February 1, 2022

STATEMENT FROM ADA ON THE FDA OTC HEARING AID PROPOSED RULE PROVISIONS FOR MAXIMUM SOUND OUTPUT AND GAIN

I. THE BIG PICTURE

Following the release of the Food and Drug Administration (FDA) Over-the Counter (OTC) Hearing Aid Proposed Rule (Proposed Rule) in October 2021,[1] the Academy of Doctors of Audiology (ADA) convened an internal task force for the purpose of evaluating whether the Proposed Rule (i) meets the statutory requirements outlined in FDARA (FDA Reauthorization Act) and (ii) supports evidence-based practices, professional autonomy, consumer access, and competition.

During this process, the ADA OTC task force conducted a comprehensive literary review of scientific presentations, research articles, the President's Council of Advisors on Science and Technology (PCAST) report (2015)[2] and National Academy of Science Engineering and Medicine (NASEM) Report (2016)[3], FDA regulations, ANSI standards, and the "Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness" (2018 Consensus Paper)[4] to assess the Proposed Rule provisions for technical and performance standards for OTC hearing aids.

ADA advocates for public policies that improve consumer access to audiology services and access to safe, effective, and affordable treatments for hearing loss, including OTC hearing aids. ADA believes that through the evaluation of science and the application of the information found, consumers and the profession of audiology will be best served by a legal framework that is evidence-based.

After a careful evaluation of the evidence, the ADA OTC task force and the ADA Board of Directors concluded the original methodologies used to justify the 25 dB (decibel) gain limit and the 110 dB output limit in the 2018 Consensus Paper—published as a consensus paper from several hearing healthcare organizations, including ADA—was flawed. In January 2022, ADA subsequently submitted the following recommendations to the FDA:

- ADA **supports** FDA's proposal to allow an output limit up to 120 dB OSPL90 for OTC hearing aids with input-controlled compression and user adjustable volume control.
- ADA **urges** the FDA to implement a general output limit for OTC hearing aids of 110 dB OSPL90 when the hearing aid *does not* include input-controlled compression and user adjustable volume control.
- ADA **supports** FDA's proposal to forgo gain limitations for OTC hearing aids.

---

[1] https://www.govinfo.gov/content/pkg/FR-2021-10-20/pdf/2021-22473.pdf
[2] https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf
[3] Hearing Health Care for Adults: Priorities for Improving Access and Affordability: https://www.nationalacademies.org/our-work/accessible-and-affordable-hearing-health-care-for-adults
[4] Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness, Consensus Paper from Hearing Care Associations, August 14, 2018. https://hearinghealthmatters.org/hearingnewswatch/2018/consensus-otc-hearing-aid-classification/

ADA continues to endorse several portions of the recommendations contained in the 2018 Consensus Paper's five major areas. However, after a renewed and objective review, ADA maintains strong concerns and no longer agrees with two specific recommendations.

ADA **does not** support the 2018 Consensus Paper recommendations regarding maximum gain and maximum output:

- The 2018 Consensus Paper working group recommended a high-frequency average full on gain (HFA-FOG) limit of 25 dB as defined for measurement in a 2cc coupler, with an input level of 50 dB SPL per ANSI standard S3.22-2014.
- The 2018 Consensus Paper working group recommended a peak (or maximum) 2cc coupler OSPL90, per ANSI S3.22-2014, not to exceed 110 dB SPL.

Furthermore, ADA remains committed to collaborating with other professional organizations to ensure that federal and state laws for OTC hearing aids are implemented responsibly, transparently, and in a manner that maximizes consumer access to audiology services.

II. THE TIMELINE

A multi-organization opinion paper, "Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness," was released in August 2018 (2018 Consensus Paper). This 2018 Consensus Paper is a 35-page document from three associations representing audiologists (ADA, the American Academy of Audiology (AAA), and the American Speech-Language-Hearing Association (ASHA)), and one association representing hearing instrument specialists, the International Hearing Society (IHS). While the hearing aid industry trade association, Hearing Industries Association (HIA) was not credited with authorship, several employees of their member companies (i.e., industry personnel) were included in the 2018 Consensus Paper working group and HIA immediately endorsed the paper upon release.

