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Before the
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061, (HFA-305)
Rockville, MD 20852

In the Matter of

Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids 21 CFR 800, 801, 808, and 874	))))	Docket No. FDA-2021-N-0555

COMMENTS OF JANICE S. LINTZ
January 5, 2022

Comment on Proposal to establish a regulatory category for over-the-counter (OTC) hearing aids and to make related amendments to update the regulatory framework for hearing aids

Action Requested: The FDA should confirm the Proposed OTC Hearing Aid Regulations and include easy-to-understand descriptions of OTC hearing aid features so lay consumers will be able to understand the technical information.

Discussion:

Hearing aids offer various features, but it is difficult for consumers to compare brands. Manufacturers do not use common names for features, and many manufacturers trademark the terms they use.

Comparing features is virtually impossible without consistent representations.

The FDA states in its proposed rule, “As part of the 2016 FDA hearing aid workshop, the Hearing Loss Association of America presentation stressed the importance of clear labeling to inform consumers so that the consumer 'is empowered and knows what they’re buying and knows the limitations and what’s possible.’ ” It was my testimony that stated, “Standardizing terminology for hearing aid features will also help consumers to evaluate personal sound amplification products (PSAPs) which are not hearing aids and thus not regulated by the FDA. PSAPs are flooding the market, and consumers have no idea how effective these devices are for people with hearing loss—they only know that PSAPs are more affordable. If generic names for hearing aid features were used, then consumers could compare PSAPs to hearing aids and see what they are or are not receiving.’

The ruling which is terrific, however, it does not include an easy-to-use rating system so consumers can easily compare hearing aids. As the FDA notes, “the interpretation of [ANSI/CTA-2051] information is highly technical, so the information is useful to a professional but generally not the lay user.” Having a rating system to aid consumers is therefore critical, yet the document omits any mention of one. While the future comprehensive guidance document will assist, it is too confusing and cumbersome, and most consumers will likely not read it. Most are not experts and need easy-to-use rating comparisons.

The FDA should mandate a 30-day return policy to ensure that consumers can try the OTC hearing aid and return it if it doesn’t meet their needs. Further, companies should have online videos with captions that demonstrate how to use the OTC hearing aid.

I am also hopeful that the finalization of this ruling will cause the FDA to apply the same electroacoustic performance requirements to prescription hearing aids, which my daughter uses, since people with “red flag” conditions need protection against unethical hearing aid vendors. Contrary to the FDA’s statement that the “involvement of a licensed professional for prescription hearing aids will help provide for reasonable assurance of safety and effectiveness for those devices,”

this is not the case, since the professionals have an inherent conflict of interest by both prescribing and selling hearing aids.

A licensed professional does not carry every brand or the full line of hearing aids and has a disincentive to lose a sale by sending a client to someone else. Our family wasted thousands of dollars on unsuitable hearing aids based on a professional's advice, including telling my daughter that hearing aids no longer work for her when they do. She just needed different hearing aids from those the professional sold.

The FDA should also mandate inclusion of telecoils and require audiologists and dispensers to include the telecoil information with the bill, as is required by Arizona.

Conclusion:
The FDA will bring greater transparency and accountability to the dispensing of OTC hearing aids for people with mild to moderate hearing loss in people age 18 or older by standardizing the naming of hearing aid features and developing a rating system using international ANSI standards for the various features.

Bio:

I am Janice S. Lintz, CEO of Hearing Access & Innovations (HAI) (f/k/a Hearing Access Program). I am a 2023 Harvard Kennedy School Candidate, recipient of the 2018 Bill & Melinda Gates Foundation Goalkeepers Partnership with ThePointsGuy.com; 2016 Aspen Institute Spotlight on Health Scholar; 2016 Nominated United State of Women Changemaker by the White House, the US Department of State, the US Department of Labor, and the Aspen Institute; 2015 Delta Salutes; 2008 People magazine's Heroes Among Us; and member of the following: 2013-2015, US Access Board's Committee on Rail Vehicle Accessibility; 2009, NYC Mayor's Office Taxi of Tomorrow Stakeholder Committee; 2008-2014, New York State Interagency Council for Services to the Deaf, Deaf-Blind, and Hard of Hearing, established by Governor David A. Paterson (not currently funded); 2007-2008, US Access Board's Passenger Vessel

Emergency Alarms Advisory Committee; 2006-2015, Lower East Side Tenement Museum's Advisory Board; 2004-2008 (two terms), FCC Chairman Kevin J. Martin's Consumer Advisory Committee; and a current member of the Syracuse University Burton Blatt Institute's Advisory Board since 2012. Also, I frequently write on topics related to hearing loss.

Sincerely,

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