Congress of the United States
Washington, DC

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VIA ELECTRONIC TRANSMISSION

Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Commissioner Califf:

Congress passed the Over-the-Counter Hearing Aid Act of 2017 requiring the U.S. Food and Drug Administration (FDA) to establish a new category for over-the-counter (OTC) hearing aids to help consumers with perceived mild-to-moderate hearing loss.[1] We believe OTC hearing aids will have a positive impact by providing a new category of safe and effective low-cost OTC products aimed to improve the health and wellbeing of millions of Americans. However, the regulation must balance establishing criteria and standards for innovative technologies and consumer safety protections. To this end, we write in response to the FDA proposed rule, *Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids*, and urge you to carefully consider concerns raised by Kansan stakeholders as you draft the final rule.[2]

Safe and effective OTC hearing devices largely depend on the decibel (dB) output sound pressure level (SPL). While there is no clear scientific consensus on maximum output levels, health professionals and U.S. Centers for Disease Control and Prevention (CDC) have provided sufficient recommendations. In 2018, a consensus paper developed by representatives from the Academy of Doctors of Audiology, the American Academy of Audiology, the International Hearing Society, and the American Speech-Language-Hearing Association provided five recommendations for the FDA to incorporate in the proposed regulation.[3] Among their recommendations, hearing care professionals found that the peak SPL should be no greater than 110 dB, with a gain limit. The CDC's National Institute for Occupational Safety and Health and the World Health Organization also considers length of exposure and noise level in its

[1] FDA Reauthorization Act of 2017, Pub. L 115-52 (2017).
[2] Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, 86 Fed. Reg. 58150 (October 20, 2021), 58150-58191, https://www.federalregister.gov/documents/2021/10/20/2021-22473/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids.
[3] American Speech-Language-Hearing Association, Regulatory Recommendations for OTC Hearing Aids: Safety and Effectiveness, Consensus Paper from Hearing Care Professionals, August 2018, https://www.asha.org/siteassets/uploadedFiles/Consensus-Paper-From-Hearing-Care-Associations.pdf.

respective occupational setting guidelines finding that noise exposure be limited to 85 dB in an eight-hour day.[4, 5] Despite these recommendations, the FDA is proposing to allow a general output limit of 120 dB SPL. To mitigate the potential damage of 120 dB, FDA is requiring devices to have input-controlled compression and user-adjustable volume controls. Utilization rates must be considered as louder sounds have the potential for more damage, even with less exposure. OTC hearing devices, unlike consumer electronics, are intended to be used to address a medical issue, and consequently, will be utilized in higher rate.

The Kansas Board of Examiners in the Fitting and Dispensing of Hearing Instruments (KBHAE) and Kansas members of the American Academy of Otolaryngology-Head and Neck Surgery raised concerns with the proposed rule citing the risk of noise-induced auditory damage.[6, 7] Noised-induced auditory damage is a common sensory disability but unfortunately has been unrecognized as a growing, yet preventable, medical condition.[8, 9] How consumers perceive their hearing may differ when measured in a clinical setting. According to the CDC, one in four adults who reported excellent to good hearing already had measurable hearing loss.[10] The CDC also found that noise-induced hearing loss increased to one in five adults aged 20-29 and one in four adults aged 50-59. Hearing aids, when used improperly, can cause further damage.[11] Therefore, it is unclear whether 120 dB SPL is be a suitable limit for an OTC product to address perceived mild-to-moderate hearing loss. In addition, the Kansas Attorney General (AG), who works collaboratively with KBHAE, has stated to the FDA concerns with the proposed rule limiting state and local consumer protections. It has long been tradition that states-requested exemptions complement FDA's labeling and dispensing requirements. In a comment letter with 42 other state AGs, AG Derek Schmidt requested the agency to better define preemption that would recognize the critical role his office and KBHAE have in protecting consumers while providing greater access to high-quality, low-cost products.[12]

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[4] U.S. Centers for Disease Control and Prevention, Noise and Hearing Loss Prevention, accessed February 28, 2022, https://www.cdc.gov/niosh/topics/noise/default.html#:~:text=NIOSH%20Recommendations%3A,this%20level%20are%20considered%20hazardous.

[5] World Health Organization, World Report on Hearing, March 3, 2021, https://www.who.int/publications/i/item/world-report-on-hearing.

[6] Kansas Board of Hearing Aid Examiners, Comment on Medical Devices; Ear Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids (FDA-2021-N-0555-0969), January 18, 2022, https://www.regulations.gov/comment/FDA-2021-N-0555-0969.

[7] American Academy of Otolaryngology-Head and Neck Surgery, Over-the-Counter Sale of Hearing Aids, January 18, 2022, https://www.entnet.org/advocacy/federal-legislative-advocacy/over-the-counter-sale-of-hearing-aids/.

[8] Rabinowitz, P. (2000), Noise-induced hearing loss, *American family physician*, 61(9), 2749-2756, https://www.aafp.org/afp/2000/0501/p2749.html.

[9] Sliwinska-Kowalska, M., & Davis, A, (2012), Noise-induced hearing loss. *Noise and Health*, 14(61), 274, https://www.noiseandhealth.org/article.asp?issn=1463-1741;year=2012;volume=14;issue=61;spage=274;epage=280;aulast=Sliwinska-Kowalska.

[10] Carroll, Y. I., Eichwald, J., Scinicariello, F., Hoffman, H. J., Deitchman, S., Radke, M. S., ... & Breysse, P. (2017), Vital signs: Noise-induced hearing loss among adults—United States 2011–2012, *MMWR Morbidity and mortality weekly report*, 66(5), 139, https://www.cdc.gov/mmwr/volumes/66/wr/mm6605e3.htm#:~:text=Almost%20one%20in%20four%20adults,already%20have%20measurable%20hearing%20loss.&text=The%20presence%20of%20noise%2Dinduced,adults%20aged%2050%E2%80%9359%20years.

[11] Kirland, K., Do Hearing Aids Help Prevent Further Hearing Loss?, January 27, 2021, WebMD, https://www.webmd.com/connect-to-care/hearing-loss/do-hearing-aids-help-prevent-further-hearing-loss.

[12] National Association of Attorneys General, Comment on Medical Devices; Ear Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids (FDA-2021-N-0555-1078), January 18, 2022, https://www.regulations.gov/comment/FDA-2021-N-0555-0929.

Given the above, we strongly encourage the FDA to address these consumer safety concerns in the final rule. We also urge you to work with stakeholders in educating consumers to consult with their health care provider – otolaryngologists and audiologists – to determine whether an OTC hearing device will be a quality option for them. Thank you for your efforts to finalize this important regulation.

Sincerely,

Roger Marshall, M.D.
U.S. Senator

Ron Estes
U.S. Representative

Jake LaTurner
U.S. Representative

Sharice L. Davids
U.S. Representative