

REGULATORY RECOMMENDATIONS FOR OTC HEARING AIDS: SAFETY & EFFECTIVENESS

CONSENSUS PAPER FROM HEARING CARE ASSOCIATIONS

August 2018

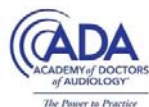


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Forward

In August 2017, Congress passed into law the OTC Hearing Aid Act of 2017. The Act mandates the FDA to establish a new category of hearing aids available over-the-counter (OTC) for sales, without the involvement of a licensed professional. While the goal of making hearing health care solutions more accessible is agreeable, the FDA needs to provide reasonable reassurance that safety and efficacy will be maintained. As representatives of the major hearing healthcare professional associations in the United States, we believe that we can contribute, based on our combined expertise, to the current rule making process by submitting proposals that would provide for the reasonable assurance of safety and effectiveness, while adhering to the congressional mandate.

This Consensus Paper is the result of several months of discussions, work and reviews developed by the major U.S. hearing health care professional associations (Working Group). The Working Group consisted of leaders from the American Academy of Audiology (AAA), Academy of Doctors of Audiology (ADA), American Speech-Language and Hearing Association (ASHA), and International Hearing Society (IHS). This Consensus Paper contains **five key recommendations** which have been developed by this Working Group. This paper includes suggestions on how to incorporate and detail the recommendations into the rule; it also incorporates the scientific evidences and data to substantiate and support our recommendations.

The Working Group is looking forward to additional discussions and opportunities to further contribute to the current rule making process in any means deemed appropriate.

Introduction

In August 2017, Congress passed into law the FDA Reauthorization Act of 2017 (FDARA), legislation which included the OTC Hearing Act of 2017¹. The Act mandates the Food and Drug Administration (FDA) to establish a category of over-the-counter hearing aids. According to the Act, these new devices should use “*the same fundamental scientific technology*” as (wireless) air conduction hearing aids and should be available over-the-counter without the supervision, involvement, or intervention of a licensed person.

At the same time, the Act requires that the FDA promulgate regulations for this category that include requirements providing “*reasonable assurances of safety and effectiveness,*” “*establish or adopt output limits appropriate for over the counter hearing aids,*” “*appropriate labeling,*” and “*requirements under which the sale of over the counter hearing aids is permitted.*” Prior to the enactment of the Act other institutions have discussed the possibility of the creation of a category for OTC hearing aids, however, no contribution has addressed comprehensively how the Congressional mandate could be implemented.

For this reason, at the end of 2017, representatives from the major U.S. hearing healthcare professional associations met together as a Working Group to assist in providing input for the regulation around the future over-the-counter hearing aid category. The Working Group consisted of leaders from AAA, ADA, ASHA, IHS. The purpose of this paper is to provide the Working Group’s input and recommendations with regards to execution on the congressional mandate for safety and effectiveness within this new medical device category while ensuring accessibility and affordability. The Working Group fully supports any effort aimed at making hearing care solutions more accessible; however, it also strongly advocates that any solutions presented to the consumer rely on safe and effective medical devices and include safeguards that optimize consumers’ awareness and use of appropriate hearing care treatment. Therefore, the Working Group urges the FDA to follow a thorough, transparent process and to establish an appropriate set of requirements to ensure the safety and effectiveness of OTC hearing devices.

¹ FDA Reauthorization Act (FDARA) of 2017, Sec. 709.

Recommendation 1: establish product requirements appropriate for OTC hearing devices targeting mild-to-moderate hearing impairment

The Over-the-Counter Hearing Act of 2017 mandates the FDA to promulgate regulation “*that provide reasonable assurances of the safety and effectiveness*”, including “*requirements that establish or adopt output limits*”² appropriate for this new category of over-the-counter devices. Since the rule will establish a new category of medical devices, the development of technical specifications for these new devices will be a critical component for regulatory development. In doing so, the Agency should follow the 2017 congressional mandate for ensuring appropriate safety and effectiveness for these devices. This mandate is reinforced by the FDA’s mission³; it is also consistent with the Agency’s standard to consider the effectiveness and safety for both intended and unintended but foreseeable users.⁴ The FDA has recently confirmed such interpretation of FDARA 2017 by stating that “*Section 709 reflects a careful balance between consumer access to new technologies and consumer protections to assure safety and effectiveness of OTC Hearing Aids*”.⁵

Definition of intended users for OTC hearing devices

The OTC Hearing Aid Act of 2017 states that the new category of hearing devices “*is intended to be used by adults age 18 and older to compensate for perceived mild to moderate hearing impairment.*”⁶ This passage highlights two dimensions for the definition of intended users for OTC hearing devices

- Age of users; and
- Level of hearing impairment.

² FDA Reauthorization Act (FDARA) of 2017, Sec. 709

³ Available on FDA website - <https://www.fda.gov/AboutFDA/WhatWeDo/>

⁴ Cfr. FDA-2011-D-0469

⁵ FDA, Letter to Hearing Aid Manufacturers about Over-the-Counter (OTC) Hearing Aids, July 24, 2018.

⁶ FDA Reauthorization Act (FDARA) of 2017, Sec. 709

With regard to the age of intended users, the Congressional mandate is very clear in limiting the use of OTC hearing devices to adults only. On this aspect, the rule will need to ensure that the risk of usage by children under the age of 18 is minimized. Since these devices are to be distributed over-the-counter and without the supervision or intervention of a licensed professional, there are concerns that these devices might be used by or on individuals under the age of 18 without the specific direction and supervision of an audiologist, as required by the current FDA regulation on hearing aids.⁷ Also, there is the concern that individuals with varying degrees of cognitive function and dexterity will consider this option. Recommendations for these issues will be shared in the sections of this Consensus Paper focused on labeling requirements and conditions for sale.

As regarding the level of hearing impairment, the implication of an over-the-counter delivery model is that a hearing evaluation by a licensed hearing healthcare professional is not required. In this context, the definition of the degree of hearing loss is based upon potential user's subjective perception of his/her hearing difficulty. At the same time, an audiometric definition of hearing loss is needed for defining desired product specifications. Utilizing ASHA's classification of degree of hearing loss as the guideline, a hearing loss between 26 and 40 dB HL would be classified as mild, and a hearing loss between 41 and 55 dB HL would be classified as moderate. Thus, **the product requirements for a mild-to-moderate hearing impairment should consider a set of amplification characteristics that fit a range of hearing loss from 26 to 55 dB HL** (over a 30 dB range), a variety of possible hearing loss configurations (flat, sloping, reverse, notch), and a range of user characteristics (experienced and new wearers, sound tolerance issue). In fact:

- Mild losses (26 – 40 dB HL) account for most of the adult population with hearing impairment, being estimated in the range of 66%^{8,9}- 70%¹⁰ of all hearing impaired. At the same time use of hearing aids for individuals with mild hearing loss is in the range

⁷ 21CFR801.420

⁸ Cheng et al (2009), based on data from NHANES I and NHANES 1999-2004 as reported by NASEM, Hearing health care for adults: Priorities for improving access and affordability (2016), pg. 54

⁹ Gonam AM and Lin FR (2016), *Prevalence of hearing loss by severity in the United States*, American Journal of Public Health

¹⁰ Stevens et al. (2013), *Global and regional hearing impairment prevalence: an analysis of 42 studies in 29 countries*. *European Journal of Public Health*, Volume 23, Issue 1, 1 February 2013, Pages 146–152.

of 10%. This adoption rate is much lower than individuals with moderate (50%) or severe/ profound hearing impairments (70%);¹¹