Throughout the development of the 2018 Consensus Paper, there was strong debate among participating organizations regarding recommendations for maximum sound pressure level (SPL) output and gain. Despite best efforts to align on assumptions, evidence, and a rationale supporting one recommendation or another, in the end, every organization, including ADA, made concessions to arrive at the 110 dB SPL (output) and 25 dB (gain) recommendations.

The 2018 Consensus Paper had five key recommendations to the FDA regarding OTC hearing aids:

1. Establish product requirements appropriate for OTC hearing devices targeting mild-to-moderate hearing impairment.
2. Define concise, out-of-the box labeling appropriate for OTC, with strong recommendation to consult with a hearing health care professional.
3. Define comprehensive, inside-the-box labeling appropriate for over-the-counter medical devices.
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.
5. Adequate provisions for consumer protection, in coordination with the Federal Trade Commission (FTC).

ADA was pleased that the FDA addressed all five areas in the 2021 OTC Hearing Aid Proposed Rule.

The 2018 Consensus Paper provided a valuable "strawman" framework for regulators to consider as they implement the OTC Hearing Aid Act (a subsection of FDARA, the FDA Reauthorization Act of 2017). The conclusions drawn, however, were simply an amalgamation of the positions and opinions supported by selected evidence put forward by the authoring organizations and other stakeholders, including the Hearing Industries Association (HIA), and should not be confused with or portrayed as a peer-reviewed research publication.

Following the release of the FDA OTC Hearing Aid Proposed Rule in October 2021, ADA convened an internal task force for the purpose of evaluating whether the Proposed Rule meets the statutory requirements outlined in FDARA and supports evidence-based practices, professional autonomy, consumer access, and competition.

During this process, the ADA OTC task force conducted a comprehensive literary review of scientific presentations, research articles, the PCAST report, the NASEM report, FDA regulations, ANSI standards, and the 2018 Consensus Paper to assess the Proposed Rule provisions for technical and performance standards for OTC hearing aids.

In a meeting of representatives from AAA, ADA, ASHA, IHS, HIA, and the American Academy of Otolaryngology-Head Neck Surgery (AAO-HNS), and the Hearing Loss Association of America (HLAA) (2021, December 2), the question was put forward to all organizations as to whether all organizations would use the 2018 Consensus Paper as an agreed-upon starting point for harmonizing comments on the FDA OTC Hearing Aid Proposed Rule. At that time, ADA notified the other organizations that ADA was not prepared to do so without first completing the full review by its own task force.

Following the completion of the work by the ADA task force, ADA held a member town hall webinar (2022, January 12) on "Analysis of FDA Proposed OTC HA Rule." Here, ADA presented a scientifically supported response to the request from the FDA for comments on the proposed rule, including some positions that differed from the 2018 Consensus Paper.

Specifically, ADA **does not support** the 2018 Consensus Paper recommendations regarding maximum gain and maximum output.

- The 2018 Consensus Paper working group recommended a high frequency average full-on gain (HFA-FOG) limit of 25 dB as defined for measurement in a 2cc coupler, with an input level of 50 dB SPL per ANSI standard S3.22-2014.
- The 2018 Consensus Paper working group recommended a peak (or maximum) 2cc coupler OSPL90, per ANSI S3.22-2014, not to exceed 110 dB SPL.

After a thorough review of the science related to electroacoustic performance, ADA concluded that the original methodologies used to justify the 25 dB gain limit and the 110 dB output limit in the 2018 Consensus Paper was incomplete. In January 2022, ADA submitted the following recommendations to the FDA:

- ADA **supports** FDA's proposal to allow an output limit up to 120 dB OSPL90 for OTC hearing aids with input-controlled compression and user adjustable volume control.
- ADA **urges** the FDA to implement a general output limit for OTC hearing aids of 110 dB OSPL90 where the hearing aid *does not* include input-controlled compression and user adjustable volume control.
- ADA **supports** FDA's proposal to forgo gain limitations for OTC hearing aids and notes that this was not a statutory requirement under FDARA.

