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**SUBMITTED ELECTRONICALLY**

Division of Dockets Management  
U.S. Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20857

**Re: Docket No. 2021-N-0555—*Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids; Proposed Rule*, 86 Fed. Reg. 58,150 (Oct. 20, 2021).**

The Hearing Industries Association (“HIA”) is pleased to submit these comments in response to the Notice of Proposed Rulemaking (“NPRM”) published in the Federal Register by the U.S. Food and Drug Administration (“FDA”) on October 20, 2021, implementing section 709 of the Food and Drug Reauthorization Act of 2017 (“FDARA”). In FDARA § 709, Congress established the definition of an Over-the-counter (“OTC”) hearing aid and directed FDA to adopt governing regulations for those products that would “provide reasonable assurances of the safety and effectiveness of [OTC] hearing aids,” including technical, regulatory, and labeling specifications. FDRARA, Pub. L. 115-52 § 709, 131 Stat. 1005, 1067 (Aug. 18, 2017). In this NPRM, FDA fulfills that directive by proposing to adopt 21 C.F.R. § 800.30, Over-the-Counter Hearing Aid Controls, specifying the requirements for a hearing aid to be made available without the involvement of a hearing health professional, as well as revising and conforming existing hearing aid regulations accordingly.

HIA was formed in 1955 and serves as a forum for hearing aid manufacturers, suppliers, distributors, and hearing health professionals. Our members consist of 13 companies representing approximately 30 hearing aid brands that constitute over 90 percent of the hearing aids sold in the United States on an annual basis. As the national trade association of manufacturers of hearing aids, assistive listening devices, component parts, power sources, and hearing health professionals, HIA has a considerable interest in this issue.

HIA supports the endeavor to reduce the barriers to access hearing loss treatment and appreciates the careful consideration that FDA has demonstrated in the crafting of these proposed rules. Nevertheless, HIA recommends that some of the proposals should be revised to better address the risks involved with hearing aid use absent guidance from a hearing health professional. As FDA itself repeatedly recognizes in the NPRM, it is critical that the proposed rules adequately balance accessibility and affordability of hearing aids with safety and effectiveness considerations. 86 Fed. Reg. 58,150, 58,152 (Oct. 20, 2021) (“We intend these proposals to provide for reasonable assurance of safety and effectiveness for these devices and improve access to and foster innovation in hearing aid technology for Americans, thereby promoting and protecting the public health.”). Hearing aids are, after all, medical devices

intended to treat a medical condition, and they present both benefits and risks that must be balanced. HIA believes that the best way to accomplish this is to ensure the continued application of FDA regulatory oversight to hearing aids—OTC or otherwise—and that regulatory controls maintain the safety and effectiveness of these devices while promoting broader access. With that in mind, HIA provides the following comments on FDA’s proposal.

## I. Background of Hearing Aid Landscape

As both FDA and HIA’s members know well, hearing loss is a widespread medical condition affecting one in ten Americans. It is a common corollary to aging, but the impact of untreated hearing loss for patients of all ages can be serious. Indeed, scientific literature demonstrates that untreated hearing loss is associated with social isolation, loss of independence, depression, anxiety, dementia, tinnitus, increased risk of falls, and physical, anatomic, and physiologic brain changes.<sup>1</sup> 86 Fed. Reg. 58,150, 58,152 (Oct. 20, 2021). Consequently, treatment of hearing loss is important to help protect the public health, particularly as hearing loss often affects some of the most vulnerable patient populations.<sup>2</sup> It is no wonder, therefore, that Congress set out to address the hearing loss “epidemic.”<sup>3</sup> As hearing aids are the treatment of choice for the vast majority of adults with hearing loss, Congress’s emphasis on reducing barriers to access is logical. Nevertheless, HIA emphasizes that ensuring the safety and efficacy of hearing aids is as important as affordability and access; allowing patients to buy unsafe or ineffective hearing aids does not advance public well-being, and indeed presents new and significant risks.

