The White House
Rachel Levine, MD, Assistant Secretary of Health, HHS
Andrea Palm, Deputy Secretary, HHS