- Individuals with mild hearing loss mainly experience decreased audibility, a reduced range of hearing, difficulty hearing speech in the presence of noise, and increased listening fatigue. In individuals with moderate or more severe hearing loss, two new dimensions of difficulty are added (reduced frequency resolution and temporal resolution) that significantly complicates the use of amplification to address these levels of loss.¹² WHO's decision to define "disabling" as any hearing impairment that is moderate or higher further supports a conclusion that individuals with at least moderate hearing loss may present with complex needs.¹³
- Mild hearing loss shows a lower co-presence with other medical conditions, including the risk of reporting a fall,¹⁴ the risk of incident all-cause dementia,¹⁵ stroke,¹⁶ diabetes^{17,18} and hypertension.¹⁹

At the same time, it is important for rule makers to be aware of the discordance between self-reported and audiometric hearing loss.²⁰ These studies showed that only half to two-thirds of individuals can correctly classify their hearing losses. Among them, younger individuals tend to over-estimate their hearing losses while older individuals tend to underestimate their hearing losses. As stated above, the audiometric definition of the hearing loss

¹¹ Granholm-Leth N. (2017), *Hearing Healthcare: market conditions better than perceived*, Carnegie Sector Report, as reported by hearingreview.com on May 24th, 2017

¹² Møller KN and Jespersen CT (2013), *What are Some Common Misconceptions of Mild Hearing Loss?*, available from Audiology Online, December 2013.

¹³ World Health Organization (WHO), *Grades of hearing impairment*, available on WHO, Prevention of blindness and deafness, website. Note: WHO uses an average of hearing loss at frequency of 0.5; 1; 2; 4 kHz. Disabling hearing impairment is defined as a loss of 41 dB or higher in adults (31 dB or higher in children)

¹⁴ Lin F and Ferrucci L (2012), *Hearing loss and falls among older adults in the United States*, Intern Med. 2012; 172(4)[Feb]:369

¹⁵ Lin F et al (2011), *Hearing loss and incident dementia*, Arch Neurol. 2011;68(2):214

¹⁶ Lin HC et al. (2009), *Sudden sensorineural hearing loss increases the risk of stroke: A 5-year follow-up study*. Stroke. 200839(10) [Oct]:2744

¹⁷ Lerman-Garber I et al (2012), *Sensorineural hearing loss – A common finding in early-onset Type 2 Diabetes Mellitus*. Endocrine Practice. 2012; 14[July]:549

¹⁸ Bainbridge K (2010), *Diabetes and hearing impairment: an epidemiological perspective*

¹⁹ Rolim L et al (2015). *Interaction between diabetes mellitus and hypertension on hearing of elderly*. CoDAS. 2015;27(5) [Sept]:428

²⁰ Supporting evidences available through several studies developed worldwide, as for example: Kim et al. 2017, Tedeschi & Khim 2016, Kamil et a. 2015, Kiely et al. 2012, Nondahl et al. 1998

range is for the purpose of estimating desired product requirements and it may not reflect the actual degree of hearing loss of OTC hearing aids' users as this is based on the users' self-perception of their hearing difficulty. Therefore, the rule making of OTC hearing aids need to account for the implications for the following two groups:

- Intended users, defined as adults of age 18 or older who correctly self-report a mild to moderate hearing impairment defined as a loss of 26 – 55 dB HL according to ASHA's classification; and
- Unintended but foreseeable users. Considering that this category will be sold over-the-counter, this group may include adults who perceive they have a mild to moderate hearing impairment but either have a normal hearing (25 dB HL or less) or have a more severe hearing impairment (56 dB HL or higher). It also may include adults who have hearing difficulty because of poor cognition, an auditory processing disorder, cochlear synaptopathy, or caused by a medical condition which would be better addressed by a treatment other than hearing aids (e.g. excessive wax, tumor, etc.), and children under the age of 18.

Gain requirements

Gain is essentially the difference between the level of sound that enters a hearing aid versus the amplified sound level that comes out of the hearing aid. Gain is based on the individual's specific degree of hearing loss and is a critical factor for the efficacy of the hearing device. As mentioned before, the new category of OTC hearing devices is potentially set to encompass a wide range of hearing loss (from 26 dB to 55 dB HL based on ASHA's classification) and many possible configurations and hearing loss etiologies. This may pose some challenges when defining a "gain strategy" through a one-size-fits-all approach. Additionally, elements linked to the OTC delivery model need to be considered, including the lack of audiometric data as well as any information on age and gender of the individual wearing the device.

There are numerous prescriptive formulas available today to determine gain requirements and all have different variations with regards to the amount of gain necessary to maximize

conversational speech. The National Acoustics Laboratories NAL-NL2²¹ is the most widely used formula world-wide for the calculation of gain for adults. This formula allows for loudness equalization that will yield the potential for the best outcome for audibility and intelligibility for speech communication. Correction factors have been defined over the years to take into consideration needs of individuals users, like binaural usage (decrease 2-3 dB for losses lower than 50 dB)²² and new users (preferred less gain).²³ The main objective of the NAL formula is to determine the gain level required for several input levels, including soft, comfortable and loud.²⁴ Correctly meeting these levels will have a maximum effect for audibility and speech intelligibility for the specific user.

The Working Group has used the NAL-NL2 gain estimator to determine the desired 2 cc coupler HFA full-on gain considering the upper limit of a mild hearing loss (40 dB HL) and a moderate hearing loss (i.e., 55 dB HL) as defined by ASHA. In addition, the Working Group has also considered a flat hearing loss configuration (e.g., 55 dB HL across all frequencies) and a sloping hearing loss configuration (e.g., 0 dB HL at 250 Hz, 10 dB HL at 500 Hz, 20 dB HL at 1000 Hz, 30 dB HL at 2000 Hz, and 55 dB HL at 4000 Hz and beyond). The experience level (experienced and new) of the wearer, and monaural/binaural usage are added as co-variables. Finally, the use of a nonlinear hearing aid that varies gain with input levels is assumed. Results in the Table below highlight the key variables influencing the desired gain:

- **degree of hearing loss:** a moderate loss requires greater gain than a milder loss;
- **configuration of hearing loss:** a flatter loss requiring greater gain than a sloping loss;
- **input level:** the lower input level the greater gain;
- **experience level:** an experienced wearer with flat loss opting for greater gain;
- **mode of usage:** monaural usage requires greater gain than binaural.

²¹ Dillon H et. al. (2011), 1(e24) *The NAL-NL2 Prescription Procedure*, 88

²² Epstein M and Florentine M (2009), *Binaural loudness summation for speech and tones presented via headphones and loudspeakers*. *Ear and Hearing* 30 (2)

²³ Keidser G, Dillon H, et al. (2008), *Variation in preferred gain with experience for hearing aid users*. *International Journal of Audiology* 47(10).

²⁴ Dillon, H., Katsch, R., Byrne, D., Ching, T., Keidser, G., & Brewer, S., *The NAL-NL1 prescription procedure for non-linear hearing aids*. National Acoustic Laboratories Research and Development, Annual Report 1997/1998, Sydney: National Acoustic Laboratories

		Flat 55 dB Hearing Loss				Flat 40 dB Hearing Loss			
		Monaural Usage		Binaural Usage		Monaural Usage		Binaural Usage	
		Experienced	New User	Experienced	New User	Experienced	New User	Experienced	New User
Input Level	50 dB	30.1	23.8	28.7	22.3	22.3	20.9	19.3	17.9
	65 dB	21.8	15.4	19.8	13.4	16.2	14.8	12.2	10.8
	80 dB	11.3	5.3	8.7	3.6	8.5	7.1	4.1	3.3

		Sloping 55 dB Hearing Loss				Sloping 40 dB Hearing Loss			
		Monaural Usage		Binaural Usage		Monaural Usage		Binaural Usage	
		Experienced	New User	Experienced	New User	Experienced	New User	Experienced	New User
Input Level	50 dB	11.3	11.3	9.0	9.0	7.5	7.5	5.3	5.3
	65 dB	7.7	7.7	5.2	5.2	4.6	4.6	3.2	3.2
	80 dB	3.1	3.1	2.0	2.0	2.3	2.3	1.9	1.9

Table 1. Full on 2 cc coupler high frequency average (HFA, 1000 Hz, 1600 Hz, and 2500 Hz) gain for a moderate (left, 55 dB HL) and a mild (right, 40 dB HL) hearing loss in a flat (upper) and a sloping (lower) hearing loss configuration. The experience level and the mode of usage are included as co-variables.