Currently, air-conduction hearing aids are classified as Class I devices, the lowest risk classification, and those that incorporate wireless or bone conduction features are classified as Class II, or moderate risk devices. Class II devices require greater regulatory controls to provide reasonable assurance of safety and effectiveness.<sup>4</sup> More than 90 percent of hearing aids sold in the United States in 2020 contained wireless features and were therefore categorized as Class II devices. Wireless hearing aids are exempt from premarket notification requirements (“510(k)’’); they are, however, restricted devices under section 520(e) of the Federal Food, Drug, and Cosmetic Act (“FDC Act”) that require a medical evaluation or a waiver for purchase. In addition hearing aid with tinnitus features are also classified as Class II devices.

Exercising enforcement discretion, FDA has not, since 2016, required medical evaluation to purchase a hearing aid,<sup>5</sup> but all hearing aids remained prescription devices—legally available only from a hearing health professional—until 2018. In 2018, pursuant to a De Novo Request

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<sup>1</sup> See also Seniors Research Group, *The Consequences of Untreated Hearing Loss in Older Persons*, Nat’l Council on the Aging (May 1999); Stag Arlinger, *Negative Consequences of Uncorrected Hearing Loss—A Review*, 42 Int’l J. of Audiology 2S17 (July 2003); National Academy of Sciences, Engineering, and Medicine, Hearing Health Care for Adults, at 273-74 (“NASEM Report”) (2016).

<sup>2</sup> World Health Organization (WHO), World Report on Hearing at 144, <https://www.who.int/publications/item/world-report-on-hearing> (2021).

<sup>3</sup> Jo A. Jenkins, Listen Up!, AARP Advocacy, <https://www.aarp.org/politics-society/advocacy/info-2018/hearing-loss-epidemic.html> (Apr. 27, 2018).

<sup>4</sup> 21 U.S.C. § 360c(B).

<sup>5</sup> FDA, Guidance for Industry: Immediately In Effect Guidance Document: Conditions for Sale for Air Conduction Hearing Aids (Dec. 12, 2016).

submitted by Bose Corporation, FDA classified a new category of “self-fitting” hearing aid, available without assistance from a hearing health professional, as a Class II medical device that requires the submission of a 510(k). FDA’s imposition of the 510(k) requirement for self-fitting hearing aids makes sense; while traditional hearing aids are available only through a learned intermediary (a licensed professional)—who helps ensure that a selected hearing device is both safe and appropriate for a given individual—self-fitting hearing aids require untrained patients to evaluate, select, fit, and program the self-fitting hearing aid without such assistance. FDA review of the self-fitting hearing aid 510(k) helps to ensure both that the proposed product is safe and effective, and that the patient can use it without help. FDA’s review, in other words, helps to ensure that the hearing aids can be used safely and effectively without the intervention of a licensed hearing health professional.

All hearing aids, self-fitting or otherwise, remain subject to the Quality System Regulations (“QSRs”), as well as other general controls, such as establishment registration, device listing, labeling, reporting, and correction and removal notification requirements. FDA regulations also require all medical device labeling or promotion to avoid false or misleading claims, whether overt, implied, or by omission. Further, hearing aids are subject to various state requirements, typically imposed through professional state licensing requirements for the distribution, fitting, programming, or sale of hearing aids.

On October 20, 2021, FDA issued its NPRM proposing the establishment of the category of OTC hearing aids for the treatment of adults with perceived mild and moderate hearing loss and related controls pursuant to section 709 of FDARA. 86 Fed. Reg. 58,150 (Oct. 20, 2021). The NPRM defines OTC hearing aids, in brief, as any air-conduction hearing aid that, through tools, tests, or software, allows the user to control and customize the hearing aid to a patient’s needs and is available without the supervision, prescription, or other involvement of a licensed person.<sup>6</sup> 86 Fed. Reg. at 58,177. FDA also consolidates all legacy, wireless, and self-fitting hearing aids under the same regulation—21 C.F.R. § 874.3305. 86 Fed. Reg. at 58,190. Importantly, FDA has determined that not all OTC hearing aids are “self-fitting” and thus not all OTC hearing aids must comply with the special controls FDA established in 2018 for self-fitting hearing aids to be sold and used without the assistance of a licensed professional; OTC hearing aids that are not self-fitting may be marketed without FDA premarket review.

