November 12, 2021

Janet Woodcock
Acting Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids (Docket No. FDA-2021-N-0555)

Commissioner Woodcock:

As an otolaryngologist and surgeon with clinical specialties that include clinical cochlear implantation, middle ear implants, otosclerosis, superior semicircular canal dehiscence, and chronic ear disease, among others, I write to provide my comments on the FDA's proposed rule for establishing over-the-counter hearing aids.

These comments are based on my medical and clinical experience serving as the Associate Dean for Student Research at Columbia University Irving Medical Center's (CUIMC) Vagelos College of Physicians and Surgeons, several roles where I currently serve at Columbia University, Department of Otolaryngology, Head and Neck Surgery, including Professor of Otolaryngology-Head & Neck Surgery; Vice Chair for Research; Co-Director of Columbia Cochlear Implant Program in the Department of Otolaryngology, as well as the Medical Director of Perioperative Services at New York-Presbyterian Hospital/CUIMC.

While I applaud the FDA's attempt to craft a balanced regulatory framework that seeks to foster increased access and affordability of hearing devices with providing reasonable assurances of safety and efficacy, I am concerned by (1) the omission of a regulatory definition of "mild-to-moderate hearing loss" and the lack of a more thorough self-assessment to ensure individuals can safely wear OTC hearing aids; (2) the proposed maximum output standard and its potential to cause harm for those with mild-to-moderate hearing loss, and (3) the omission of a gain limit could allow for devices to reach hearing loss levels beyond mild-to-moderate, which was mandated by law.

1. **FDA Should Define "Mild-to-Moderate Hearing Loss" and Provide for a More Adequate Means of Self-Assessment.**

As an initial matter, I note that FDA does not define or otherwise cross-reference a standard for mild-to-moderate hearing loss, but rather only describes four vague symptoms that

an individual who perceives such level of hearing loss might experience.[1] While the degree of hearing loss and associated hearing loss ranges used by other organizations are similar, there are slight differences.[2,3,4] Therefore, FDA should either cross reference one of these established, well-known standards into the rule, or simply define what mild and moderate hearing loss means. This is extremely important as it relates directly to the requirements that are necessary to meeting the needs of an individual with mild to moderate hearing loss. Further, FDA should go a step further and establish a more adequate way for individuals to self-assess whether their perceived level of hearing loss is accurate.

In my experience, older individuals—the demographic with highest incidence of hearing loss and most likely to need hearing aids—underestimate their degree of hearing loss. Given the lack of an objective tool for self-assessment or a licensed professional conducting a hearing loss assessment, there is a high likelihood that individuals will at best select a hearing aid that does not provide sufficient benefit, or worse, delay the diagnosis of or completely miss a much more serious condition that may be causing an individual's hearing loss.

2. FDA's Proposed Output Limits Should be Reduced to Decrease Risk of Harm

The FDA's proposed maximum output levels must be reduced to decrease the risk of harm. Excessive amplification by hearing aids causes temporary threshold shift (TTS) which can lead to permanent threshold shift (PTS).[5] Essentially, TTS is temporary hearing loss after exposure to high level of noise; PTS is sudden or gradual shift in auditory threshold resulting permanent hearing loss.

As explained by Johnson (2017) in the *International Journal of Audiology*, a principle purpose of maximum output "is to limit the amount of amplification to higher level inputs occurring more consistently over a longer duration (e.g., greater than or equal to 8 hours)."[6] Further, he noted "[t]he intention of hearing aids is most often…to amplify speech and there are no speech recognition performance benefits of additional amplitude levels beyond that

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[1] See proposed rule, which states the following: This hearing aid is designed and intended for perceived mild to moderate hearing loss in adults. If you experience any of the following, you may have this kind of hearing loss: Difficulty hearing or understanding conversations, especially in groups or noisy places, or when you can't see who is talking; difficulty hearing while using a telephone; fatigue due to greater listening efforts; needing to turn up the volume of television, radio, or music louder than normal or loud enough for others to complain.

[2] Compare, for example, the American Speech-Language-Hearing Association standard for mild and moderate hearing loss to standards established by the World Health Organization.

[3] Degree of Hearing Loss. Asha.org. Accessed November 10, 2021. https://www.asha.org/public/hearing/degree-of-hearing-loss/.

[4] Olusanya BO, Davis AC, Hoffman HJ. Hearing loss grades and the International classification of functioning, disability and health. *Bull World Health Organ.* 2019;97:725–728. doi: http://dx.doi.org/10.2471/BLT.19.230367.

