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December 8, 2021

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

RE: Docket No. FDA-2021-M-0555, RIN 0910-AI21, *Medical Devices; Ear Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids*
Comments submitted electronically via www.regulations.gov

Dear Commissioner Woodcock:

The American Academy of Audiology (the Academy) appreciates the opportunity to comment on the proposed rule, ***Medical Devices; Ear, Nose and Throat Devices; Establishing Over-the-Counter Hearing Aids*.** The Academy is the largest organization in the nation of, by, and for audiologists. We are dedicated to the provision of quality hearing and balance care services through professional development, education, research, and increased public awareness of hearing and balance disorders.

The Academy acknowledges the significant task assigned to the Food & Drug Administration (FDA) to create rulemaking for over-the-counter (OTC) hearing aids as established by the FDA Reauthorization Act of 2017 (FDARA). We recognize that an underlying intent of FDARA was to improve access to hearing aid technology for American adults over the age of 18 with perceived mild-to-moderate hearing impairment and to "include requirements that provide reasonable assurances of the safety and effectiveness of over-the-counter hearing aids." As noted in the proposed rule, the FDA attempted to couple access and consideration of public health protection in the regulations: "We believe the proposals set forth in this rulemaking will protect the public health by providing reasonable assurance of safety and effectiveness for hearing aids, as well as promote the hearing health of Americans by lowering barriers to access and fostering innovation in hearing aid technology" (p. 6-7).

The Academy believes that the FDA significantly fell short of honoring the key principles of the authorizing legislation and ensuring public health protection in the regulations. The FDARA specified that the FDA would create a new category of hearing aids specific to OTC; however, the FDA instead has proposed to retain the existing classifications and offer only the distinction of "non-prescription" for OTC devices. In **Appendix A**, we delineate this and other points of variance between the guidance in the legislation and what the FDA has provided in the proposed rule. In its totality, the proposed rule fails to target the intended audience for OTC hearing aids and does not offer any assurance of reasonable safety measures. Rather than "protecting the public health," these regulations as drafted may instead put at risk the very people they are supposed to benefit. Our comments herein are to address major areas in the proposed regulations that do not satisfy minimal expectations relative to patient safety, efficacy and consumer protection. We respectfully request that the FDA reconsider these areas in moving forward with drafting final regulations.

PATIENT SAFETY: Lack of Inclusion of Gain Limits with High Output Limits

A key patient protection concern that the Academy would like to highlight is the lack of inclusion of a specified effective but safe gain range (lower and upper limits) and high recommended output limits for OTC hearing aids.

The proposed rule posits an output of 120 dB SPL limit and that these devices would also have to include both input-controlled compression and a user-adjustable volume control. The rationale is that these two functionalities would provide users with "ample time to take appropriate action to mitigate unacceptably high sound levels" by adjusting the volume, removing the device, or moving out of the loud environment. This rationale falls short in that copious evidence related to noise induced hearing loss indicates that individuals do not know when sound is potentially harmful and do not take action to reduce their exposure. In addition, the vast majority of individuals with hearing loss who will be the primary consumers of these types of devices are aging adults and may have multiple comorbidities that prevent them from taking the expected mitigating actions to reduce uncomfortable or potentially damaging loud sound levels. The guidance lacks mention of requiring a volume control (VC) on all OTC devices and should also define VC operating criteria.

The proposed rule states that a gain limit was not included due to the belief that the proposed maximum output limit together with other proposed requirements alone will provide "a reasonable assurance of safety and effectiveness." The proposed rule also states that this decision was made so as not to "unduly constrain the design of effective devices." The National Institute on Deafness and Other Communication Disorders (NIDCD) estimates that nearly 25 percent of those aged 65 to 74 and 50 percent of those who are 75 and older have disabling hearing loss.[1] In addition, multiple comorbidities are known to accompany hearing loss in older adults, including cognitive decline/dementia, depression, balance disorders/falls, cardiovascular disease and diabetes.[2] The lack of inclusion of a gain requirement presents a danger particularly for certain vulnerable populations who, for a variety of reasons or associated conditions, may not recognize the dangerous sound levels in the requisite time or may be unable to perform the mitigating steps. In this way, these individuals may be at a greater risk of worsening their hearing loss through excessive noise exposure. The proposed construct relies on an individual's perception that a sound or situation is unacceptably loud. This reliance on subjective perception may result in damaging the hearing of potentially many individuals.

