

The Over-the-Counter Hearing Aid Act of 2017

Approximately 30 million Americans experience age-related hearing loss, including over half of adults between the ages 70-79.¹ Yet only a small share of Americans with hearing loss – around 14 percent – use assistive hearing technologies, primarily because they cannot afford to buy costly hearing aids.² Hearing aids are not covered by Medicare or most private insurance plans, and out-of-pocket costs for a single hearing aid average \$2,400 – far out of reach for many consumers.³ As a result, individuals living in poverty are substantially less likely to have access to hearing aids than those with higher incomes.⁴

Complex hearing aid regulations exacerbate this problem by restricting the availability of hearing aids. In 1977, the FDA imposed a set of special regulations on hearing aids, including a requirement that individuals obtain a medical evaluation or sign a waiver of that evaluation before being allowed to purchase or use a hearing aid. After an extensive review, the National Academies of Sciences, Engineering, and Medicine found “no evidence that the required medical evaluation or waiver of that evaluation provides any clinically meaningful benefit” and recommended “removing this regulation to serve consumers’ best interests.”⁵

Both the National Academies and the President’s Council of Advisors on Science and Technology (PCAST) have also recommended making some types of hearing aids available over the counter – similar to the way in which basic reading glasses are available without a prescription. PCAST’s analysis of the hearing aid market concluded that “consumers find it difficult to shop for the best value.”⁶ Hearing aids are typically sold “bundled” with fees charged for evaluation, follow-up, and adjustments to the device, even though many consumers never use these services.⁷ Allowing hearing aids to be sold over the counter will expand consumer choice, open the market to innovative hearing technologies, and drive down prices so that millions more Americans can access affordable hearing aids.

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The Over-the-Counter Hearing Aid Act of 2017 implements recommendations from PCAST and the National Academies to help the millions of Americans affected by hearing impairment. The Act:

- Makes certain types of hearing aids – those intended to be used by adults to compensate for perceived mild to moderate hearing impairment – available over the counter.
- Removes an unnecessary and burdensome requirement that consumers obtain a medical evaluation or sign a waiver of that examination in order to obtain an OTC hearing aid.
- Requires the FDA to issue regulations containing safety and labeling requirements for this new category of OTC hearing aids.
- Maintains existing safety, labeling, and manufacturing protections and applies them to OTC devices in order to ensure that OTC hearing aids are held to the same high standards as other medical devices.
- Requires the FDA to update its draft guidance on Personal Sound Amplification Products (PSAPs), consumer electronics products that may use similar technology to hearing aids, but are intended for use by individuals with normal hearing.

¹ Frank R. Lin, John K. Niparko, and Luigi Ferrucci. 2011. "Hearing Loss Prevalence in the United States," *Archives of Internal Medicine* 171: 1851-1853 (online at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564588/>).

² National Academies of Sciences, Engineering, and Medicine. 2016. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. Washington, DC: The National Academies Press (online at: <http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx>), p. 183.

³ President's Council of Advisors on Science and Technology, *Aging America and Hearing Loss: Imperative of Improved Hearing Technologies* (October 2015) (online at: https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf), p.

1. National Academies of Sciences, Engineering, and Medicine. 2016. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. Washington, DC: The National Academies Press (online at:

<http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx>), p. 21-22. Sergei Kochkin. 2007. "MarkeTrak VII: Obstacles to Adult Non-User Adoption of Hearing Aids," *The Hearing Journal* 60: 24-50 (online at: [http://www.betterhearing.org/sites/default/files/hearingpedia-resources/MarkeTrak%20VII%20Obstacles%20to%20adult%20non-](http://www.betterhearing.org/sites/default/files/hearingpedia-resources/MarkeTrak%20VII%20Obstacles%20to%20adult%20non-user%20adoption%20of%20hearing%20aids.pdf)

[user%20adoption%20of%20hearing%20aids.pdf](http://www.betterhearing.org/sites/default/files/hearingpedia-resources/MarkeTrak%20VII%20Obstacles%20to%20adult%20non-user%20adoption%20of%20hearing%20aids.pdf)). Karl E. Strom. 2014. "HR 2013 Hearing Aid Dispenser Survey: Dispensing in the Age of Internet and Big Box Retailers," *The Hearing Review* 21 (4): 22-28 (online at: <http://www.hearingreview.com/2014/04/hr-2013-hearing-aid-dispenser-survey-dispensing-age-internet-big-box-retailers-comparison-present-past-key-business-indicators-dispensing-offices/>).

⁴ Kathleen E. Bainbridge and Virginia Ramachandran. 2014. "Hearing Aid Use among Older United States Adults: The National Health and Nutrition Examination Survey, 2005-2006 and 2009-2010," *Ear and Hearing* 35: 289-294.

⁵ National Academies of Sciences, Engineering, and Medicine. 2016. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. Washington, DC: The National Academies Press (online at: <http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx>), p. 120-121.

⁶ President's Council of Advisors on Science and Technology, *Aging America and Hearing Loss: Imperative of Improved Hearing Technologies* (October 2015) (online at: https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf), p.

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⁷ Karl E. Strom. 2014. "HR 2013 Hearing Aid Dispenser Survey: Dispensing in the Age of Internet and Big Box Retailers," *The Hearing Review* 21 (4): 22-28 (online at: <http://www.hearingreview.com/2014/04/hr-2013-hearing-aid-dispenser-survey-dispensing-age-internet-big-box-retailers-comparison-present-past-key-business-indicators-dispensing-offices/>).

National Academies of Sciences, Engineering, and Medicine. 2016. *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*. Washington, DC: The National Academies Press (online at: <http://www.nationalacademies.org/hmd/Reports/2016/Hearing-Health-Care-for-Adults.aspx>), p. 242-243, 258-259. *Consumer Reports*, "How to Buy a Hearing Aid" (July 2009) (online at: <http://www.consumerreports.org/cro/magazine-archive/july-2009/health/hearing-aids/how-to-buy-a-hearing-aid/hearing-aids-how-to-buy-a-hearing-aid.htm>).