Under the proposed regulatory scheme, OTC hearing aids must comply with controls set forth in proposed 21 C.F.R. § 800.30, which include specific labeling requirements, technical specifications, and regulatory controls. 86 Fed. Reg. at 58,177. While the NPRM suggests that a 510(k) may be necessary for OTC hearing aids should they exceed the limit of the 510(k) exemption for air-conduction hearing aids, *see* 86 Fed. Reg. at 58,172, it stops short of requiring a 510(k) generally for all OTC hearing aids; the 510(k) requirement only applies to hearing aids that are self-fitting. The NPRM also proposes to adopt QSRs and technical specifications for OTC hearing devices, but FDA asks for comments on the application of or modification to QSRs for OTC hearing aids, the physical fit of hearing aids with respect to maximum insertion depth, and conditions for sale to prevent sales of hearing aids to persons younger than 18 years old. *See* 86 Fed. Reg. at 58,165, 58,166. FDA additionally outlines new labeling requirements for

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<sup>6</sup> A licensed person may nevertheless “service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.” 86 Fed. Reg. at 58,183.

prescription hearing devices. 86 Fed. Reg. at 58,190.

In addition to an OTC hearing aid category, the NPRM, in accordance with FDARA, preempts certain state laws that “would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of [OTC] hearing aids.” FDARA § 709(b)(4). FDA has proposed implementing the preemption provision so that any state or local law interfering with commercial activity related to OTC hearing aids is preempted, but state licensing requirements remain in place with respect to prescription hearing aids. *Id.* at 58,166-67. Further, any seller of hearing aids that purports to be “licensed” must comply with all state licensing requirements even in the sale and distribution of OTC hearing aids. *Id.* at 58,167-68.

FDA proposes that the Final Rule will become effective 60 days after publication in the Federal Register. Hearing aids that currently are marketed legally will be required to come into compliance with the Final Rule within 180 days of the effective date. Hearing aids for which a new 510(k) is required or that have not been offered for sale prior to the effective date of the Final Rule must come into compliance with the Final Rule as of the effective date.

## **II. FDA Should Include Additional Measures to Ensure Safety and Effectiveness of OTC Hearing Aids.**

To implement Congress’s directive that FDA establish the OTC hearing aid category, the NPRM proposes to reduce the regulatory requirements pertaining to hearing aids. While HIA recognizes that this proposal may meaningfully reduce barriers to hearing aid access, we caution that the proposed rule, in its current form, also has the effect of reducing regulatory assurances of safety and effectiveness. The NPRM relies heavily on labeling to ensure patient safety and product effectiveness but does not cite data showing that the suite of proposed technical and labeling measures will result in the safe and effective use of OTC hearing aids in the intended use population; it is not clear that these measures will, in fact, protect patients from harm and misuse. Absent such data, absent premarket requirements to ensure safety and effectiveness, and absent intervention of a hearing health professional, it is unlikely that the regulatory scheme will achieve FDA’s intended objectives. Consequently, HIA is concerned that the labeling and design controls proposed to substitute for professional oversight do not adequately assure patient safety. HIA therefore urges the Agency to reconsider the regulatory, technical, and labeling controls set forth in 21 C.F.R. § 800.30.