In 2018, the Academy joined with other hearing care organizations to draft a document outlining regulatory recommendations for OTC hearing aids.[3] On the issue of gain, this document recommends a high frequency average (HFA) full on gain of 25 dB as defined for measurement in a 2cc coupler, with an input level of 50 dB SPL per ANSI S3.22-2014. This recommendation was made to "ensure adequate audibility for the broadest range of individuals in the "mild-to-moderate spectrum." Not only does this provide protection simply due to making sure sound isn't too loud, but ideally these regulations should outline a low-end gain and a high-end gain to allow an individual to judge if they are a candidate for this category of devices. For example, if they are at the lowest gain and things seem loud, they know they don't have a threshold loss and may be experiencing a different problem (e.g., auditory processing problem). If they are at the highest gain and aren't receiving adequate sound, they know they have more than moderate hearing loss or a more complex hearing loss and should pursue professional assistance. By leaving the gain undefined, the FDA has removed significant safety measures.

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[1] National Institute on Deafness and Other Communication Disorders."Quick statistics about hearing." Accessed on November 29, 2021,at https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing#6

[2] Abrams, H. *Hearing loss and associated comorbidities: what do we know?* Accessed on November 29, 2021, at https://www.hearingreview.com/wp-content/uploads/2017/07/HearLoss-Abrams.pdf

[3] Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness. Consensus Paper from Hearing Care Associations. August 2018. Available: https://www.audiology.org/hearing-associations-release-consensus-recommendations-for-new-over-the-counter-hearing-aid-classification/

It is worth emphasizing that there are standard hearing loss benchmarks that attach specific audiometric measurements with varying degrees of hearing loss. For example, mild to moderate hearing loss is generally defined as a hearing threshold in decibels from 25-60 dB HL. There is also a well- documented discordance between self-reported and audiometric hearing loss.[4] [5] [6] [7] [8] [9] Studies show that only half to two thirds of individuals correctly classify their hearing loss. The Academy recognizes that these devices are intended for individuals with perceived mild to moderate hearing loss. However, because perception of hearing loss tends to be imprecise and many times erroneous, it is critical that the technical specifications and specifically the gain requirement for these devices truly be targeted to this demographic. By not including gain parameters, the proposed technical specifications for these devices exceed the stated scope to address mild to moderate hearing loss.

The Academy feels strongly that the inclusion of an effective and safe gain range (lower and upper limit) requirement is essential for the purposes of patient protection and to ensure that OTC hearing aids are appropriately targeted to individuals with perceived mild to moderate hearing loss.

EFFICACY: Acoustic Coupling

In the proposed rule, the FDA states: "We are not proposing a specific design feature or strategy because such specificity may constrain the design of an OTC hearing aid and impede design innovations" (p 51). The guidance specifies the following:

> (1) *Insertion depth.* The design of an OTC hearing aid shall limit the insertion of the eartip to the bony-cartilaginous junction of the external auditory canal and no deeper.
>
> (2) *Use of atraumatic materials.* The material for the eartip of an OTC hearing aid shall be atraumatic.
>
> (3) *Proper physical fit.* The OTC hearing aid shall be designed to enable consumers to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear."

[4] Kamil R.J., Genther D.J., and Lin F.R. (2015) Factors associated with the accuracy of subjective assessments of hearing impairment. Ear Hear. 2015 Jan; 36(1): 164–167.

