Over-the-counter Hearing Aids: From Research to Policy to Practice

Regulations recently issued by the US Food and Drug Administration (FDA) mark a new era in health care for hearing as the agency establishes a new category for over-the-counter (OTC) hearing aids. Announced in August 2022, this action will bring accessible and affordable devices to millions of US residents aged 18 years and older with perceived mild to moderate hearing loss. These new regulations allow manufacturers of hearing aids, as well as companies that have not traditionally produced medical devices, to enter the market with devices that are safe, effective, less expensive, and more commercially appealing. Easing entry into the market for hearing aid manufacturers, circumstances that created steep barriers to market entry for potential manufacturers, as well as concerns that may affect hearing before hearing aid use further restricted access. In response to these concerns, the FDA issued guidance in 2016 stating that in general it would no longer enforce this requirement for adults, effective immediately.

In addition to this targeted response, a series of collaborations involving multiple US health agencies and advocacy organizations began to coalesce in 2009 around the urgent need to improve access to hearing aids and technology and service delivery. Recognizing that in addition to numerous problems there were also significant opportunities to challenge the status quo, the National Institute on Deafness and Other Communication Disorders (NIDCD) at the National Institutes of Health (NIH) played a major role in directing and funding research in support of this public health effort. After an NIDCD-sponsored workshop on this topic in 2009, funding opportunities were designed to enable a hearing health care environment that would be consumer friendly, empowering, and supportive of a competitive and innovative marketplace. Sponsored research included studies on new hearing health delivery models for underserved populations and research on technology to enable the development of effective self-fitted hearing aids.4

Research funded by the NIDCD was responsive to congressional language in the institute’s fiscal year 2010 appropriation, which recommended that NIDCD support research to develop, improve, and lower the cost of hearing aids.

As it responded to these challenges, the NIDCD was joined by the National Institute on Aging, the FDA, the US Department of Veterans Affairs, the US Centers for Disease Control and Prevention, and the Hearing Loss Association of America in sponsoring the Committee on Accessible and Affordable Hearing Health Care for Adults, convened by the National Academies of Sciences, Engineering, and Medicine (NASEM). One of the committee’s key recommendations called for the FDA to implement a new device category for OTC-wearable hearing devices.5

Research solicited and sponsored by the NIDCD confirmed the feasibility of this novel service delivery model. The charge to the

Addressing a Leading Cause of Disability

Hearing is a vital human sense and is critically important for maintaining health and quality of life. Hearing loss is a leading cause of disability both in the US and globally.2 By age 70 years, nearly half of all adults report hearing loss; the changing demographics of the aging US population suggest that an increasing portion of the population will struggle with hearing disability in coming years. Although lack of affordable and accessible hearing care is a problem that cuts across socioeconomic groups, it particularly affects minority populations and those in rural and inner-city geographic settings.

Before the finalization of the FDA’s rule establishing a category of OTC hearing aids, this therapeutic arena was characterized by a limited-competition marketplace dominated by a handful of large international hearing aid manufacturers, circumstances that created steep barriers to market entry for potential manufacturers and resulted in high prices for consumers. In addition, hearing aid fitting has traditionally been performed by audiologists or hearing instrument specialists, the expense of which was typically bundled with the cost of hearing aids. Taken together, this has had the effect of limiting price transparency and has afforded scant opportunity for consumers to engage in informed comparison shopping. A requirement for an examination by a physician (or a signed waiver declining this examination) to identify any medically treatable conditions that may affect hearing before hearing aid use further restricted access. In response to these concerns, the FDA issued guidance in 2016 stating that in general it would no longer enforce this requirement for adults, effective immediately.

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NASEM committee stated that “…in the circumstance where robust evidence is lacking or absent, the committee is encouraged to make recommendations based on sound scientific reasoning in the context of the current healthcare environment.”

As the NASEM committee was deliberating, the President’s Council of Advisors on Science and Technology (PCAST) was also considering the question of how to make hearing aid technology more accessible to older US residents. In 2015, PCAST issued its report, which recommended that the FDA create a new category for “basic” OTC hearing aids.

The Over-the-Counter Hearing Aid Act

These 2 committee recommendations resulted in the introduction of the Over-the-Counter Hearing Aid Act of 2017, a version of which was included as a part of the FDA Reauthorization Act of 2017, which was signed into law in August 2017. The law defined OTC hearing aids and required the FDA to establish a regulatory category for them. It also required the FDA to issue regulations for OTC hearing aids that include requirements that provide reasonable assurances of safety and effectiveness, include requirements that establish appropriate output limits and labeling, and describe requirements for sale without the involvement of a licensed person. The law also removed some existing barriers to access and prevented the creation of others by preempting certain state laws, making it possible to create a feasible category of OTC hearing aids. The FDA issued the proposed rule for public comment in October 2021 as called for in President Biden’s executive order “Promoting Competition in the American Economy.” The final rule was issued on August 17, 2022, after the agency reviewed and responded to more than 1000 public comments. The rule went into effect in October 2022.

During the past decade or so, close partnerships among the NIH, the FDA, the broader scientific community, and other stakeholders have produced substantial advances in public health related to hearing loss. The new framework introduced by the FDA provides a platform for developing safe, effective, and less costly hearing aids for the millions of US residents with perceived mild to moderate hearing loss. The widespread use of safe and effective devices should substantially decrease the burden of hearing loss and associated disabilities, improve overall health, and contribute to the normalization and destigmatization of hearing aid use.

Although previous efforts have enabled this new era, the potential benefits of matching technologic advances with the needs of people with hearing loss will be realized only with continued collaborative research. In addition, that research must be translated into improvements in therapeutics and delivery to ensure that all persons, including those in marginalized and geographically inaccessible communities, receive the care they need and have access to the best technology possible. Today, statistics show that the majority of individuals who could benefit from hearing aids do not use them. The new regulations are an important further step in improving access to these life-changing devices. Proactive approaches by the clinical community to support use of these new channels for broader access, by the clinical research community to help consumers take advantage of the technology, and by the biomedical and technology communities to drive product improvements will all be needed to translate this opportunity into improved health for the millions of people with hearing loss.

ARTICLE INFORMATION

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Conflict of Interest Disclosures: Dr Tucci is an employee of the National Institute on Deafness and Other Communication Disorders (National Institutes of Health). Dr Califf is an employee of the US Food and Drug Administration (FDA); reported that before his appointment to the FDA as Commissioner for Food and Drugs, he was an employee of and held equity in Verily Life Sciences and Google Health (Alphabet); and reported serving on boards of directors for Cytokinetics, Centessa, Clinetic, Keystone Symposia, the Center for Policy Analysis on Trade and Health (CPATH), the Clinical Research Forum, and One Fifteen. No other disclosures were reported.

REFERENCES