As with every FDA regulated medical product, safety and effectiveness must be paramount. Patients will obtain no genuine benefit from easier access to hearing aids that are unsafe or ineffective. And, to increase access in a manner that achieves FDA’s and Congress’s objectives, patients need to be able to rely on design features and labeling to choose, and then safely and effectively use and maintain, OTC hearing products. Otherwise, accessible and affordable OTC hearing aids may be purchased but nonetheless relegated to the “dresser drawer.” 86 Fed. Reg. at 58,160 (“This is a common description of the phenomenon of relegating the device to disuse—putting it away, never to use it again—and foregoing the potential benefit of a more-satisfactory device”). Unsafe and ineffective hearing devices—or devices with inadequate design features and labeling and inappropriate acoustic characteristics—would likely contribute to the “dresser drawer” phenomenon, as patients would not actually use

the hearing device, and any investment would be rendered worthless, dissuading patients from trying again. Bad experiences with OTC hearing aids would *decrease* the rate of hearing aid utilization, which, of course, is contrary to congressional intent.

Thus, it is imperative that FDA ensure that OTC hearing aids are safe and effective prior to patient purchase. This is because, without a licensed hearing health professional protecting patients from “hearing aids” that may be inappropriate for them or used inappropriately by a given patient, patients have no option but to rely on FDA oversight. Consequently, FDA will be the patients’ last line of defense against hearing aids that cannot be used safely and effectively without assistance—in other words, to protect patients from unsafe, ineffective, and non-compliant “OTC” hearing devices—which raise serious financial and physical risks of harm to patients.

To that end, HIA recommends that FDA take steps to ensure the safety and effectiveness of hearing devices *before* they come to market. FDA can do that in several ways:

- 1) FDA should revise the NPRM definitions to provide more clarity, particularly with respect to the applicability of the self-fitting regulations;
- 2) FDA should clarify its requirements with respect to 510(k)s for non-self-fitting OTC hearing aids and make clear that all hearing aids coming to market as OTC must be submitted to FDA in a 510(k);
- 3) FDA should revise the proposed technological specifications to provide more protection for patients;
- 4) FDA should require compliance with QSRs to ensure that all manufacturers employ thoughtful, methodic, and compliant manufacturing practices; and
- 5) FDA should revise the mandated OTC product labeling to more clearly advise patients of appropriate selection and use of OTC hearing aids.

**a. The NPRM Definitions for OTC Controls Are Ambiguous and Vulnerable to Circumvention.**

At the outset, HIA urges FDA to adopt more precise definitions than those set forth in the NPRM. As demonstrated repeatedly since the adoption of 2017 OTC hearing aid legislation, some manufacturers will find and exploit regulatory ambiguity. This is illustrated by FDA’s tacitly authorized “direct-to-consumer” (DTC) category of hearing aids, which directly led to a plethora of companies unlawfully promoting “OTC” hearing aids. For this very reason, FDA in July 2018 was compelled to issue a letter to manufacturers stating that OTC hearing aids do not yet exist. As HIA advised FDA on multiple occasions, that letter failed to achieve compliance, which is why at least 17 Attorneys Generals issued statements in 2020 and 2021 to address the influx of so-called “OTC hearing aids.”<sup>7</sup> Lack of clarity regarding “DTC” hearing aids, coupled

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<sup>7</sup> Listen Carefully, Over-the-Counter (OTC) Hearing Aids: States Where AGs Are Taking Action, <https://www.listencarefully.org/over-the-counter>. On October 6, 2021, Michigan Attorney General Dana Nessel published a “Notice of Intended Action” (“Notice”) informing King Crawford Enterprises, LLC, doing business as

with a lack of enforcement, led to the introduction of numerous brands of OTC hearing aids that did not comply with regulatory requirements and instead were ineffective, of poor quality, and in some cases, dangerous.<sup>8</sup> Unless FDA establishes clear lines and then enforces them, this likely will happen again.

Because the definitions FDA chooses to adopt in the Final Rule dictate the controls applicable to hearing products and the regulatory requirements with which their manufacturers must comply, FDA, for the avoidance of any doubt, must be expressly clear in all facets of the rule. Thus, while HIA appreciates the definitions FDA provides in the NPRM, we suggest additional definitions that would strengthen the proposed rule.