[5] Kiely K.M. et al. (2012) Evaluating a dichotomized measure of self-reported hearing loss against gold standard audiometry: prevalence estimates and age bias in a pooled national data set. . J Aging Health 24(3):439–458.

[6] Kim S.Y et al. (2017) Discrepancy between self-assessed hearing status and measured audiometric evaluation. PLoS One 12(8):e0182718.

[7] West J.S, Smith S.L, and Dupre M.E. (2021) Hearing loss. In: D. Gu, M. E. Dupre (eds.*), Encyclopedia of Gerontology and Population*. Springer Publishing, Geneva.

[8] McCarrigle R. et al. (March 2014). Listening effort and fatigue: What exactly are we measuring? A British Society of Audiology Cognition in Hearing Special Interest Group ' white paper. *International Journal of Audiology,* (53)7: Early online 1-13.

[9] Alhanbali S., Dawes P., Lloyd S., and Munro K.J. (2017). Self-reported listening-related effort and fatigue in hearing-impaired adults. *Ear Hear.* Jan/Feb 2017;38(1):e39-e48.

In the context of an OTC hearing aid, the Academy supports the use of only instant-fit eartips, or custom/semi-custom eartips that were fabricated based on non-invasive scans of the patient's ears, as the forms of coupling between the OTC device and the wearer's ear canal. With an OTC product, users will start without the support of a professional. A portion of hearing aids delivered today are dispensed with custom earmolds; this approach requires a hearing healthcare provider to perform an earmold impression. If such a process were to be performed by an individual on themselves, it would come with a risk of physical injury (such as tearing the eardrum, pushing earwax or impacting ear wax further down the ear canal). This risk would be magnified in the elderly if an individual has decreased cognitive function, sensitivity, or dexterity. However, we acknowledge that semi-custom or custom eartips **may** be fabricated in the future based on non-invasive ear scanning techniques. If such techniques are found to be safe because they do not require anything to be inserted into the ear canal and produce an efficacious and comfortable fit, they could be used while protecting patient safety.

A common approach available for several styles of hearing aids is the use of an instant-fit eartip, which does not require taking an ear impression. This approach supports reasonable amplification for individuals with mild to moderate hearing loss and prevents the possibility of injury caused by injecting impression materials. Injection of earmold material into a surgically modified ear canal by a lay person is especially problematic.

We encourage the FDA to stipulate that only instant-fit eartips, or custom/semi-custom eartips that were fabricated based on non-invasive scans of the patient's ears, be used as the forms of coupling between the OTC device and the wearer's ear canal. In the case where a custom earmold or ear shell would be required, based on current and future techniques that require inserting impression materials or scanners inside the ear canal, the service of a licensed hearing healthcare professional should be required.

EFFICACY: 510(k) Requirements

The Academy finds that the guidance, as written, is confusing as to whether or not OTC hearing aids will be subject to 510(k) requirements that would offer some assurance of consistency for patient protection. The guidance describes that the device classifications remain unchanged relative to Class I and Class II and denotes which ones are exempt from the 510(k) requirements, but the proposed rules do not specify explicitly if OTC hearing aids would fall under one class. The consensus opinion offered in 2018 by hearing care organizations was that the FDA should define the new OTC hearing aid devices in a category that would have risk protections for safety and effectiveness and be easy to understand by the average consumer.[10]

In an effort to seek clarification, the Academy reached out to the FDA and received an email communication from the FDA on October 26 that offered assurance that the regulations do not impact the requirements for device classifications and submitting 510(k)s. The response provided the specific example of self-fitting air conduction hearing aids falling under Class II and needing 510(k) clearance before marketing and further surmised that "we believe that many of the hearing aids pursuing an OTC indication for use will fall under this regulation."

