



The Honorable Lamar Alexander  
Chairman, Senate HELP Committee  
428 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Patty Murray  
Ranking Member, Senate HELP Committee  
428 Dirksen Senate Office Building  
Washington, D.C. 20510

May 17, 2017

**Re: Countering misleading pushback to over-the-counter hearing aids**

Dear Chairman Alexander and Ranking Member Murray:

The Niskanen Center and R Street Institute write in support of the improvements to over-the-counter (OTC) hearing aid regulation as contained in Sec. 711 of the Food and Drug Administration Reauthorization (FDA) Act of 2017. If enacted, this provision will help to increase access to innovative health care options for the 48 million Americans who suffer from hearing loss, without sacrificing patient safety.<sup>1</sup>

Under current law, many assistive hearing products cannot make accurate claims about their ability to compensate for hearing impairment unless they are approved for sale as FDA-regulated hearing aids. While the FDA's regulatory requirements are themselves often burdensome, the greater regulatory burden in this case comes from the panoply of state laws which restrict the sale of FDA approved hearing aids to licensed health care professionals and audiologists. These state-level restrictions create barriers to entry that reduce competition and drive up cost. The establishment of a new OTC hearing aid category will be a major leap forward toward eliminating health care barriers to entry, and will make it much easier for innovative hearing aid technologies to reach a national market. Moreover, without having to be medically evaluated and go through a licensed audiologist, this provision will permit the emergence of free or low cost services for self-evaluation and self-fitting, just as online vision tests have for direct-to-consumer eyeglasses.

Due to the high cost of existing hearing aids, the hearing impaired often resort to purchasing so-called "personal sound amplification products" (PSAP), cheaper OTC alternatives intended for non-hearing impaired consumers. The quality of PSAPs vary widely, and include devices that meet or surpass the capabilities of conventional hearing aids. Organizations representing the interests of audiologists, licensed hearing aid dispensers, and legacy hearing aid manufacturers have recently pushed back against the over-the-counter hearing aid provision in the FDA Reauthorization Act by suggesting that the provision will lead to increased regulation of PSAPs, and / or endanger patient safety. Both of these claims are false.

First, the provision contains no new regulations on PSAPs, other than to direct the FDA to update its guidance on the definition of PSAPs. Instead, the new OTC hearing aid category

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<sup>1</sup> Lin, F. R., Niparko, J. K., & Ferrucci, L. (2011). Hearing Loss Prevalence in the United States. *Archives of Internal Medicine*, 171(20), 1851–1852. <http://doi.org/10.1001/archinternmed.2011.506>

simply makes it possible for high-end PSAPs to voluntarily reclassify themselves as hearing aids, which they could do now if it did not require sacrificing the ability to sell OTC. Nothing in the provision necessarily prevents high-end PSAPs from also continuing to be sold as a PSAPs as long as do not claim to treat hearing loss or compensate for hearing impairment.

Second, there is no reason to believe an OTC hearing aid option represents a danger to patient safety. This was affirmed in the official findings of the National Academies of Sciences,<sup>2</sup> which, along with the Obama administration's Council of Advisors on Science and Technology,<sup>3</sup> put forward expert statements recommending the creation of an OTC hearing aid category. The May 2nd testimony of Dr. Frank Lin before the Subcommittee on Health provided additional evidence that this provision protects device and consumer safety.<sup>4</sup>

We invite your support of this provision as a bipartisan and evidence-based effort to reduce health care costs for millions of Americans.

Sincerely,

Samuel Hammond  
Poverty and Welfare Policy Analyst  
Niskanen Center

Caleb Watney  
Technology Policy Associate  
R Street Institute

CC: The Honorable Greg Walden, Chairman, Committee on Energy and Commerce  
The Honorable Franke Pallone, Ranking Member, Committee on Energy and Commerce  
Members, Subcommittee on Health, House Energy and Commerce Committee

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<sup>2</sup> 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*.

<sup>3</sup> President's Council of Advisors on Science and Technology (2015). Report on Hearing Aids: Aging America & Hearing Loss: Imperative of Improved Hearing Technologies.

<sup>4</sup> *Examining Improvements to the Regulation of Medical Technologies: Hearing before the Subcommittee on Health of the Committee on Energy and Commerce*, House of Representatives, 115th Cong. (2017) (Testimony of Dr. Frank Lin)