ADA Supports Bipartisan, Bicameral Over-the-Counter Hearing Aid Act of 2017

March 22, 2017

The Academy of Doctors of Audiology (ADA) supports S. 670/H.R. 1652, the Over-the-Counter Hearing Aid Act of 2017, and commends Senators Warren and Grassley, and Representatives Blackburn and Kennedy for their foresight in introducing this legislation, which if enacted, will remove unnecessary and burdensome barriers to hearing care for millions of Americans.

The Over-the-Counter Hearing Aid Act of 2017 would allow hearing aids, intended to be used by adults to compensate for mild to moderate hearing impairment, to be sold over the counter (OTC), and would eliminate the requirement that adult consumers obtain a medical evaluation or sign a waiver in order to acquire these hearing aids. This landmark legislation also directs the FDA to issue regulations containing safety and labeling requirements for this new category of OTC hearing aids and to update FDA draft guidance on Personal Sound Amplification Products (PSAPs).

The Over-the-Counter Hearing Aid Act is consistent with ADA's longstanding position to implement recommendations from the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering, and Medicine (NASEM), which have both recommended making some types of hearing aids available over the counter and removing the requirement of a medical evaluation in order to allow millions more Americans to access hearing aids.

The availability of FDA-registered OTC hearing devices will allow consumers to make better informed decisions about their treatment options, and will also facilitate increased competition, enhance quality and improve transparency with regard to the purchase of direct-to-consumer hearing amplification products.

"The ADA is unaware of any credible research demonstrating that the medical evaluation requirement actually leads to the identification and treatment of medical conditions that would not otherwise be identified appropriately by the patient," said ADA President, Angela Morris, Au.D. "There is no evidence that the required medical evaluation, as a condition of purchasing a hearing aid, improves the outcome for patients seeking hearing health care. Further, anecdotal evidence suggests that the medical evaluation waiver is widely used."

The ADA stipulates that there are risks with self-treatment, including overlooking conditions that warrant medical intervention. However, we contend that in the current regulatory environment, those risks are already being taken by consumers with either limited information--or worse yet, misinformation.

There is a preponderance of data available today that demonstrates that, when it comes to hearing loss, the risk of non-treatment may be greater than the risk of self-treatment. The tremendous co-morbidities and maladies associated with untreated hearing loss are well documented, as are the benefits of amplification in improving quality of life and mitigating serious health conditions. Therefore, the public will be best served if basic hearing devices are available to consumers over the counter, just as they are already available over the internet.

The regulatory environment has struggled to keep pace with rapid advances in hearing amplification technology. Creating an OTC hearing device market will foster competition, broaden consumer choice, improve affordability, and accelerate future innovation. As consumers already have direct-to-consumer internet access to hearing aids and similar unregulated technologies, the creation of a regulated OTC class will not increase existing risks to the public.

The ADA and its members seek expanded access for consumers to audiology services. We strive to accomplish this goal through the advancement of practitioner excellence and high ethical standards in the provision of quality audiologic care. The Over-the Counter Hearing Aid Act will help to facilitate these objectives and is consistent with the ADA's mission and philosophy.

In summary, the removal of the medical clearance requirement and the availability of a regulated OTC hearing device, which calls for FDA to include appropriate labeling and safety measures, will expand access to quality hearing health products and services, reduce duplicative costs, and remove unnecessary, non-beneficial barriers to care. For this reason, the ADA is pleased to support the Over the Counter Hearing Aid Act.

Contact:

Stephanie Czuhajewski, CAE
Executive Director
446 E. High St.
Lexington, KY 40507
sczuhajewski@audiologist.org
859-977-7444