[10] Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness. Consensus Paper from Hearing Care Associations. August 2018. Available: https://www.audiology.org/hearing-associations-release-consensus-recommendations-for-new-over-the-counter-hearing-aid-classification/

The Academy contends that, in the absence of guidance, any OTC hearing aid could be considered self-fitting because it is purchased without any pre-fitting. If self-fitting is to be the primary determinant for 510k, the FDA needs to define the threshold for meeting their definition of self-fitting and therefore being subject to 510k. The FDA would serve the industry and consumers best by specifying parameters that qualify a device to be self-fitting along with clear validation guidelines for such self-fitting procedures.

Although the communication from the FDA offers assurance of intended oversight for some OTC hearing devices, the Academy has concern that as worded the regulations may incentivize manufacturers to introduce devices that could fall under legacy devices rather than self-fit and therefore be exempt from 510(k) submission. Consequently, these devices could be introduced into the market without any review as to efficacy and appropriateness and without any oversight for consumer protection. Given the wide range of hearing loss that can fall under the mild-to-moderate determination without any gain limit, it is plausible for a significant number of these pre-fit devices, left for the user to fine tune, to fit the legacy definition. **The Academy encourages the FDA to specify that all OTC hearing aid devices will need 510(k) clearance prior to marketing and sales.**

EFFICACY: Self-Fitting

The Academy believes there is a need for stronger definition for the expectations and minimum specifications for self-fitting hearing aids and language ensuring OTC hearing aid options will include some degree of self-fitting capabilities. The premise of OTC hearing aids is built upon the foundation that modern digital hearing devices can be manipulated with relative ease by the consumer to meet an individual's needs without the help of a trained professional. There is little research on self-fitting OTC hearing aids. However, recent research demonstrated that individuals can self-fit and adjust their hearing aids when using integrated smartphone applications however more vulnerable adults (e.g., cognitive decline) still may require the aid of a professional.[11] [12] It is vital to understand that this research is built upon the use of interactive and easy-to-manipulate devices.

In the current regulations, the term self-fitting is undefined and is not a clear requirement for devices labelled as OTC hearing aids. The current language would easily allow the sale of devices under the OTC hearing aids label that are unusable by the public (e.g., unable to manipulate or customize the output). Several scenarios are plausible including predatory business tactics embracing the sale of devices that are not programmable which would be unethical and ineffective for addressing hearing loss and/or the sale of devices as OTC that require specialized skills or software to customize which would require a professional. Each of the aforementioned situations would pose patient efficacy and consumer protection issues. Moreover, these situations could necessitate the involvement of a licensed professional which would run counter to the language in the Bill itself: "…*That is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person*…"

The Academy requests that the FDA: 1) define self-fitting in a manner such that it is clear OTC hearing aids must be manipulatable by the general public; and 2) add some requirement that OTC hearing aids be self-fitting.

[11] Convery, E., Keidser, G., Seeto, M., & McLelland, M. (2017). Evaluation of the self-fitting process with a commercially available hearing aid. *Journal of the American Academy of Audiology*, *28*(02), 109-118.

[12] Keidser, G., & Convery, E. (2018). Outcomes with a self-fitting hearing aid. *Trends in Hearing*, *22*, 2331216518768958.

CONSUMER PROTECTION: Return & Claims Policies

The Academy notes that the FDA, while proposing that OTC hearing aid manufacturers should disclose the return policy within outside labeling, does not go as far as stating that manufacturers should accept returns under the regulations (p.33-34). We believe that such an omission in the federal regulation does not offer a sufficient level of consumer protection. The FDA should take a leadership role in this area of Consumer Protection and include the recommendation of state mandates for consumers to have the ability to return OTC devices, allowing them the opportunity for reallocation of resources to try another product or hearing health care pathway for improved outcomes. This flexibility is particularly important given the anticipated price point of OTC hearing aids and the legislative intent of making OTC hearing aids widely accessible. Many of the consumers who could benefit from OTC devices, such as older adults and vulnerable populations, may not be able to invest in additional devices if an initial purchase does not work for them. This is especially true since "candidacy" is based on self-perception of degree of hearing loss which is known to be inaccurate in the majority of individuals. The potential for some products not to meet consumer expectation exists given that the regulations do not establish a process for manufacturers to substantiate claims for their OTC hearing aid devices with data and scientific evidence.