Depending on the combination of variables, the desired 2 cc coupler HFA full on gain could vary from as little as 3 dB to as much as 30 dB. In view of such complexity, the Working Group has made the following assumptions in order to define a gain recommendation requirement for OTC hearing aids:

- Flat loss of 55 dB HL at the high end of the mild-to-moderate range;
- Input level at 50 dB ensuring audibility of sound softer than conversational speech;
- Binaural usage, as 80% of hearing aid users are bilateral wearers²⁵;
- Incidence of new users consistent with current hearing aid usage by degree of hearing loss, i.e., 90% new users in the mild losses range and 50% for moderate.

²⁵ Kochkin S. (2009), MarkeTrak VIII: 25-year trends in the hearing health market, hearingreview.com (October 2009)

Based on the outcome of the NAL-NL2 gain estimator and following these assumptions,

The Working Group recommends a high frequency average (HFA) full on gain limit of 25 dB as defined for measurement in a 2 cc coupler, with an input level of 50 dB SPL per ANSI S3.22-2014.

It is important to underline that the suggested limit for the HFA full on gain has been defined to ensure adequate audibility for the broadest range of individuals in the “mild-to-moderate” spectrum. Changes in the assumptions for the considered variables will most likely suggest a lower HFA full on gain than the one recommended. The Table below highlights the impact for two of the main variables: degree of hearing loss and level of input. The HFA full on gain for a mild hearing loss of 40 dB is 19 dB, at an input level of 50 dB SPL. When considering an input level consistent with normal conversational speech (65 dB SPL), the suggested gain is 16 dB for a flat moderate loss of 55 dB HL and 12 for a flat mild loss of 40 dB HL respectively. As shown previously, a sloping hearing loss configuration will require a lower HFA full on gain than a flat hearing loss.

	Soft input (50 dB SPL)	Normal speech (65 dB SPL)	Loud input (80 dB SPL)
Flat Mild 40 dB Loss	19	12	4
Flat Moderate 55 dB Loss	25	16	6

Table 2. Full on 2 cc coupler high frequency average (HFA, 1000 Hz, 1600 Hz, and 2500 Hz) gain for a moderate flat 55 dB hearing loss and a mild flat 40 dB hearing loss in a flat (upper) at different input levels.

Finally, it should also be noted that these numbers assume the use of a nonlinear amplification in the hearing aid. In the event a linear amplification type of hearing aid is used, the specified gain will be available at ALL input levels. This could result in under-amplification for the sounds softer than the input level considered to define the gain limit and over-

amplification for the sounds louder than the input level considered to define the gain limit. Therefore, **the Working Group strongly recommends that all OTC devices use a signal processing scheme that reduces gain as input level increases.** A more specific recommendation is defined in the paragraph on compression strategies.

Gain itself does not pose a potential risk due to excessive noise damage. However, linear gain levels greater than 25 dB coupled with high input acoustic signals may put individuals at risk for Leq levels²⁶ more than 85-90 dB (for example, loud speech). Leq is the preferred method to describe sound levels that vary over time, resulting in a single decibel value which takes into account the total sound energy over the period of time of interest. Additionally, increased gain levels, especially in the high frequencies, are the primary cause of acoustic feedback in hearing aids. As the max gain is increased above 25 dB in the high frequencies, the chance for acoustic feedback increases. Acoustic feedback carries with it negative consequences for hearing aid users,²⁷ such as loudness discomfort, sound annoyance, reduced sound quality, and, eventually, reduced speech understanding. In addition, the presence of acoustic feedback can reinforce negative stigmas by reinforcing the opinion among potential hearing aid users that hearing aids do not work very well.²⁸ Therefore, it is again recommended that gain remain at a level not to exceed 25 dB.

Maximum Power Output Limitation

Unsafe listening practice and over amplification have been increasingly pointed out as a cause of noise induced hearing loss. The literature has demonstrated extensively the causative relationship between hearing loss and sound levels in excess of 85 dBA for sound

²⁶ Leq is the preferred method to describe sound levels that vary over time, resulting in a single decibel value which takes into account the total sound energy over the period of time of interest.

²⁷ 1. Mueller HG, Ricketts TA, Bentler R (2014), *Modern Hearing Aids: Pre-Fitting Testing and Selection Considerations*, San Diego: Plural Publishing, as reported by Herbig R and Lueken C (2018), *A comparison of feedback cancellation systems in premier hearing aids*, published on The Hearing Review

²⁸ Ibidem

exposure.²⁹ This evidence has supported initiatives and actions from national and international agencies and organizations to reduce such risk. To list a few:

- Since the 1970s, the Occupational Safety and Health Administration (OSHA) has set limit standards for noise exposure of 90 dBA for eight-hour duration;³⁰
- In 1998, the National Institute for Occupational Safety and Health (NIOSH) established Recommended Exposure Limits (REL) of 85 dB(A) as the maximum for eight hours of exposure;³¹
- In 2015, The WHO launched the Make Listening Safe initiative with the goal of ensuring that people of all ages can enjoy listening with full protection of their hearing. WHO estimates that 1.1 billion people worldwide could be at risk for hearing loss due to unsafe listening practices;³²
- In 2009, The European Commission issued a Commission Decision pursuant Directive 2001/95/EC³³ stating that exposure to sound levels shall be limited in time to avoid hearing damage. At 80 dB(A) exposure, the Commission stated that time shall be limited to 40 hours per week; whereas at 89 dB(A) exposure time, shall be limited to five hours per week. The Decision is based on a study conducted by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The committee concluded in its opinion³⁴ that “listeners risk both hearing and non-hearing problems. In particular, listeners risk permanent hearing loss if they use a personal music player for more than 40 hours per week at high volume settings (exceeding 89 dB(A)) for at least five years.”³⁵

²⁹ Passhler-Vermeer W and Passhler WF (2000), *Noise exposure and public health*, Environ Health Perspective, 2000 Mar, 108(Suppl 1): 123-131

³⁰ US DOL, Occupational Health and Safety Administration, General Industry Standards, 29 CFR 1910

³¹ US DHHS (1998), *Criteria for a recommended standard. Occupational Noise Exposure*. DHHS (NIOSH) Publication No. 98-126

³² Info available on the dedicated page on WHO website (<http://www.who.int/pbd/deafness/activities/MLS/en/>)

³³ European Commission (2009), Commission Decision of 23 June 2009 on the safety requirements to be met by European standards for personal music players pursuant to Directive 2001/95/EC of the European Parliament and of the Council

³⁴ SCENIHR (2008), *Potential health risk of exposure to noise from personal music players and mobile phones including a music playing function*, opinion adopted at the 26th plenary on September 23rd, 2008 after public consultation

³⁵ SCENIHR (2008) as reported by European Commission (2009) – cfr. Note 29 and 30

Any sound exposure that can cause deterioration of hearing for individuals with normal hearing would also have the potential to cause additional hearing loss for the individual with a hearing impairment. Therefore, when regulating OTC hearing devices, the implications of possible over amplification related to the safety and efficacy for intended users as well for unintended, but foreseeable users, needs to be considered. One important safeguard against over amplification with the use of medical devices for amplification is avoiding the potential to cause additional hearing loss or discomfort. The proper adjustment of maximum output is the critical parameter that serves the purpose to limit the amount of:

- Intermittent, short duration sounds, to levels that are neither damaging nor uncomfortable to the wearer, and
- Over amplification of higher level inputs occurring more consistently over a longer duration (e.g. over six-eight hours).