Following the member town hall webinar, ADA received immediate and strong written (2022, January 14, *enclosed*) and oral (2022, January 17) criticism from representatives of the hearing aid industry regarding ADA's revised position on the 2018 Consensus Paper. In the January 17, 2022, virtual meeting with industry representatives, in which multiple issues were discussed, it was explained by the industry representatives that ADA's continued endorsement of the 2018 Consensus Paper recommendations (with lower limits on gain and output) was important to support the "traditional hearing aid business to … remain the traditional hearing aid business." ADA views the Over-the-Counter Hearing Aid Act of 2017 as an opportunity to improve on the traditional hearing aid business and ADA supports new methods to increase access to hearing care services and affordability of hearing devices.

III. THE DETAILS

ADA diverges from the 2018 Consensus Paper on the gain and output recommendations as follows:

Comments on "Definition of intended users for OTC hearing devices" (pp 4-7 of the 2018 Consensus Paper):

- The OTC Hearing Aid Act of 2017 covers hearing devices "intended to be used by adults aged 18 and older to compensate for perceived mild to moderate hearing impairment" (page 4). The 2018 Consensus Paper states that "older individuals tend to underestimate their hearing loss" (page 6). The combination of these two statements is that a person with a perceived mild-to-moderate hearing loss may also be in the audiometry confirmed category of what many, but not all, American audiologists would term "moderately-severe hearing" loss of up to 70 dB HL. This issue is addressed in the section "Unintended but foreseeable users" (page 7) where it is stated "Considering that this will be sold over-the-counter, this group may include adults who perceive they … have a more severe hearing impairment (56 dB HL or higher)." ADA agrees that these are foreseeable users but disagrees that these are unintended users. The legislation expressly states that the devices are for user-perception of mild-to-moderate hearing loss and does not state the devices are for users with ≤ 55 dB HL hearing loss.
- A second point is whether to use any concrete number, or what number, for degree of hearing loss, when intended users have "perceived" hearing loss. The selection of a flat 55 dB HL hearing loss (page 5) as the designation of maximum degree of hearing loss that is applicable for OTC hearing aids is controversial, as many audiologists, organizations, hearing aid and cochlear implant manufacturers categorize moderate hearing loss up to 60 dB HL or 70 dB HL. This conversation was further complicated when the FDA, in their 2021, December 7 webinar on OTC hearing aids, displayed an audiogram categorizing moderate hearing loss up to 70 dB HL. Selecting 70 dB HL hearing thresholds as the limit of "moderate" hearing sensitivity are consistent with a global view of "moderate" hearing loss but are inconsistent with some US-oriented audiometry classification systems where hearing threshold responses consistent with of 56 – 70 dB HL are referred to as "moderately-severe."

In summary, ADA does not propose that *perceived* mild-to-moderate hearing loss be defined as 55 dB HL, 60 dB HL, 70 dB HL, or indeed any audiometry-confirmed level. ADA submits that using any audiometry-defined limit moves away from "perceived" as an inseparable part of the candidacy criteria and is inconsistent with the congressional intent of the legislation. A generalized definition that promotes discussions on gain and output limits would lead to flexible recommendations, and ADA believes this would be consistent with the Congressional intent of the OTC Hearing Aid Act of 2017.

Comments on "Gain requirements" (pp 7-11)

- ADA has objections to the underlying assumptions used to determine the maximum gain limits for a 55 dB HL hearing loss. The assumptions include binaural usage by new users to amplification as one example (page 9). These assumptions exclude monaural users, experienced users, and users with any type of hearing loss other than sensorineural. These exclusions are highly questionable as the assumptions could have easily included monaural, experienced users, and users who may have mixed or conductive hearing loss that does not require medical intervention.