[5] Macrae JH. Temporary and permanent threshold shift caused by hearing aid use. *J Speech Hear Res.* 1995;38(04):949–959. doi: 10.1044/jshr.3804.949.

[6] Johnson EE. Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss. *Int J of Audiol*. 2017;56(11):829-836. doi: 10.1080/14992027.2017.1346306.

recommended by modern day hearing aid prescriptions."[7] Given the possibility that exposure of too great an amplitude level over a period of time could cause the user to experience further auditory system damage and progression of hearing loss, Johnson set forth recommendations on safe output limits for sound amplification devices that are not set to prescriptive levels. FDA's output limit of 115/120 dB exceeds Johnson's recommended safe output sound pressure levels for such devices used by individuals with mild to moderate hearing loss,[8,9] which are roughly in the 100-110 dB range.

Additionally, FDA's proposed limits far exceed the output limit for PSAPs recommended by the World Health Organization (WHO) in conjunction with the International Telecommunications Union (ITU).[10] In the proposed OTC hearing aid rule, FDA applies ANSI/CTA-2051, a standard for PSAPs, reasoning that OTC hearing aids "provide personal sound amplification…for purposes of aiding with or compensating for impaired hearing." WHO/ITU established safe listening guidelines for PSAPs because such products are often listened to at unsafe volumes and for prolonged periods of time. Regular participation in such activities poses a serious threat of permanent or irreversible hearing loss. Therefore, WHO/ITU recommended that smart hearing devices be equipped to measure weekly sound dose, so the user is informed and warned if he or she reached 80 dBA exposure for 40 hours.[11] For products that are incapable of measuring weekly sound dose, WHO/ITU recommended a maximum output of 95 dBA.[12] While PSAPs are typically worn by users for far less time each week compared to hearing aids, the WHO/ITU standard nonetheless based its recommendations around a significant period of exposure (40 hours). As such, even if the FDA chooses to use a standard used for safe PSAP use, its current limits would be considered unsafe by the WHO/ITU. If FDA chooses to use a standard for PSAPs, then I recommend that it reduce maximum output to more closely align with the limits recommended by WHO/ITU.

Finally, I believe that FDA's reliance on reaction times to justify its proposed output limits is misplaced. As explained above, repeated or routine exposure to high sound intensities can cause pain and discomfort, temporary or permanent auditory system injury, and hearing loss.[13] For instance, the CDC explains that exposure to sounds at 95 dB can potentially damage

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[7] Johnson EE. Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss. *Int J of Audiol*. 2017;56(11):829-836. doi: 10.1080/14992027.2017.1346306.

[8] Mild hearing loss and moderate hearing loss, as defined by ASHA.

[9] Degree of Hearing Loss. Asha.org. Accessed Nov. 10, 2021. https://www.asha.org/public/hearing/degree-of-hearing-loss/.

[10] *Safe listening guidelines for personal sound amplifiers: Recommendation ITU-T H.871.* International Telecommunications Union; 2019. Accessed Nov 10, 2021. https://www.itu.int/rec/T-REC-H.871-201907-I.

[11] Safe listening devices and systems: a WHO-ITU standard. Who.int. Published Sep. 18, 2019. Accessed Nov. 10, 2021. https://www.who.int/publications/i/item/safe-listening-devices-and-systems-a-who-itu-standard.

[12] *Safe listening guidelines for personal sound amplifiers: Recommendation ITU-T H.871.* International Telecommunications Union; 2019. Accessed Nov 10, 2021. https://www.itu.int/rec/T-REC-H.871-201907-I. "When these devices do not have the capacity to measure weekly sound dose, the maximum output of the device needs to be permanently limited to 95 dBA; a user then is unlikely to use the device at a level higher than 80 dBA since the dynamic range of speech has a crest factor of 12 to 17 dB."