### **i. Customization Terms**

It is clear from the NPRM that prescription hearing aids encompass all hearing aids that are not OTC hearing aids, and it is also clear that OTC hearing aids can be any air-conduction hearing aid for perceived mild to moderate hearing loss as long as that medical device includes “tools, tests, or software” to allow the user to “control or customize” the hearing aid, and as long as it is available without the intervention of a “licensed person.” Thus, the distinction between an OTC hearing aid and a prescription hearing aid is well-defined by exclusion: Prescription hearing aids are all hearing aids that are not OTC.

However, the critical distinction between OTC hearing aids and “self-fitting hearing aids”—a subset of OTC hearing aids—is not well-defined.

Under the NPRM, self-fitting hearing aids are subject to more stringent regulatory procedures than other OTC devices. These proposed differences in regulatory requirements will provide incentives to some manufacturers to avoid the “self-fitting” category, thereby reducing regulatory oversight. For that reason, some of the terms used to define the OTC hearing aid require clarification so that it is crystal clear whether a given hearing product is a “self-fitting” or is a “non-self-fitting” OTC product. Unless “self-fitting” is defined with enough rigor, hearing aids that do, in fact, require “self-fitting” will be sold as “non-self-fitting,” denying patients assurances that these self-fitting capabilities have been tested clinically and conform to the parameters, software analysis, and usability testing required only of self-fitting hearing aids. Inevitably, the blurred line between self-fitting and “non-self-fitting” would result in negative outcomes for patients purchasing hearing products that manufacturers deem “non-self-fitting” and therefore subject to a lower level of regulatory oversight than FDA has determined necessary

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Nano Hearing Aids, that its business practices violate both Michigan law governing unlawful business practices and the FDC Act. In the Notice, Attorney General Nessel explains that the Better Business Bureau has received *dozens* of complaints from patients with respect to Nano Hearing Aids within the last two years. These complaints include consumer protection related claims, such as the failure to comply with warranty and return requirements, as well as complaints specifically related to safety and effectiveness.

<sup>8</sup> See e.g. Press Release, AZ Attorney General’s Office, AG Brnovich Warns Consumers About Over-The-Counter Hearing Aids (Oct. 8, 2020); Press Release, OH Attorney General’s Office, AG Yost Issues Warning of Over-The-Counter Hearing Aids (May 3, 2021); Press Release, NV Attorney General’s Office, Attorney General Ford Cautions Consumers to Watch Out for Deceptive Sales Tactics Related to Over-the-Counter Hearing Aids (May 12, 2021).

to ensure safety and effectiveness.

As noted, the NPRM defines an OTC hearing aid as a device that “through tools, tests, or software, allows the user to control the hearing aid and customize it to the user’s hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss.” 86 Fed. Reg. at 58,177. “Tools, tests, and software” are further defined as “components of the device that, individually or in combination, allow a lay user to control the device and customize it sufficiently, such as the device’s output, to meet the user’s hearing needs.” *Id.* Neither “customize” nor the “user’s needs” are defined other than through the example of “the device’s output.”

While “tools, tests, and software” are apparently to be a part of *any* OTC hearing aid, it is not clear what types of tools, tests, and software would result in a hearing aid falling in the subset of a “self-fitting hearing aid.” A “self-fitting hearing aid,” both in the NPRM and under current 21 C.F.R. § 874.3325, is defined as “a wireless air-conduction hearing aid that incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fittings and settings.” *Id.* at 58,190. Thus, under these definitions, any OTC hearing aid—which, by definition, allows users to *control* and *customize* the hearing aid and can be wireless—that also allows users to “derive and customize” the hearing aid and has a “self-fitting” strategy is self-fitting. But the NPRM does not differentiate “control the device and customize it . . . to meet the user’s hearing needs” (OTC) from “independently derive and customize the hearing aid fittings and settings” (self-fitting). Nor does the NPRM define what a “self-fitting strategy” means. All of these terms overlap so much as to blur the line between an OTC hearing aid and an OTC self-fitting hearing aid. Clear definitions that expressly characterize this distinction are necessary to ensure regulatory clarity and promote regulatory compliance, thereby protecting patients.