  The real-world impact of the modeling decisions of 55 dB HL hearing loss and only binaural, new users with sensorineural hearing loss is an inappropriate limitation on the maximum permissible gain limit to 25 dB HFA FOG for OTC hearing aid fittings, thereby reducing the number of potential users with hearing impairment who would benefit from an OTC device. An example of the consequences of these exclusionary assumptions can be seen in Table 1 (page 9), where a monaural, experienced hearing aid user with 55 dB HL thresholds is prescribed 30.1 dB HFA FOG using the National Acoustic Laboratories, Non-Linear Revision 2 prescriptive fitting rationale (NAL-NL2),[5] the most common method of fitting prescription hearing aids in the United States.

  If the 25 dB HFA FOG recommendation is implemented by the FDA, this individual with a moderate, sensorineural hearing loss would only be able to have their amplification needs met with a prescription hearing aid. This is a clear example of where the 2018 Consensus Paper does not meet the congressional intent of the OTC Hearing Aid Act of 2017 by conflating concerns over safety with a demonstrable impact on effectiveness.

- ADA further considered the algorithmic analysis referenced in the 2018 Consensus Paper regarding a mathematical model using the NAL-NL2 prescriptive use-gain target. The use-gain targets were translated into a 2cc coupler HFA FOG values, serving as the proxy for a maximum gain limit. This procedure ignores the clinical mandate that hearing aids are not to be fit or worn at the maximum setting, or full-on gain (FOG).

  Hearing aids should be fit to user gain targets and have reserve gain available so the device user can increase the volume (gain) when they desire to hear sounds of low intensity (soft sounds). A typical amount of reserve gain in hearing aid fittings is greater than or equal to 5 dB but less than or equal to 10 dB. The lack of accounting for reserve gain means that the effective performance limit of these devices will be less than or equal to 20 dB HFA FOG, not the intended 25 dB HFA FOG. Devices with usable gain of less than or equal to 20 dB are appropriate for persons with mild hearing loss and will meet the needs of some, but not all, individuals with moderate hearing loss. This is another clear example of where the 2018 Consensus Paper does not meet the Congressional intent of the OTC Hearing Aid Act of 2017.

In summary, ADA does not support the 2018 Consensus Paper use of exclusion criteria, based on assumptions from most-common device usage for determining a gain limit. Instead, ADA supports using an inclusion criterion that would account for all intended device usage. As such, ADA supports FDA taking a more flexible position insofar as gain limitations may negatively impact competition and innovation for new OTC devices. A low gain limit, as was recommended in the 2018 Consensus Paper, would reduce

[5] Keidser, G., Dillon, H., Flax, M., Ching, T., & Brewer, S. (2011). The NAL-NL2 prescription procedure. *Audiology Research*, *1*(1), e24. https://doi.org/10.3390/audiores.2011.25

device effectiveness for the large population of individuals who could benefit from OTC devices, is not a statutory requirement under FDARA, and is inconsistent with the Congressional intent of the Over-the-Counter Hearing Aid Act of 2017.

Comments on "Maximum Power Output Limitation" (pp 11-17)

- ADA maintains the 2018 consensus document misconstrues the relationship between the maximum output for any single pure tone and that for a broadband signal. In the 2018 Consensus Paper, it was written (pp. 15-16):

  > *"… 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 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."*

  ADA maintains this passage is incorrect and reflects a misunderstanding of the relation between the maximum output for any single tone and that for a broadband signal. Broadband signals can be output from the hearing aid only at average (e.g., root-mean-square or RMS) levels that will be well below the OSPL90 value. Even if care is not taken to prevent peak clipping distortion, output from the hearing aid will still not exceed OSPL90.

- ADA maintains the 2018 Consensus Paper misinterprets and misapplies the information from the Johnson (2017) paper[6] used to justify an unnecessarily low maximum output level in OTC hearing aids. The 2018 Consensus Paper rationale for the 110 OSPL90 limit is as follows:

  > *"Johnson estimated limit standards to determine the safe output sound pressure level (SPL) for sound amplification devices to preserve hearing sensitivity after amplification usage. 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 threshold with flat 55 dB configuration, a safe overall output SPL would be no greater than 111 dB." (page 13)*
  >
  > *"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." (page 15)*
  >
  > *"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*

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

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 users 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." (page 16)*