Johnson estimated limit standards to determine the safe output sound pressure levels (SPL) for sound amplification devices to preserve hearing sensitivity after amplification usage.³⁶ In this study, the author developed an algebraic restatement of the correlation between hearing loss threshold and safe output limits. For example, the author's results determined that for a hearing loss with flat 55 dB configuration, a safe overall output SPL would be no greater than 111 dB (as shown in the table below).

³⁶ Johnson E (2017), *Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss*, International Journal of Audiology, 2017; 56: 829-836

4FA dB HL threshold	Safe Output SPL (overall dB)
0	90
10	94
20	97
25	99
30	101
40	105
45	107
50	109
55	111
60	113
70	117
80	120
110	132

Table 3. An algebraic restatement of the regression equations holding expected PTS constant at 3.5 dB HL to show safe output SPL as a function of hearing loss (selected HL thresholds). From Johnson E. (2017)³⁷

Johnson’s study mainly takes the perspective to limit overamplification, which may occur over a long duration (e.g. over eight hours). This is consistent with other available studies on behavior for individuals with mild-to-moderate hearing loss that use amplification either supported by a professional or self-directing themselves to this solution that indicate usage of approximately eight to eight and a half hours daily.^{38,39} As a consequence, the implications would be very similar to the consequences of prolonged usage of consumer listening products like headphones or ear buds.

The study’s findings are further corroborated by the National Health and Nutrition Examination Survey studies that have shown a significant increase in the prevalence of

³⁷ Ibidem

³⁸ Timmer B. et al. (2017), *Hearing aid use and mild hearing impairment: learnings from big data*, Journal of American Academy of Audiology, J Am Acad Audiol 28:731-741 (2017)

³⁹ Tedeschi TJ and Khim J, *Implications of an over-the-counter approach to hearing health care: a consumer study*, Hearing Review 2017;24(3) [Mar];14-22

hearing loss in the U.S. with adolescents, who have sustained use of consumer listening products.⁴⁰ This is an indication that users are unable to self-determine when a prolonged exposure to over amplification can cause (further) damages. Unlike consumer listening products, medical devices for amplification must be regulated for the safety of both intended and unintended but foreseeable users.

In addition to estimating safe output limits, Johnson further detailed that, for the safe implementation of this standard, a device should utilize input-output compression. This compression strategy would allow the device to provide adequate gain for audibility and comfortable listening while also ensuring protection against further hearing loss.

While Johnson's argument is based on safety, another consequence of setting the maximum output too high is related to efficacy and benefit for the intended users is creating aided loudness discomfort for high-level sounds. Loudness discomfort has been cited as a reason for dissatisfaction with hearing aids. One survey of over 2,600 hearing aid users, Kochkin noted that 27% of the respondents reported dissatisfaction with loud sounds.⁴¹

At the same time, limiting the maximum power output for OTC hearing devices will protect unintended but foreseeable users, such as adults with normal hearing and children.

One reporting parameter that characterizes the maximum output of a hearing aid is the Output Sound Pressure Level at 90 dB SPL Input (OSPL90, ANSI S3.22-2014). The OSPL90 measurement is done using a swept frequency (i.e., one frequency at a time) presented at a 90 dB SPL input level. The OSPL90 curve represents the maximum output of the hearing aid when **a single frequency** is employed. Indeed, when the input signal is a pure tone, the maximum output of the hearing aid is limited by the OSPL90 of the hearing aid.

On the other hand, when a broadband signal (such as speech or music that includes energy over a broad range of frequencies) is presented to the hearing aid, the output of the hearing aid is the sum of the energy at all the frequencies. Indeed, the maximum output of the hearing aid will be limited by the peak OSPL90 at each frequency but summed across all the

⁴⁰ JAMA and Archives Journals. "Prevalence of hearing loss among US adolescents has increased significantly, study finds." ScienceDaily. ScienceDaily, 17 August 2010.

⁴¹ Kochkin S (2002), *10-year customer satisfaction trends in the US hearing instrument market*, Hearing Review 10:14, 18-25, 26. 2002.

frequencies of interest. Thus, a sinusoid or a very narrow band of noise of the same spectral level presented at a 90 dB SPL level may have an overall output closely related to the value of the peak OSPL90. However, a broadband signal (such as speech or music) of the same spectral level at all frequencies will have an overall output level far exceeding the value of the peak OSPL90. For example, a 75 dB SPL sinusoid may have an output of 85 dB from a hearing aid. An octave band of noise with the same center frequency and spectral level as the sinusoid would have an output of 101 dB SPL. Thus, the OSPL90 on a hearing aid is not the same as the maximum overall output of the hearing aid. The latter could be significantly higher than the value of the OSPL90, depending on the spectral level and bandwidth of the input signal.

Thus, considering Johnson's (2017) recommendation of an overall output level lower than 111 dB SPL as a safe level for a moderate degree of hearing loss, and considering that the 2 cc coupler OSPL90 is a required parameter in reporting the characteristics of a hearing aid, the Working Group recommends that the peak OSPL90 not be greater than 110 dB SPL in order to avoid the potential of an output greater than 111 dB SPL. Balancing the issues of sound quality (such as in music appreciation), optimal speech intelligibility, listening comfort and minimal risk of discomfort and over-amplification for the intended wearers of OTC, the Working Group makes the following recommendation.

*The Working Group's recommendation is that **the peak (or maximum) 2 cc coupler OSPL90, per ANSI S3.22-2014, not be greater than 110 dB SPL.***

As for the proposal on gain limit, it is worth highlighting that the recommended limit level has been defined with regards to users who have a moderate hearing loss of 55 dB HL. By applying the same logic for individuals with a flat, mild hearing loss of 40 dB HL, the recommended 2 cc peak coupler OSPL90 must not exceed 105 dB SPL.

This Working Group believes that any output above the recommended limit will increase exposure to over amplification and be detrimental for users. Based on the evidence reported above, this Working Group believes that the recommended OSPL90 limit coupled with input

compression will ensure protection against further damage to users. The gain and output recommendations will provide adequate gain for audibility and comfortable listening.

Compression Strategies

The previous two sections substantiate the recommendations on gain and maximum output limits. These specifications will help to ensure that no (further) damage occurs to the hearing of users of OTC devices and will provide an adequate and comfortable listening experience while avoiding any distortion. The issues of discomfort and (further) damages linked to intense sound exposure can be reduced simply by limiting the output. Today the use of linear amplification with peak clipping is a cost-effective way to provide some amplification while limiting the output. Using this method, the output SPL that would have the potential to exceed 110 dB would be “clipped” or kept at or below that limit. Peak clipping may be an acceptable form of output limiting; however, it is also associated with saturation-induced distortions from clipping that may result in poor speech intelligibility and decreased sound quality with high input levels.

