

THE OVER-THE-COUNTER HEARING AID ACT

- The Over-the-Counter Hearing Aid Act would require the FDA to create a new category of hearing aids for consumers **with mild to moderate hearing loss**. The legislation would make hearing devices affordable for millions of Americans who cannot currently afford them.
- An estimated **86 percent** of people who would benefit from hearing aids do not use them, primarily because of the high cost. Hearing aids licensed by the FDA typically cost thousands of dollars, putting them out of the reach of millions of Americans. Medicare and most health insurance plans do not cover hearing aids, and there are few resources available to Americans who need hearing aids but cannot afford them.
- Advances in technology have dramatically improved the quality of hearing devices for people with mild to moderate hearing loss. These devices are available at only a fraction of the cost of traditional hearing aids. Under current regulations, however, such devices cannot be marketed to people with hearing loss.
- Two recent federal government studies recommended the creation of a category of over-the-counter hearing wearable devices. Both the National Academies of Sciences, Engineering, and Medicine (NAS), and the President's Council of Advisors on Science and Technology (PCAST) conducted in depth studies of hearing loss and hearing technologies. Both groups recommended FDA approval of over-the-counter hearing aids.
- It is unclear if the FDA currently has the legal authority to create a category of over-the-counter hearing aids absent legislative authorization. The Over-the-Counter Hearing Aid Act would provide such authority. The legislation also requires the FDA regulations to include specific requirements regarding patient safety and efficacy of over-the-counter hearing aids, such as appropriate consumer labeling.
- The benefit of making hearing aids more affordable and accessible extends far beyond the well-being of the individual with hearing loss and his or her family. As more consumers with hearing loss make use of hearing aids, workers become more productive creating a potential economic benefit to the nation at large. And a new category of OTC devices will allow innovation that could drive down costs of all hearing aids.

- Opponents of the legislation, those who benefit from the current high cost of hearing aids, argue that consumers cannot be trusted to make correct decisions about purchasing hearing devices. As the nation's largest organization of consumers with hearing loss, HLAA believes that such paternalism is unwarranted. We support empowering people with hearing loss. The FDA regulations and labeling requirements mandated by the legislation will provide consumers with the information they need to make informed decisions.
- Opponents also point to two studies from other countries showing that access to over-the-counter hearing aids have not increased hearing aid use. These studies are of countries that have different health care delivery systems than the United States and are of questionable relevance. If over-the-counter hearing devices are not found to be beneficial in the United States, the FDA will have the power to rewrite or rescind the regulations.

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