[13] Centers for Disease Control and Prevention. What Noises Cause Hearing Loss? Cdc.gov. Page last reviewed Oct. 7, 2019. Accessed Nov. 11, 2021. https://www.cdc.gov/nceh/hearing_loss/what_noises_cause_hearing_loss.html.

the auditory system after about 50 minutes of exposure.[14] Exposure to sounds at 120 dB can cause pain and hearing injury almost immediately.[15] A publication by the National Institute for Occupational Safety and Health suggests exposure to sounds at 120 dB could become dangerous within nine seconds.[16] Yet, the proposed rule states, "As ANSI/CTA-2051 explains, 115 dBA is equivalent to an OSPL90 value of approximately 120 dB SPL with an allowance of 28 seconds to react" before exposure becomes dangerous. Regardless of which time frame is more accurate, hearing aid users are typically older individuals who may have reduced dexterity, coordination, and reaction times. As a result, hearing aid users may have difficulty responding while in pain and removing their devices in short order. Assuming that all users will be able to do so within 28 seconds (let alone nine seconds), is an assumption that could significantly harm users of OTC hearing aids.

3. FDA's Omission of a Gain Limit Could Distort Speech and Lead to Overamplification in Devices Intended for Mild-to-Moderate Hearing Loss.

An analysis of thousands of real-world audiograms showed that individuals with mild-to-moderate hearing loss were fitted for hearing aids with limits that prescriptively required no more than 100 dB output and 25 dB gain.[17] "Gain is the ability to take the low level of a signal and raise it to a higher level. Gain is simply the output level minus the input level. Thus, a 60-dB sound signal, which is amplified to an output of 90 dB, has a 30-dB gain."[18] Gain can also represent the effectiveness of a hearing aid algorithm, making the sound of speech more effective. Without a gain limit, sound can get distorted at high levels. Thus, if the amount of gain present in the amplifier is too high, it will overload, saturate and distort the input signal causing distortion for the user.[19] High output and high gain (e.g., 120 dB max output and no gain limit, as proposed by the FDA) can cause distortion of an individual's auditory system which can be distracting at best and, if loud enough, can mask components of speech. As such, high gain hearing aids are normally fitted on users with severe hearing losses because the higher output is required with higher gain hearing aids so that sound may be perceived by users with more severe hearing loss.[20] Given the high output limits proposed by the FDA, along with the fact that OTC

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[14] Centers for Disease Control and Prevention. What Noises Cause Hearing Loss? Cdc.gov. Page last reviewed Oct. 7, 2019. Accessed Nov. 11, 2021. https://www.cdc.gov/nceh/hearing_loss/what_noises_cause_hearing_loss.html.
[15] Centers for Disease Control and Prevention. What Noises Cause Hearing Loss? Cdc.gov. Page last reviewed Oct. 7, 2019. Accessed Nov. 11, 2021. https://www.cdc.gov/nceh/hearing_loss/what_noises_cause_hearing_loss.html.
[16] *Criteria for a Recommended Standard: Occupational Noise Exposure, Revised Criteria 1998.* National Institute for Occupational Safety and Health. 1998. Accessed Nov. 11, 2021. https://www.cdc.gov/niosh/docs/98-126/pdfs/98-126.pdf.
[17] Tedeschi T, Jones C, Stewart E. Real world evidence on gain and output settings for individuals with mild-to-moderate hearing loss. *Hearing Review*. 2020;27(7):9-11. Accessed Nov. 11, 2021. https://www.hearingreview.com/inside-hearing/research/real-world-evidence-on-gain-and-output-settings-for-individuals-with-mild-to-moderate-hearing-loss.
[18] Stab W. What is Unity Gain in Hearing Aids? Hearinghealthmatters.org. Mar. 9, 2014. Accessed Nov. 11, 2021. https://hearinghealthmatters.org/waynesworld/2014/unity-gain-hearing-aids/.
[19] Agnew J. The causes and effects of distortion and internal noise in hearing aids. Trends Amplif. 1998;3(3):82-118. doi: 10.1177/108471389800300302.
[20] Agnew J. The causes and effects of distortion and internal noise in hearing aids. Trends Amplif. 1998;3(3):82-118. doi: 10.1177/108471389800300302.

hearing aids are intended for perceived mild-to-moderate hearing loss, the omission of a gain limit is especially problematic because it could make the device not safe for extended use on a daily basis. This leads me to the question, what is the point of making a device accessible if it is bound to be ineffective and unsafe?

In conclusion, the FDA should define mild-to-moderate hearing loss through an objective means to ensure that appropriate individuals are using OTC hearing aids; reduce the proposed output limit to a more appropriate and safe threshold to prevent the risk of harm for those with mild-to-moderate hearing loss; and establish a gain limit to prevent over amplification in OTC devices that are intended for mild-to-moderate hearing loss.

Thank you for considering my comment on this matter.

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