Most personal sound amplifying products (PSAPs) that are in use today utilize linear amplification and peak clipping. A joint analysis developed by the European associations of hard of hearing and of hearing professionals in Europe in 2015 found that all 27 PSAPs assessed in different countries showed an OSPL90 level over 120 dB SPL.⁴² Most importantly none of the products had a limiter for maximum power. These results are consistent with the assessment of nine amplifiers conducted in the United States; only two out of nine had an OSPL 90 lower than 110 dB.⁴³

A compression strategy is key to achieving the goals of ensuring protection from (further) damages, delivering comfortable listening, and maximizing speech intelligibility. The most basic type of compression is input-controlled compression. Input compression acts on the

⁴² European Federation of Hard of Hearing People (EFHOH) and European Associations of Hearing Aid Professionals (AEA), *Paper on the potential risk of using “Personal Sound Amplification Products” PSAPs*, Dec 2015

⁴³ Ruch H. (2016), as presented to FDA’s Public Workshop on “Streamlining Regulations for Good Manufacturing Practices for Hearing Aids”, Silver Spring, MD, April 21st, 2016

incoming signal to the hearing aid. That is, once the input exceeds the threshold “kneepoint,” the compressor is activated, and gain at the preamplifier is reduced.

Compression may also be applied at the output of the device to prevent the amplified sound from exceeding the recommended 110 dB output limit. A device utilizing both input and output compression (I/O) would allow for amplification to be applied to low intensity sounds so they are audible, and I/O compression would be applied to higher intensity sounds so they do not become uncomfortably loud and are free from distortion. Research findings have shown that compression limiting is preferable over peak clipping. This is because of compression’s ability to reduce distortion while maintaining the temporal and spectral integrity of the signal most of the time. Dillon⁴⁴ corroborates that such benefits can be enjoyed by hearing impaired patients with mild-to-moderate degree of hearing loss. Johnson (2017) also suggested that a hearing aid should utilize input-output compression.

There is another reason why an input compression circuit may be particularly helpful in formulating the specifications for OTC hearing aids. Because no objective verification of hearing loss is required in the purchase of OTC, a wearer with a perceived mild-to-moderate hearing loss may indeed have normal hearing. In addition to gain and output limits, the use of input compression on a hearing aid that allows user adjustment of gain via a volume control (either on the hearing aid or remotely) is additional safeguard mechanism.

The figure below shows the hypothetical input-output curve of an input (left) and output (right) compression hearing aid as a function of user adjusted volume control settings. While lowering the volume control (from 3 - max to 1 - min) results in a lower output (because of lower gain) for both types of compressors, lowering the volume also results in a lowering of the maximum output of the input compression hearing aid (e.g., from 110 dB SPL to 95 dB SPL). The same is not true for the output compression hearing aid (e.g., maximum output remains at 110 dB SPL for all volume control settings).

⁴⁴ Dillon H. (1988), *Compression in hearing aids*. In: Sandlin R. (editor), *Handbook of hearing Aid Amplification, Vol. I, Theoretical and Technical Considerations*. College-Hill Press

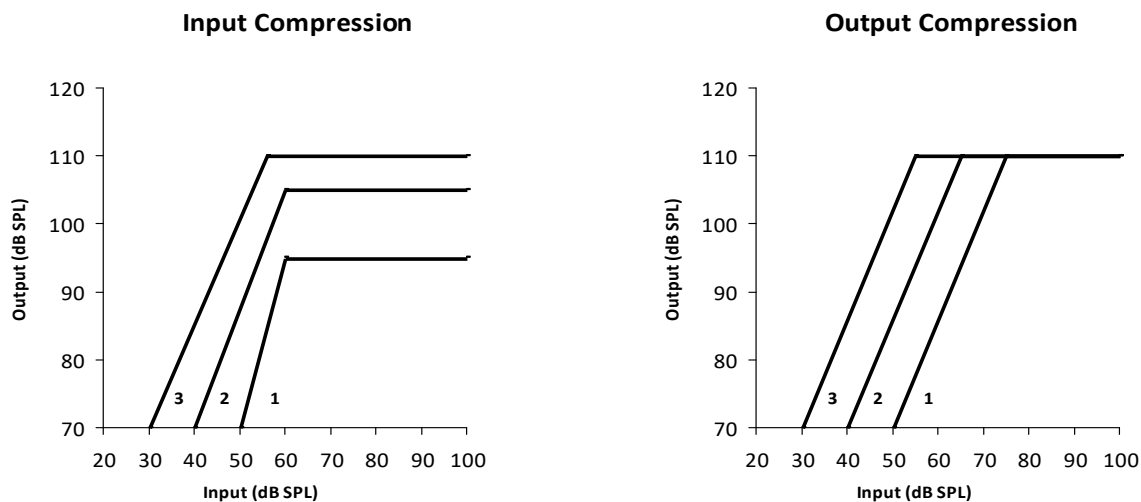


Figure 1. Hypothetical input-output functions of an input compression (left) and output compression (right) hearing aid as the volume control setting is changed (1 = minimum volume control; 3 = maximum volume control)

This suggests that a wearer with less than a moderate degree of hearing loss may lower the volume control on the input compression hearing aid to achieve the purposes of a lower gain and a lower maximum output. However, it should be noted that with output compression only lowering the volume control will not reduce the maximum output of the OTC hearing aid putting an individual with a mild hearing loss at risk for over amplification and the potential for increased hearing loss. It also needs to be pointed out that volume control only offers a limited range of gain/output adjustment (typically around 10 dB).

The Working Group's recommendation is for the FDA to establish product specifications that include, as the minimum standard, input compression and a volume control (in addition to the already recommended requirements for gain and maximum output limit).

This requirement would allow for the achievement of safety for both the intended and unintended, but foreseeable users of OTC hearing devices as well as provide adequate effectiveness in terms of speech intelligibility, listening comfort, and restoring loudness perception.

Other Product Requirements

The Working Group also encourages the FDA to adopt requirements in additional areas in order to further increase the safety and effectiveness of the OTC hearing device category.

Instant-fit ear-tips

An important factor to consider is how the device is coupled to the ear. In this context users of a hearing aid purchased over-the-counter will need to get started without the support of any 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 any 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). Also the risk is magnified in the elderly if the individual has decreased cognitive function or dexterity. A common approach available for several styles of hearing aids and degree of hearing losses is the use of an instant-fit ear-tip, which does not require the taking on an ear impression. This approach provides reasonable amplification (gain) to that provided by an earmold made through an earmold impression taking process⁴⁵. It also prevents the possibility of injecting impression materials into a surgically modified ear canal (such as radical mastoidectomy). Therefore,

*It is the recommendation of the Working Group that **only instant-fit eartips be used as the form 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, the Working Group strongly recommends that the service of a licensed hearing healthcare professional be required.*

⁴⁵ Jespersen CT and Moller KM (2013), Reliability of real ear insertion gain in behind-the-ear hearing aids with different coupling systems to the ear canal, *International Journal of Audiology*, 52:3, 169-176

Compatibility for digital wireless phones

Americans today are increasingly connected to the world of digital information while “on the go” via smartphones and other mobile devices. According to the Pew Research Center⁴⁶, in 2018 the vast majority of Americans – 95% – own a cellphone of some kind; with 77% of Americans owning smartphones. Even in older segments of the population the ownership of a smartphone is significant (73% for adults aged 50 - 64 years; 46% for those aged 65 or older). People who use hearing aids may experience some difficulties when trying to use cell phones. A buzzing noise may be audible due to interference from radiofrequency (RF) emissions from the phone. RF interference does not occur for all combinations of digital wireless telephones and hearing aids. However, when interference does occur, the buzzing sound can make understanding speech difficult, communication over cell phones annoying, and in the worst case, render the cell phone unusable for the hearing aid user. The Federal Communications Commission (FCC) requires cell phone manufacturers to test and rate their wireless handsets’ hearing aid compatibility using the American National Standards Institute (ANSI) C63.19 standard. These ratings give an indication of the likelihood that a cell phone may interfere with hearing aids. The Working Group, therefore, recommends that OTC hearing device manufacturers also use the ANSI Standard rating system for RF immunity.