The 2018 Consensus Paper refers to Table 1 (page 834) in the Johnson paper where 4FA threshold values from 0 to 120 dB HL correspond to safe output SPL (overall dB) values from 90 to 136 dB (RMS). The 2018 Consensus Paper identifies that a person with hypothetical hearing sensitivity of 55 dB HL corresponds to 111 dB of prescribed device output and concludes from this data that the 110 OSPL90 value is the maximum safe output level. ADA contends that the two values [111 dB from Johnson (2017) and 110 dB OSPL90 from the 2018 Consensus Paper] are fundamentally different and any attempt to make a direct comparison is inconsistent with a correct application of the mathematics of acoustics. The 111 dB value is dB (RMS) for average speech level in the ear canal whereas the 110 dB value is for peak pure tone output level in the 2cc coupler at the single frequency of greatest intensity. This is a misleading comparison that ADA seeks to clarify in diverging from the 2018 Consensus Paper.

- ADA has another criticism of the 2018 Consensus Paper justifying the 110 dB OPL90 value from the Johnson paper. In the Introduction to his paper, Johnson writes "MPO levels have two basic uses. One use is to limit the amount of intermittent, short duration sounds to levels below those that are uncomfortable for the wearer. The other purpose is to limit the amount of amplification to higher level inputs occurring more consistently over a long duration (e.g., ≥ 8 hours). This second use was the perspective taken by the study." [7, 8, 9] (page 830)

  First, Johnson's line of reasoning is endorsed in the 2018 Consensus Paper (page 13).

  > *"The proper adjustment of maximum output is the critical parameter that serves the purpose to limit the output of:*
  > - *Intermittent, short duration sounds, to levels that are neither damaging nor uncomfortable to the wearer, and*
  > - *Overamplification of higher level inputs occurring more consistently over a longer duration (e.g. over six-eight hours)."*

To determine a hypothetical peak SPL value (appropriate to create an OSPL90 value), both the first point (intermittent, short duration sounds) and the second point (long duration sounds) must be considered. The 111 dB SPL (RMS) is only the long duration value for speech. Johnson addresses this issue and cautions that "The safe output SPL in Table 1 are RMS levels so that peak levels 15 dB higher could be allowed to preserve the sound quality of incoming speech inputs so as not to clip the speech and perhaps allow higher peak levels for other inputs like music." This second factor discussed by Johnson (2017) is

[7] The Occupational Safety Health Administration (OSHA) and National Institute for Occupational Safety & Health (NIOSH) limits for exposure are applicable only to industrial noise in a sound field for age-adjusted normal hearing persons. For these occupational standards to be applicable to hearing aids, in-ear (ear drum referenced) levels would have to be diffuse field referred and then adjusted for the hearing loss.

[8] https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.95

[9] https://www.cdc.gov/niosh/docs/98-126/pdfs/98-126.pdf?id=10.26616/NIOSHPUB98126

not considered in the 2018 Consensus Paper. If it had been, the result would have been far above 110 and closer to 120 dB.

It is important to point out that the FDA recommended maximum output limit of 120 dB SPL in the 2cc coupler, using a pure tone (the OSPL90), does not mean this level will be presented to the OTC hearing aid user in the ear for complex signals. Real-world signals are dynamic, unlike steady tones. Speech at a constant level has a crest factor (dB ratio of instantaneous peak to RMS level) of about 15 versus that of 3 dB for a tone.[10] Music often has crest factors that are even higher.[11] These crest factors of speech and music, when compared to that of a tone, correspondingly decrease the highest output level that these signals can be played without distortion (from clipping) and negatively affecting sound quality. Therefore, due to the frequency dependence of OSPL90 and the above crest factors, an OSPL90 limit of 120 dB SPL will allow actual speech (and music) to be played only up to approximately 105 dB SPL, with some variability depending on specific compression settings and prescriptive algorithm selection. The proposed 120 dB OSPL90 limit is needed to ensure there is adequate dynamic range headroom for undistorted output of short-term peaks in speech and music.

In summary, on the issue of maximum output power limitation, ADA does not support several statements, assumptions, and rationales that led to a recommendation for a hard limit of 110 dB OSPL90 for OTC hearing aids. ADA supports the more flexible FDA position with an allowance of 120 dB OSPL90 to promote device efficacy including sound fidelity, when combined with user-controlled methods to lower device output, promoting device safety.