FDA purposefully applied tighter controls on self-fitting hearing aids precisely because they are essential to protect the well-being of patients, but under the current scheme, those controls could be readily evaded. Absent definitions—or a clear, expressed distinction between “self-fitting” and “other” non-self-fitting hearing aids—a manufacturer selling a hearing aid with extensive customization capabilities could avoid a 510(k) by characterizing the hearing product as an OTC hearing aid and using the terms “control” or “customize” rather than “self-fitting” and “program.”<sup>9</sup> Marketing verbiage, or whether a manufacturer chooses to use certain words, should not dictate the safety and effectiveness requirements applicable to a hearing aid. Rather than nomenclature, the regulation classification should be based on the intended use derived from the inherent features of the hearing device as permitted under 21 C.F.R. § 801.4. And, if that is already what FDA intends—that the self-fitting category will apply broadly to most “customizable” products—that intent must be reflected in the rules to ensure that all of industry understands and adequately complies with its responsibilities and requirements, and to facilitate enforcement against companies that mischaracterize their hearing aids.

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<sup>9</sup> And indeed FDA already has experienced this in the Personal Sound Amplification Product (“PSAP”) market. A lack of precision in the definition of PSAP led to the promulgation of unregulated hearing aids with no FDA oversight, to the detriment of patients. NASEM Report, *supra* note 1, at 178-81.

Given that the regulatory distinction between OTC and self-fitting categories arises from these definitions, HIA proposes that the “Definitions” section of the OTC controls is the appropriate place to make such clarifications. There, HIA recommends that FDA clarify the distinction between self-fitting and other OTC hearing aids by defining the currently undefined term “self-fitting strategy.” HIA proposes that FDA draw the line between “self-fitting hearing aids” and “other” OTC hearing aids (or non-self-fitting hearing aids) at the availability of user interaction to customize the device to a specific hearing profile beyond volume or loudness control. A “self-fitting strategy” would be defined as “strategy for personalization of a device in accordance with a specific and individualized user profile or preference with respect to features other than loudness.” Under such a definition, a self-fitting hearing aid would be one that allows the user to interact with the hearing device or relies on machine learning or artificial intelligence to customize the device or user experience. A user might interact with the device and included software or tools to customize sound, apply hearing measurements, create defaults, parameterize, or change the number of types of programs or program assignments. Tone, frequency response, maximum output changes, application and features of sound processing capabilities, selection of default program from pre-programmed sound profiles, and assignment of functionalities to on board controls or actions would be hallmarks of the “self-fitting” category; the presence of any or all of these should be sufficient to place a hearing aid in the “self-fitting” category.

Conversely, “other” or “non-self-fitting” OTC hearing aids could be defined as using “tools, technology, and software” to allow volume or loudness adjustment or multiple preset programs or sound profiles as long as the available sound profiles remain the same for all patients upon removal from the box.<sup>10</sup> These hearing aids should be limited to 110 dB SPL maximum output, and FDA should provide examples in the Final Rule of the features that might be included in “non-self-fitting” OTC hearing aids, as well as examples of products that are marketed as “non-self-fitting” but, based on promotion and features, actually are “self-fitting.”

HIA also brings to FDA’s attention that some OTC hearing aids may include technology that would allow the hearing product to be classified as either a “non-self-fitting” or a “self-fitting” hearing aid, or to transcend categories, depending on how the specific version of the product is configured. For example, a hearing aid may be offered for sale only with preset programs but nonetheless contain “locked” self-fitting software limiting device features for “other” OTC sale. That hearing aid manufacturer might seek to evade a 510(k) by only offering limited customization but patients may be able to, on their own, unlock that hearing aid to access self-fitting features. FDA therefore must assess the application of these controls to products that could result in abuse of the non-self-fitting category.