The Working Group’s recommendation is that OTC hearing devices meet the M2/T2 standard (if a T-coil is available), which today is the current minimal standard for hearing aids.

Finally, the Working Group recommends appropriate labeling, warning and reporting be required within the technical specifications section of the user manual. Consumer surveys suggest that today users are largely unaware of what the different technical features are in hearing amplification devices, and therefore, they do not consider them in the selection of a device.⁴⁷

⁴⁶ Pew Research Center (2018), *Mobile Fact Sheets*, Results of survey conducted Jan 3-10, 2018

⁴⁷ Tedeschi TJ and Khim J, *Implications of an over-the-counter approach to hearing health care: a consumer study*, *Hearing Review* 2017;24(3) [Mar];14-22

Recommendation 2: define concise, outside-of-the-box labeling appropriate for OTC, with a strong recommendation to consult with a hearing healthcare professional

The labeling is essential to assure safe and effective use for this new category of hearing devices. According to the Food, Drug & Cosmetic Act,⁴⁸ labeling for medical devices should, among other things, reflect the intended use and contain adequate directions for use. Today, the FDA defines specific labeling requirements for hearing aids⁴⁹. The OTC Hearing Aid Act of 2017⁵⁰ explicitly defines that the FDA establish appropriate labeling for the over-the-counter sale of this new category including *“a conspicuous statement that the device is only intended for adults age 18 and older, information on how consumers may report adverse events, information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss, and advisement to consult promptly with a licensed health care practitioner.”*

In developing the recommendations about how to implement those directions, the Working Group believes it is key to adhere to the principle that labeling needs to empower potential intended users and unintended users to make informed choices about whether purchasing these devices is the right hearing care option for them. Since these devices are intended for use by consumers without professional assistance, the information on the outside of the box is critical to assure safe and effective use. The outside of the box labeling should be designed to inform interested consumers about the intended use, benefits, and risks of the device. At the same time, the labeling needs to deliver all key information in a limited space and in a concise self-explanatory manner.

⁴⁸ 21CFR801 – Subpart A

⁴⁹ 21CFR801.420

⁵⁰ FDA Reauthorization Act (FDARA) of 2017, Sec. 709

The Working Group's recommendation is that the outside-of-the-box labeling contain the following information:

- **Name of the category;**
- **Intended use, and consequently recognition of usage and/or users for whom this category of devices is not intended;**
- **Important notice for the prospective users about hearing loss being a medical condition best addressed in consultation with a licensed professional, including the list of the "red flag" conditions.**

Specifically, with regards to the labeling about **intended use** the Working Group suggests the following wording: "This device is intended for use only by adults (minimum age 18) with mild-to-moderate hearing loss, who have difficulties hearing conversational speech. This device is not intended for use by children. Benefits from this device may vary from individual to individual. If you have any questions, concerns or need further assistance with regards to your ability to hear it is recommended that you consult with a hearing healthcare professional before purchasing this device."

In addition, the Working Group recommends that the outside-the-box labeling contain the following wording: "**Important notice for the prospective users:** Hearing loss is a medical condition best addressed in consultation with a licensed hearing healthcare professional. If you experience any of the following conditions, do not purchase this product and consult a hearing care professional before proceeding:

- Visible deformities of the ear since birth or from injury
- Fluid, pus, or blood coming out of the ear within the previous three months
- Sudden, quickly worsening, or fluctuating hearing loss within the previous three months
- Dizziness or periodic vertigo associated with hearing loss
- Hearing loss in only one ear or a large difference in hearing between ears
- Ear wax build up or feeling that something is in the ear canal
- Pain or discomfort in the ear
- Tinnitus or ringing in one or both of your ears"

Recommendation 3: define comprehensive, inside-the-box labeling appropriate for OTC hearing devices

While the outside-the-box labeling is key to quickly inform and empower consumers to make the decision about whether to buy the device, the information on the inside labeling should provide the user of the device information relating to the device's operation, care, and maintenance as well as to provide information concerning potential problems that the user may encounter with the device. Adequate directions for operation of the device are required to ensure the device is safe and effective.

The Working Group's recommendation is that the inside labeling should include, but not be limited to the following:

- ***A warning that the device is not intended for children.*** *"Hearing loss in children is not the same as hearing loss in adults and may represent other non-ear related, conditions that require specialized treatment. Self-Fit Over-the-Counter Hearing Devices are not intended for use by children with hearing loss. Children treated with these devices are at risk for severe complications due to untreated ear disease and/or inadequate amplification. This could lead to severe, permanent, and disabling speech, language, auditory impairment and auditory development as well as additional hearing loss due to inappropriate levels of amplification."*
- ***"Important notice for the user.*** *Special care should be exercised in the use of this device. You should not use your hearing device for more than (12) hours a day nor should you use your device if the device exceeds your comfort level. If set to the maximum output level and worn for periods of time exceeding these recommendations, there may be risk of damaging the remaining hearing of the device user."*
- ***Important notice about lack of benefit:*** *"Lack of benefit with this device could indicate a more severe or complex type of hearing loss exists, requiring the assistance of a licensed hearing healthcare professional. Seek professional assistance if after use of this product you note the following:*

- *No or little improvement in listening in conversational settings*
- *No improvement in hearing speech in noisy environments*
- *Speech is still unclear*
- *Poor sound quality*
- *All sounds are too loud*
- *Loud sounds are too uncomfortable*
- *Notice of or increased ringing in the ear*

Stop use of this product and consult with a medical professional if you experience any of the following conditions:

- *Fluid, pus, or blood coming out of the ear within the previous three months;*
- *Sudden, quickly worsening, or fluctuating hearing loss within the previous three months;*
- *Dizziness or periodic vertigo associated with hearing loss;*
- *Ear wax build up or feeling that something is in the ear canal;*
- *Pain or discomfort in the ear;*

Inside-the-box materials should also include the **User Instructional Brochure**. The FDA recommends⁵¹ that the user needs to know what to do, how to do it, and when to do it. The operating instructions should focus on how to operate the device. The developer of the User Instructional Brochure should assume that the user does not have device or medical knowledge. The User Instructional Brochure should provide logically ordered steps for use and instruct the user on the importance of following the steps in order; explain the purpose and the expected outcome of each step and highlight to the user which steps are essential versus optional. The User Instructional Brochure should be written at an eighth-grade

⁵¹ FDA-CDRH (2011), *Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers*, Rockville, MD

reading level or below so that to make it easy to understand irrespective of education level and should be clear the first time it is read.⁵² The User Instructional Brochure must contain at least the following information:

- Clear instructions on how to get start using the device;
- Cleaning instructions;
- Maintenance instructions;
- Storage instructions;
- Battery life and battery warning;
- Troubleshooting;
- Possible adverse effects: Warning and Precautions Section
- User assistance information

Finally, the inside-the-box materials must contain all key relevant technical data, including, but may not be limited to, the following:

- Maximum OSPL90: ≤110 dB SPL
- HFA-FOG: ≤25 dB
- Frequency Response: Lower 250 Hz to equal or great than 5 kHz
- Response Smooth: ≥12 dB/ octave rule
- EIN: ≤30 dB Maximum
- Harmonic Distortion: Current ANSI recommendations
- Latency: Less than 15msec
- Volume Control: Yes
- Compression: Input compression (minimum)
- Battery: Type_____ disposable or rechargeable
- Battery Life: _____ current drain or _____Hours
- RF Immunity: M2/T2 (if available)
- Special features such as feedback cancellation, wireless connectivity, directional microphone, noise reduction etc. are optional but must be reported if utilized