The FDA poses the question of whether or not state or local return policies would promote, rather than restrict or interfere with, commercial activities for OTC hearing aids. The Academy does not believe that state or local policies would inhibit commercial activities and will be necessary to protect consumers. However, deference to state or local policies about returns seems in contradiction to the overall preemption of state laws in these regulations. **For consistency and for maximal consumer protection, the federal regulations should establish the guidance that manufacturers accept returns for OTC hearing aids.**

CONSUMER PROTECTION: Labeling

The Academy recognizes the importance of providing adequate labeling for consumer protection and commends the FDA for seeking to provide an exhaustive list of information to include outside and inside the box. However, the extent of information identified for labeling is staggering and may be more distracting than offering true utility in assuring some level of consumer protection. Individuals with varying levels of cognitive function or low health literacy will undoubtedly have challenges in comprehending the instructions and warnings. As seen with over-the-counter pharmaceuticals, the unique needs of vulnerable populations (e.g., older adults, individuals with low literacy) are difficult to accommodate when providing complex information even with the Drug Facts Law requirements. Studies also show that fewer than half of people using OTC medications fully read the labeling.[13] [14] Recommendations to address these problems for OTC medications include increased reliance on the role of the pharmacist for consumer education and the use of adjunctive technologies, such as mobile applications and multimedia

[13] King J.P. et al. (2011)Developing consumer-centered, nonprescription drug labeling: A study in acetaminophen. *Am. J. Prev. Med.* 2011;40:593–598.

[14] Cryer B., Barnett M.A., Wagner J., and Wilcox C.M. (2016) Overuse and misperceptions of nonsteroidal anti-inflammatory drugs in the United States. *Am. J. Med. Sci.* 2016;352:472–480. doi: 10.1016/j.amjms.2016.08.028. [PubMed] [CrossRef] [Google Scholar]

displays, to supplement labeling.[15] This research reinforces that it is unrealistic for the FDA to expect that consumers will read or have the ability to comprehend fully the extensive guidance suggested for the OTC hearing device labeling.

An important guidance lacking in the proposed labeling is any reference to the role of the hearing health care professional as a resource before the purchase of the device. The Academy recognizes that the legislative intent was for OTC hearing aids to be accessible without requiring the assistance of a hearing healthcare professional, such as an audiologist. However, the Academy recommends that the FDA consider developing educational materials informing consumers of the benefits of receiving a hearing test or baseline audiogram prior to purchasing one of these items. As we mentioned previously, given the anticipated price point for the devices and the lack of mandate for a return policy, consumers should understand the benefit of obtaining a hearing evaluation rather than relying solely on perception of hearing loss before making a purchase. Audiologists provide a breadth of specialized hearing and balance care that can assist consumers in confirming if the type and level of hearing loss is consistent with the goals of OTC hearing devices or, if the hearing loss falls outside the range for OTC devices and alternate treatment options should be identified. This further protects consumers from potentially pursuing an OTC HA option that does not provide adequate amplification for their hearing needs. Hearing loss and auditory system deficits are best mitigated through the development of a safe and effective treatment plan, that may or may not include OTC hearing aids or other devices. The current guidance on the outside of the box labeling relative to hearing health care professionals pertains only to their role after attempted use of the OTC hearing device. **The Academy recommends that the labeling for OTC hearing aids include guidance that, for optimal hearing health, the consumer is best served by obtaining a hearing test to confirm the presence and degree of hearing loss. A hearing screening obtained online or through an app or online does not capture the complexities of hearing loss.**

Other

While the Academy has attempted in this letter, and also in an overview found in **Appendix B**, to delineate specific parts of the proposed rule that warrant expanded guidance from the FDA, we also wish to caution the FDA to include more specificity overall to enhance consumer protection. The lack of clarity in the document and absence of some important detail can lead to unintended consequences. We have already cited several examples, including that the omission of a gain limit coupled with high maximum output levels introduce a known safety risk for *increased* noise-induced hearing loss. We offer here a few additional considerations:

- Unclear guidance can open the pathway for a market for OTC devices that are locked by proprietors (i.e., can't be adjusted by the public without special software) and that use rigid fitting patterns. This is a potential predatory company issue and is contradictory to legislative intent for OTC hearing devices. Currently, direct to consumer products often market themselves as programmable yet turn out to be not programmable by the consumer.