IV. CONCLUDING COMMENT

ADA has been heavily criticized for changing its position regarding key recommendations contained in the collaborative 2018 Consensus Paper. ADA must, however, prioritize accuracy over unity. Promoting and advancing the autonomous practice of audiology, guided by evidence-based practices, requires an adherence to scientific principles that withstands social pressure. A regulatory framework, built upon independently verifiable scientific methods and the earnest application of the evidence found, will deliver accessible, affordable, effective, and safe OTC hearing aids to consumers with hearing loss. ADA welcomes constructive discussion on this issue and maintains that the best way to advance the profession of audiology is by prioritizing the needs of those we serve.

Enclosure: January 14, 2022 Letter from Hearing Industry Representative to ADA

[10] American National Standards Institute (2020). ANSI S3.5-1997 (R2020). *Methods for the Calculation of the Speech Intelligibility Index.* New York: Acoustical Society of America.
[11] Chasin, M. (2003). Music and hearing aids. *The Hearing Journal, 56*(7), 36-41.

January 14, 2022

Stephanie Czuhajewski, MPH, Executive Director
Kristin Davis, Au.D., President
Victor Bray, Ph.D, Immediate Past President
Academy of Doctors of Audiology
1024 Capital Center Drive, Suite 205
Frankfort, Kentucky 40601

RE: OTC Hearing Aid Policy Recommendations Under Consideration by ADA

Dear ADA Leadership:

On January 12, 2022, the Academy of Doctors of Audiology (ADA) hosted a members-only meeting where leaders of ADA discussed the U.S. Food and Drug Administration's (FDA) proposed rule establishing over-the-counter (OTC) hearing aids as a new category of medical devices that will soon be available for adults with mild to moderate hearing loss. During this meeting, ADA leaders presented the policy recommendations under consideration by the organization with respect to the FDA's proposed rule. ADA leaders requested feedback on the information and recommendations presented.

As audiologists with significant academic, clinical, and industry experience, it is our collective belief that ADA's recommendations with respect to certain aspects of the FDA's proposed rule would significantly compromise patient safety and efficacy of OTC hearing aids. We are surprised by ADA's eleventh-hour change and disappointed by certain recommendations now under consideration. ADA's proposed recommendations, in many respects, completely contradict the organization's historical position on this important topic, as well as are so vastly out of alignment with other leading audiology associations, including the American Academy of Audiology (AAA) and American Speech-Language-Hearing Association (ASHA).

We believe it is important to call attention to the fact that ADA joined AAA, ASHA, and the International Hearing Society (IHS) in co-authoring a consensus white paper entitled "Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness." The recommendations contained within this consensus paper were developed by leaders from each of the organizations, including clinical hearing experts, auditory scientists, and educators, who all came together to develop a regulatory framework that was offered to the FDA in 2018 to ensure the safety and effectiveness of OTC hearing aids. These recommendations have been endorsed by leading medical experts, as well as a vast number of consumer, industry, and patient advocacy stakeholders, as well as nearly every single hearing care professional who has submitted comments to the FDA on this topic. In addition, these recommendations are supported by many members of Congress. Yet, despite ADA's longstanding position, and the overwhelming support for the consensus recommendations, ADA now seeks to change course.

It is for these reasons, as a group of audiologists who care deeply about the advancement of our profession and the safety of those future users of OTC hearing aids, we feel inclined to provide you with our feedback and urge ADA to reconsider its position regarding certain

recommendations. Specifically, we write to express our strong, collective opposition to the following:

1. **Expanding the Scope of Mild to Moderate Hearing Loss Beyond any Recognized Definition in the World.**