⁵² FDA – CDER, *Patient Labeling 101*, available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070801.pdf>; <https://www.fda.gov/downloads/ForPatients/About/UCM410170.pdf>

Recommendation 4: define the new OTC category so that it is easily comprehensible by consumers and in line with risk class requirements for safety and effectiveness

It is widely recognized that key drivers of consumers' non-adoption of hearing aids are attitude and stigma. In a 2007 consumer survey investigating the reasons for adult non-adoption of hearing aids, almost half of the individuals reported that they decided not to use a hearing aid due to some form of stigma, self-perception of their loss, or attitude towards hearing aids.⁵³ These drivers can be further emphasized by lower levels of health literacy associated with the target population (in particular, adults 65 years or older)⁵⁴. Consumers may have great difficulty understanding and processing information pertaining to hearing loss and the different hearing care solutions available to them. As the National Academies pointed out, “[a]ppropriate and comprehensible communication, both written and verbal, is crucial to further empower people with hearing loss”. While this principle has guided the definition of the Working Group’s Recommendations 2 and 3 above, the Working Group believes that the same principle has to guide the definition of the name and the overall regulatory framework for this new category. It should be noted that the National Academies of Sciences, Engineering, and Medicine, (NASEM) have made the same recommendation in their report about how to improve access and affordability to hearing health care for adults. NASEM’s recommendation was to create a new category of OTC hearing devices and to separate “hearing aids” and PSAPs to prevent confusion for individuals seeking hearing care solutions.⁵⁵ Finally, this principle is also congruent with the congressional mandate to “clarify which products, on the basis of claims or other marketing, advertising, or labeling material,

⁵³ Kochkin S. (2007), *MarkeTrak VII: Obstacles to adult non-user adoption of hearing aids*, *The Hearing Journal* 60(4):24-50. As also reported in 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

⁵⁴ Several studies, as reported by 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, pg. 282-284

⁵⁵ 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

meet the definition of a device [...] and which products meet the definition of a personal sound amplification product.”⁵⁶

To address the concerns above, the Working Group recommends that the new FDA rule and the related guidance needs to clarify four key elements for the new device category. This is recommended to differentiate (1) OTC hearing devices, (2) traditional hearing aids and (3) Personal Sound Amplification Products (PSAPs):

- Name of the category;
- Intended use;
- Conditions for sale;
- Risk classification.

In doing so, the Working Group has adhered to the following principles:

- The segmentation between the three product categories must be clearly distinguishable and easily comprehended by the average consumer in all elements, including name, intended uses, delivery model, etc.;
- Any instrument intended for the use in the mitigation or treatment of a medical condition is defined as a medical device and, consequently, regulated by FDA;⁵⁷
- Any condition for sale and risk classification requirement must be necessary and sufficient to provide reasonable reassurance of safety and effectiveness of the device, while avoiding excessive burdens to the manufacturers.

Based on these principles and arguments,

The Working Group’s recommendation is to name the new category as “Self-Fit Over-the-Counter Hearing Devices”. This will clearly distinguish this category from both traditional hearing aids that are professionally fit and PSAPs.

⁵⁶ FDA Reauthorization Act (FDARA) of 2017, Sec. 709(c)

⁵⁷ In coherence with the Food, Drug and Cosmetic Act – 21 U.S.C. § 321(h)

“Self-Fit Over-the-Counter Hearing Device” provides specific definitive information for the consumer. “Self-Fit” identifies that this hearing device does not come with any type of professional services; the consumer will start usage with the device independently. “Over-the-Counter” also reinforces that the device could be purchased without professional involvement. At the same time, it is key to stress that this product category is a “medical device” intended to treat a medical condition and is therefore regulated by the FDA, rather than a consumer product that is not intended to compensate for hearing loss and is non-regulated. The “Self-Fit Over-the-Counter Hearing Device” category name will allow for the setting of realistic expectations for consumers and will empower them to make informed decisions about their hearing care journey.

If the new category is called Over-the-Counter Hearing Aids, the Working Group’s concern is that the new segmentation and category naming will create a great deal of confusion for consumers. This device classification should be separate from traditional hearing aids. Traditional hearing aids currently include many professional services which are provided by licensed hearing healthcare professionals. These services include but are not limited to a professional hearing assessment, proper fitting and adjustment of the device, counselling and follow-up care. These services include several professional hours to ensure the best outcome for the hearing-impaired individual. Traditional hearing aids today are very complicated digital systems that incorporate many unique and complicated signal processing features. These defining products and services comprise today’s standard of care and are provided by a licensed audiologist or hearing aid specialist. To alleviate confusion between categories and for good health practice, it is proposed that the FDA require a person who is purchasing a hearing aid have an evaluation by a licensed hearing care professional before the purchase of a hearing aid. The purpose for this professional evaluation is to assure that all treatable conditions that may affect hearing rehabilitation are identified and are a part of the individuals treatment plan. This will alleviate confusion and ensure the safest and most effective plan of treatment.

In addition to the category name, the OTC Hearing Aid Act of 2017 directs the Secretary of Health and Human Services “to determine whether OTC hearing aids require a report under

section 510(k) to provide reasonable assurance of safety and effectiveness.”⁵⁸ A 510(k) is required to demonstrate that a device to be marketed is at least as safe and effective (i.e. substantially equivalent) as a legally marketed device that is not subject to premarket approval.⁵⁹ To find a device substantially equivalent, the FDA must find that it has the same intended use as the predicate device, and either:

1. Has the same technological characteristics as the predicate device, or
2. Has different technological characteristics and the submission contains information, including appropriate clinical or scientific data if necessary, that demonstrates the device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness than the predicate.⁶⁰

The Working Group recommends that the new category maintains the same risk classification as air conduction hearing aids – i.e. Class I for Self-Fit Over-the-Counter Hearing Devices and Class II (Exempt) for Wireless Self-Fit Over-the-Counter Hearing Devices. At the same time, it is the Working Group’s strong recommendation that any 510(k) exemptions be limited to devices that have already received a first-time FDA marketing authorization (i.e. 510(k) clearance). Therefore, the first OTC hearing device marketed by each manufacturer should be required to undergo the 510(k) processes.

In fact, Congress has established that devices in the new category will use “the same fundamental scientific technology as air conduction hearing aids.”⁶¹ The Working Group recognizes that in the long term this provision will ensure that the risk profile of OTC hearing devices will be consistent with that of traditional hearing aids. At the same time, to provide reasonable reassurance of safety and effectiveness when creating a new category of devices, a first-time 510(k) clearance should be required for the first device marketed by each

⁵⁸FDA Reauthorization Act (FDARA) of 2017, Sec. 709(b)(3)

⁵⁹ Cfr. FDA website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

⁶⁰ FDA, *Refuse to Accept Policy for 510(k)s*, Document issued on January 30, 2018

⁶¹ FDA Reauthorization Act (FDARA) of 2017, Sec. 709(a)

manufacturer in this category to demonstrate that the device utilizes a “substantially equivalent” technology as that utilized today with (wireless) air conduction hearing aids. Once a company’s device has been found to be compliant with the regulation, subsequent devices could then become 510(k) exempt and sold without FDA review, absent of any conditions that would require a 510(k)-review process.