- Defaulting to the CTA 2051-2017 (ANSI) Personal Sound Amplification Performance Criteria is not appropriate for a hearing aid. This standard is specifically designed for a consumer product that is for situational use - not full-time use - and is not intended for individuals with hearing loss. Application of this standard jeopardizes patient safety and efficacy.

[15] Catlin J.R and Bras E.P. The effectiveness of nonprescription drug labels in the United States: Insights from recent research and opportunities for the future. *Pharmacy (Basel)*. 2018 Dec;6(4):119

- The section of the proposed rule pertaining to state pre-emption needs extensive review to ensure that the effort to increase consumer access to OTC hearing aids does not have any adverse impact. The language to pre-empt state regulations would remove layers of state-level protections for consumers, and it is important to make sure that comparable protections are in place, particularly to respond to potential unethical business practices that could spring up around the devices. The FDA could consider new state exemption proposals from federal pre-emption that aim to respond to issues states are observing with respect to consumer and financial protection, and patient safety, as OTC devices enter the market.

As illustrated in **Appendix A**, the proposed rules in their current form do not match the intent of the FDARA request for a category of OTC Hearing Aids and currently fall short of minimal expectations relative to patient safety, efficacy and consumer protection. Thank you for your consideration of the issues raised in this correspondence and your anticipated efforts to refine the regulations to optimize the benefit of OTC hearing aids for consumers. If you have questions about the comments from the Academy or require additional information, please contact Patrick Gallagher, MBA, Executive Director, pgallagher@audiology.org.

Sincerely,

Sarah Sydlowski, AuD, PhD, MBA
President, American Academy of Audiology

APPENDIX A

Technical Specifications & Characteristics for Over-the-Counter Hearing Aids As outlined in the FDAR	FDAR	FDA Proposed Rule
Air conduction device or wireless air conduction device	√	√
Intended for over 18 consumer	√	√
Compensates for perceived mild to moderate hearing loss	√	No proposed gain range - not targeted at mild to moderate hearing loss, despite evidence-based fitting algorithms that clearly provide gain ranges
Tools, tests or software allows the user to control the OTC HA and customize it to the user's hearing needs	√	Silent on minimum suggested self-fitting methods
Tools may use wireless technology	√	√
May include tests for self-assessment of hearing loss	√	No guidance in this area
Available without the supervision, prescription or other order, involvement, or intervention of a licensed person	√	√
Available through in-person transactions, mail, or online	√	√
Exempt from 801.420 and 802.421 of Title 21	√	√
Establishes a category of OTC HAs	√	Does not establish a category of OTC HAs. An OTC HA can be either a class 1 or 2 devices, similar to devices traditionally prescribed and fit by a licensed professional.
Provides reasonable assurances of the safety and efficacy of OTC HAs	√	Defaults to the CTA 2051-2017 (ANSI) Personal Sound Amplification Performance Criteria. This standard is specifically designed for a consumer product not intended for individuals with hearing loss and not intended for full time use (situational).

