

INNOVATION, COMPETITION, AND ACCESS TO HEARING CARE

Advances in technology and hearing science will redefine how millions of Americans can access hearing aids. New technology will create an opportunity for consumers to purchase safe and effective over-the-counter (OTC) hearing aids, reducing costs and improving access to these devices. However, outdated FDA and state regulations stand in the way of innovation, competition, and access to hearing care.

80% of Americans with hearing loss do not use hearing aids.

- Today an estimated 48 million Americans aged 12 and older have hearing loss in at least one ear, a number that will only increase as the population ages.
- Untreated hearing loss is a major national health and social problem.

State and FDA rules inhibit access.

- FDA has not created an OTC hearing aid classification.
- State laws require a license to sell hearing aids.
- These laws inhibit OTC sales and limit competition, consumer access, and choice.

Hearing aids are expensive.

- Hearing aids cost on average \$4,700 per pair (in most cases without insurance coverage) when bought from a licensed hearing aid dispenser.
- The average life of hearing aids is 3-5 years.
- Medicare does not cover hearing aids.

Hearing aids are safe.

- Between 2011 and 2015 no corrections or removals (actions to reduce a risk to health) concerning hearing aids were reported to FDA.
- Core hearing aid technologies like transducers, digital signal processing, and standard wireless protocols are used in millions of consumer earbuds sold each year.
- Safety concerns about over-amplification have been addressed through smart amplification that does not over-amplify loud sounds.

OTC hearing aids can provide a high-quality solution for many users.

- OTC hearing aids can provide a high-fidelity audio experience.
- OTC hearing aids can include advanced features like directionality, noise reduction, and feedback cancellation at affordable prices.
- Users can control and customize OTC hearing aids with smartphones and wireless technology. Studies indicate users may prefer their own settings to those set by a professional.
- Users can achieve an effective in-ear fit with modern interchangeable eartips.

Science and public policy experts support an FDA regulatory pathway for an OTC hearing aid.

- The President's Council of Advisors on Science and Technology (PCAST) and the National Academy of Sciences Engineering and Medicine (NASEM) released recent reports urging creation of an OTC hearing aid classification by FDA.
- Rigorous NIH-sponsored study found that OTC model was effective, and recently published studies further demonstrate the ability of users to adjust their own devices.

The adoption of an OTC hearing aid class by FDA would streamline distribution and access to hearing loss solutions, incentivize new technologies, and be a significant first step to addressing the current unmet needs associated with hearing loss.