Category Name	Personal Sound Amplification Products	Self-Fit OTC Hearing Devices	Hearing Aids
Type of Products	<ul style="list-style-type: none"> • Consumer Electronic 	<ul style="list-style-type: none"> • Medical Device 	<ul style="list-style-type: none"> • Medical Device
Intended Use	<ul style="list-style-type: none"> • For non-hearing-impaired consumers to amplify sounds in certain environments or leisure activities 	<ul style="list-style-type: none"> • Only for adults with mild-to-moderate hearing impairment treatable with hearing devices 	<ul style="list-style-type: none"> • For all individuals with hearing impairment treatable with hearing devices • Children of 18 years or younger only through physicians & audiologists
Conditions for Sale	<ul style="list-style-type: none"> • <i>Not regulated by FDA</i> 	<ul style="list-style-type: none"> • Available for OTC sale without the involvement of any professional 	<ul style="list-style-type: none"> • Through the support of a licensed hearing care professional
Risk Class	<ul style="list-style-type: none"> • <i>Not regulated by FDA</i> 	<ul style="list-style-type: none"> • Not-wireless: Class I • Wireless: Class II (exempt), exemption limited to one-time FDA reviewed devices 	<ul style="list-style-type: none"> • Not-wireless: Class I • Wireless: Class II (exempt)

Table 4. Suggested segmentation of different hearing product categories

Recommendation 5: adequate provisions for consumer protection, in coordination with the Federal Trade Commission (FTC)

Since the regulation of hearing aids was first discussed at the federal level in the 1970s, consumer protection has been at the forefront of concern for prospective hearing aid users. In 1975, the Federal Trade Commission (FTC) published an initial note of a proposed rule that included, among other provisions, the right for a hearing aid buyer to cancel the order within 30 days and receive a refund as well as restrictions of certain selling techniques, and representations of hearing aid and hearing aid sellers.⁶²

Over the years federal agencies have been involved in enforcing consumer protection clauses, (e.g. false claims and misleading advertising). For example, in April of 1993 the FDA sent letters to six hearing aid manufacturers warning them to cease making unsubstantiated or false claims regarding the capabilities of hearing aids to consumers.⁶³ These manufacturers were charged with making claims that hearing aids could eliminate background noise. In addition, the FDA alleged that these specific manufacturers made claims that were unsubstantiated by clinical data, failed to disclose material information, and overstated the quality and value of the hearing aids.

In addition to federal agencies, individual states have enacted laws that affect the sale of hearing aids, including provisions that establish minimum competency standards for hearing aid dispensers and consumer protection clauses. In the preamble of the 1977 rule on hearing aid devices, the Commissioner recognized the benefit of *“strong State and local licensing laws.”*⁶⁴ Consistently, the FDA ruling on exemption from preemption of state and local hearing aid requirements *“encourages the States to remain active in regulating the hearing aid industry”*⁶⁵. The importance for consumer protection laws and of enforcement activities by state and local officials has been demonstrated by the experience in Colorado in the 1980s to mid-1990s . From 1986 to 1995, licensing laws governing hearing aid dispensing

⁶² 40 FR 26646

⁶³ U.S. Department of Health & Human Services, P93-14 HHS News 1, April 16, 1993

⁶⁴ FedReg, Vol 42, No 31, February 15, 1977

⁶⁵ FedReg, Vol 45, No 199, October 10, 1980

were suspended. The state licensing board itself had been discontinued and hearing aids were governed under the state's general consumer protection act. Sunset reviews of the legislation in 1990 and 1994 consistently found that consumers' complaints had increased tenfold compared to before 1986; most importantly, the majority of the complaints were related to the refusal to issue refunds within 30 days of purchase, contract complaints, fraud issues, misdiagnosis, and physical harm.^{66, 67} A licensing law was eventually reinstated in 1995 and complaints eventually decreased to a level comparable to prior of 1986⁶⁸.

Additionally, today 32 states have in place required return and refund policies for hearing aids.⁶⁹ Since the Over the Counter Hearing Aid Act⁷⁰ mandates that all state or local government laws are preempted by the new regulation, these consumer protections will not govern the category of OTC Hearing Devices.

The Working Group's recommendation is that FDA, in coordination with the FTC, establish strong consumer protection regulations and put in place adequate processes and resources to enforce them. Specifically, the Working Group strongly recommends that return and refund policies be defined for this new category; it is also recommended that specific attention be called to claims for this new category. Additionally, FDA and FTC put a process in to ensure that all claims are substantiated by data, scientific evidences and/or clinical studies.

⁶⁶ The Colorado Department of Regulatory Agencies – Office of Policy and Research, Regulation of Hearing Aid Dealers – 1990 Sunset Review

⁶⁷ The Colorado Department of Regulatory Agencies – Office of Policy and Research, Audiologists and Hearing Aid Dispensers – 1994 Sunset Review

⁶⁸ The Colorado Department of Regulatory Agencies – Office of Policy and Research, Research and Regulatory Reform, Audiologists and Hearing Aid Provider Regulation – 2006 Sunset Review

⁶⁹ List from Hearing Loss Association of America, accessible through the following link http://www.hearingloss.org/sites/default/files/docs/Consumer_Protection_Laws.pdf

⁷⁰ FDA Reauthorization Act (FDARA) of 2017, Sec. 709(b)(4)

Conclusion

In conclusion, the major hearing healthcare professional associations in the United States desire to contribute to the ongoing dialogue concerning efforts to improve hearing healthcare for millions of Americans. This Consensus Paper summarizes the Working Group's input and recommendations with regards to the execution of the congressional mandate for safety and effectiveness within this new medical device category, while ensuring accessibility and affordability. The Working Group has based its recommendations on substantial data and scientific evidence; at the same time, the Working Group has developed suggestions on how to incorporate and detail these recommendations into the rule.

Five recommendations have been identified as key to provide enough reassurance of safety and effectiveness and of consumer protection:

1. **Recommendation 1:** FDA to establish product requirements appropriate for OTC hearing devices targeting mild-to-moderate hearing impairment. In particular, the Working Group recommends that: a) the **2 cc coupler HFA full on gain, as measured at an input level of 50 dB SPL per ANSI S3.22-2014, is 25 dB or lower**; and b) **the peak (or maximum) 2 cc coupler OSPL90, per ANSI S3.22-2014, is not greater than 110 dB SPL**, in combination with input compression and volume control. In addition, the use of instant-fit ear-tips is encouraged.
2. **Recommendation 2:** FDA to define concise, outside-of-the-box labeling appropriate for medical devices sold over-the-counter. This should include **recognition of intended use / usage** and an important notice for the prospective users about **hearing loss being a medical condition best addressed in consultation with a licensed professional**.
3. **Recommendation 3:** FDA to define comprehensive, inside-the-box labeling including a strong warning that the device is not intended for children under the age of 18. Additionally, inside-the-box should include a User Instructional Manual with direction to the consumer on how to identify lack of benefit and what to do.

4. **Recommendation 4:** FDA to name the new category as “*Self-Fit Over-the-Counter Hearing Devices*” and to maintain for such category **the same risk classification as air conduction hearing aids** – i.e. Class I for non-wireless devices and Class II (exempt) for wireless OTC hearing devices. Additionally, the Working Group strongly recommends that **any 510(k) exemptions be limited to devices that have received a first-time FDA marketing authorization** (a 510(k) clearance). **The initial OTC air conduction hearing devices should be required to undergo the 510(k) processes.**

5. **Recommendation 5:** FDA, in coordination with the FTC, to establish **strong consumer protection laws** (e.g. return and refund policies, unsubstantiated and false claims, ...) and put in place **adequate processes and resources to enforce them**, especially in the first years of introduction of the new category.

These recommendations together will be essential to ensure safety, effectiveness and consumer protection for both intended users and unintended but foreseeable users. The Working Group is looking forward to opportunities to further contribute to the ongoing debate and support the current rule making process of Self-Fit-OTC Hearing Devices in any means deemed appropriate.