As the foundation for its positional shift, ADA explained that it was relying on the assumption that the FDA considers moderate hearing impairment to include hearing loss between 40 and 70 decibels. This assumption is deeply flawed. The FDA has neither defined in regulation nor issued guidance indicating that it classifies moderate hearing loss as including up to 70 decibels. Importantly, ADA's original recommendation, as stated in the consensus paper, was that the FDA should define moderate hearing loss as between 41 and 55 decibels, consistent with the most predominantly used hearing loss threshold standard in the United States. Moreover, classifying moderate hearing loss as up to 70 dB would violate the two most widely recognized and used hearing loss threshold standards throughout the world. Specifically, ADA's recommendation would violate the standards used by ASHA (which defines moderate hearing loss as between 41 and 55 decibels) and the World Health Organization (which defines moderate hearing loss as between 35 and 49.9 decibels). We urge ADA to support the original recommendations included in the consensus paper.

2. **Supporting an Output Limit that Risks the Safety and Wellbeing of Consumers.**

ADA is considering taking the position that user-adjustable volume control and input-controlled compression can mitigate the safety risk of OTC hearing aids that have a maximum output limit up to 120 decibels. We wholeheartedly disagree. Amplification at this level can lead to temporary and permanent auditory system injuries in as little as 28 seconds, a fact that is recognized by the Centers for Disease Control and Prevention and National Institute for Occupational Safety and Health. ADA's suggestion that an output limit of 120 decibels would be safe for OTC hearing aids is deeply troubling, particularly given the fact that these devices will largely be purchased by consumers who do not consult with or seek help from a trained hearing care professional. ADA's position relies on the assumption that all OTC hearing aid users will be able to react in an immediate manner to excessively loud or uncomfortable sounds. Many OTC hearing aid users will be older individuals who suffer from other medical conditions that limit their ability to react. In this regard, we would draw ADA's attention to comments submitted to the FDA by Dr. Anil Lalwani, Professor and Vice Chair for Research, Department of Otolaryngology at Columbia University Irving Medical Center who stated that "hearing aid users are typically older individuals who may have reduced dexterity, coordination, and reaction times. As a result, hearing aid users may have difficulty responding while in pain and removing their devices in short order. Assuming that all users will be able to do so within 28 seconds…is an assumption that could significantly harm users of OTC hearing aids." We urge ADA to support its original position that all OTC hearing be limited to having a maximum output of 110 dB SPL.

3. Supporting the Lack of a Gain Requirement.

ADA is considering taking the position that evidence exists to support FDA's omission of a gain requirement despite previously indicating in the consensus paper that establishing such a requirement was necessary to ensure safety and effectiveness. We are not aware of any evidence to support ADA's position in this regard. In fact, as highlighted in comments submitted to the FDA by AAA and ASHA, establishing a gain 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." By omitting any limit on gain in a hearing aid, users will be at greater risk of being exposed to prolonged exposure of excessively high levels of sounds, particularly in such a scenario where the maximum output level of the device is too high. Moreover, gain plays a critical role in controlling the sound intensity of a particular device ensuring its effectiveness for a particular user. We urge ADA to support its original position that establishment of 25 decibel gain limit, as recommended in the consensus paper, is necessary to ensure the safety and effectiveness of OTC hearing aids.

In conclusion, given ADA's role as a national professional association whose mission is "dedicated to the advancement of practitioner excellence, high ethical standards, professional autonomy and sound business practices in the provision of quality audiologic care," we strongly encourage the organization to reconsider its position with respect to the above recommendations. At the end of the day, the most important role we can play as hearing care professionals is to ensure the safety and well-being of our patients. To do so, we believe ADA should continue supporting its original recommendations contained within the consensus paper.

Sincerely,

Douglas L. Beck Au.D.
Vice President of Academic Sciences
Oticon, Inc.

Eric Branda, Au.D., Ph.D.
Director of Applied Audiological Research
WS Audiology

Laurel A. Christensen, Ph.D.
Chief Audiology Officer
GN Hearing

Dave A. Fabry, Ph.D.
Chief Innovation Officer
Starkey

Christine Jones, Au.D.
Vice President of Audiology
Sonova Group

Thomas A. Powers, Ph.D.
Managing Member
Powers Consulting
*ADA Member

Thomas Tedeschi, Au.D., FNAP
Chief Audiology Officer
Amplifon Americas
*ADA Member