

**Breaking: FDA Opens Doors for Unregulated Hearing Aids;  
Eliminates Medical Evaluation Requirement**

At a recent meeting on hearing health care in adults at the National Academies of Sciences (NAS), Eric Mann, MD, PhD, Clinical Deputy Director, Division of Ophthalmic and Ear, Nose, and Throat Devices of the U.S. Food and Drug Administration (FDA), announced that the FDA is issuing a guidance document stating, effective immediately, that the FDA no longer intends to enforce the requirement that individuals over 18 years of age receive a medical evaluation or sign a waiver prior to purchasing most hearing aids. The FDA will continue to enforce the medical evaluation requirement for children.

A press release from the FDA also announced a commitment to consider creating a new category of over-the-counter (OTC) hearing aids and will consider recommendations from the National Academies of Sciences, Engineering, and Medicine as well as the President's Council on Science and Technology (PCAST), who had previously issued reports supporting regulatory changes and a category of OTC hearing aids. OTC hearing aids would not require the consultation of a licensed dispenser. The FDA believes this could deliver lower cost hearing aids to consumers.

While ASHA supports greater access to technology, we continue to maintain that counseling and aural rehabilitation—provided by audiologists—are critical to the successful adaptation of technology. ASHA is also concerned that, although the FDA will still require a medical evaluation for children, there is nothing to stop a parent from purchasing an OTC device for their child with hearing loss without consultation from a hearing health care professional. We have formally commented that children treated with these devices are at risk for severe complications due to untreated ear disease and/or inadequate amplification.

ASHA has previously commented to the FDA, in both a public presentation at the FDA and through formal comments, against these changes to the current regulatory framework and stated that the FDA should:

1. Clarify and finalize guidance to make clear distinctions between personal sound amplification products (PSAPs), that are consumer electronic devices intended to amplify sound, and hearing devices, marketed for mild-to-moderate hearing loss, and strictly enforce compliance of hearing aid regulations.
2. Require warning labels on PSAPs, devices, and aids regarding "red flags" for conditions that require medical treatment. Recommendations should also be included for individuals to seek the services of a hearing health care professional for their hearing health care needs.
3. Work with the National Institute on Deafness and Other Communication Disorders, and other appropriate health research organizations, to develop pilot programs and/or demonstration projects to evaluate new delivery models. The data and findings from these studies should be made available to the public.

### **Background**

There has been an increased scrutiny by federal agencies on the affordability and accessibility of hearing aids. In 2015, PCAST wrote a report examining the technology, regulation, and marketplace of hearing aids, leading them to recommend that the FDA approve a category of OTC devices. NAS conducted a two-year study that also called for an OTC hearing aid and agreed with the PCAST recommendation.

ASHA provided feedback to both of these groups and the FDA at a stakeholders' workshop in April 2016. As part of our written comments and testimony, ASHA requested them to take a more comprehensive look at hearing health care—including the audiologist's role in addressing a hearing disability—rather than solely focusing on amplification devices. ASHA also urged them to make recommendations that consider evidence-based hearing health care practices to improve affordable access to audiology services in addition to devices.

### **Resources**

- [President's Council of Advisors on Science and Technology Report](#)
- [Institute of Medicine: Accessible and Affordable Hearing Health Care for Adults](#)

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