--Continued --

APPENDIX A

Technical Specifications & Characteristics for Over-the-Counter Hearing Aids As outlined in the FDAR	FDAR	FDA Proposed Rule
Establishes or adopts output limits appropriate for the OTC HAs	√	Recommends limits of 115 and 120 dB SPL and, despite data to the contrary, defers to users knowing when to turn down the VC or remove the devices when sounds are harmful
Includes requirements for appropriate labeling	√	Includes a variety of outside and inside of the box labeling. but does not include a warning that outputs are known to damage hearing. The labeling does not identify that optimal hearing health includes a hearing test by a licensed professional prior to exploring amplification options.
Labeling - how to report adverse events	√	√
Labeling of any conditions or contraindications	√	√
Labeling - advisements to consult promptly with a licensed physician	√	√
Determines whether OTC HAs require a report under section 510(k) to provide reasonable assurance of safety and effectiveness	√	Language is unclear as to whether or not all OTC HAs will report under section 510(k). As indicated in the bill, this is a mechanism for safety and effectiveness.
Indicates that no state or local government shall establish or continue in effect any law, regulation or order, or other requirement specifically applicable to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of the OTC HAs	√	In the absence of establishing a category of devices, language suggests the preemption of all state and local rules regulating all hearing aids - beyond the scope of the legislation.
Updates and finalizes the draft guidance "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products	√	√

APPENDIX B

Considerations Relative to the FDA Proposed Rule on OTC Hearing Aids

Patient-Safety

- Absence of gain limits. A minimum and maximum gain helps the consumer self-regulate and identify continued untreated hearing loss. (See extensive comments in letter.)
- Maximum output level that can produce sound induced hearing loss in some users without any warning to consumers.
- Lack of clarity regarding 510k requirements. The Academy feels that the 510k process is imperative to have in place for *all* OTC hearing aid devices even if a gain is specified and any other safety measures added. (See extensive comments in letter.)
- Absence of protections for vulnerable populations beyond pediatrics.
- Absence of evidence that any population can self-manage loud sound exposure from hearing aids.
- Absence of a volume control (VC) requirement when compression algorithms are not incorporated in the design. The proposed regulations do not address the range of output change for a change in volume control from the minimum to maximum position. The FDA should require a VC on any device and define VC operating criteria.

Efficacy

- Absence of guidance regarding effective ear coupling. (See additional comments in letter.)
- Absence of guidance regarding efficacy of signal processing features to ensure provision of an amplified signal that maintains or enhances speech recognition ability. The American Academy of Audiology believes all new OTC hearing aids should complete the 510(k) process in order to provide evidence of safety, efficacy, and quality.
- Absence of guidance regarding assistive device compatibility and RF exposure, although the proposed regulations open the door for OTC devices to have this capability. (M2/T2)
- Defaulting to a standard (CTA 2051-2017 (ANSI) Personal Sound Amplification Performance Criteria) that was developed for consumer products meant to be worn by individuals with normal hearing who want to improve hearing in specific situations (part-time use).

Consumer Protection

- Unclear guidance that can open the pathway for a market for OTC devices that are locked by proprietors (i.e., can't be adjusted by the public without special software) and that use rigid fitting patterns. This is a potential predatory company issue and is contradictory to legislative intent for OTC hearing devices.
- Inconsistent guidance related to return policies within and across device type. Potentially deferring to state guidance regarding returns does not assure consistency or availability of return policies.
- Absence of warnings in the labeling related to loud sound exposure. Excessive exposure to loud sounds can lead to hearing loss and other conditions, such as tinnitus.
- Absence of warnings in the labeling pertaining to batteries, which will be required for the devices.
- Extensive labeling. Either the box will need to be quite large or the font so small that the information would not be legible, particularly for the older population.
- Proposed labeling language is confusing. It is generally more than what most people can interpret. (See additional comments in letter.)
- The 510(k) process offers some positive protections and it is reasonable for consumers to expect from the FDA similar protections for all OTC hearing aid devices. Pre-fit devices have at least as much, if not more, potential for inappropriate gain and/or output levels for individual listeners (For example outcomes for one such device see: Reed, N. S., Betz, J., Kendig, N., Korczak, M., & Lin, F. R. (2017). Personal sound amplification products vs a conventional hearing aid for speech understanding in noise. Jama, 318(1), 89-90.). Consequently, the same 510K protections should be extended for all OTC devices.