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<sup>10</sup> HIA recognizes that the proposed distinction between presets and individualized profiles could allow a manufacturer to come to market with unlimited presets, providing a back door for companies to manufacture self-fitting hearing aids under the guise of non-self-fitting. However, HIA notes that FDA likely will be able to surmise both from the inordinate number of presets or from labeling and promotion—or from a combination of both—that such hearing aids are intended to treat unique hearing profiles. Thus, both the number of presets and the promotional materials will be relevant in assessing whether the hearing aid is self-fitting.

## ii. Mild to moderate hearing impairment

An OTC hearing aid is defined as “an air-conduction hearing aid that does not require implantation or other surgical intervention, and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment.” 86 Fed. Reg. at 58,177; *see also* FDARA § 709. However, the NPRM does not propose a definition of “mild to moderate hearing impairment.” While selection of the term “*perceived* mild to moderate” hearing impairment indicates that Congress intended that patients determine their own levels of hearing loss, it is important that manufacturers understand the parameters of that category and design their products accordingly. This can be done by linking subjective, perceived hearing loss to more objective, traditional measurements.

Numerous professional and health organizations, including the American Speech-Language-Hearing Association (“ASHA”)<sup>11</sup> and the World Health Organization (“WHO”),<sup>12</sup> provide similar definitions of “mild to moderate” degrees of loss, any of which could serve to establish the target population for OTC devices. Both ASHA and the WHO, for example, define mild (or “slight” in the WHO grading scale) as 26–40 dB HL; however, ASHA defines moderate as 41 to 55 dB HL while the WHO defines moderate as 41–50 dB HL. Conversely, FDA itself has, in some circumstances, referenced “moderate hearing loss” as encompassing as much as 70 dB HL.<sup>13</sup> The ambiguity in “mild to moderate” leaves the category open to wide interpretation. Given this ambiguity, OTC hearing aids from different manufacturers may be inadvertently designed to treat different patient populations. But of course, patients have no way of knowing this—or knowing which hearing aid is appropriate for their level of hearing loss—so it is important that all hearing aid manufacturers start from the same baseline.

The lack of a defined range for mild to moderate hearing loss raises concerns because the patient perception of hearing loss, which governs the appropriateness of an OTC hearing aid, can be an unreliable gauge of actual hearing loss.<sup>14</sup> Without a clear and well-understood definition of the intended user group for whom manufacturers should design products, there is significant risk that products marketed as OTC will not be safe and effective for patients with “perceived mild to moderate” hearing loss. It is foreseeable that a patient, for example, with 16 dB HL hearing loss—clinically normal hearing—*perceives* hearing loss and categorizes it as mild to moderate, but the OTC product that the patient selects is designed to address a mild to moderate category of 30 dB HL to 70 dB HL hearing loss. In other words, without an upper limit to the “mild to moderate” category, there is a risk of patients with *less than mild hearing loss* (though perceived mild) using a hearing aid intended for patients who may actually have *severe hearing*

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<sup>11</sup> American Speech-Language-Hearing Association (ASHA)- Degree of Hearing Loss, <https://www.asha.org/public/hearing/degree-of-hearing-loss/>

<sup>12</sup> Bolajoko O. Olusanya et al., Hearing loss grades and the International classification of functioning, disability and health, PMC, Bull World Health Organ.; 97(10): 725-728, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6796665/> (Oct. 1, 2019).

<sup>13</sup> In a 2012 presentation, for example, a scientific reviewer “in Audiology” defined “Moderate” hearing loss as “40-70 db.” Shu-Chen Peng, FDA Webinar, Hearing Aids: The Basic Information You Need to Know, <https://www.fda.gov/media/83390/download> (May 23, 2012), Eric Mann also used this range in a recent presentation. *See* Eric Mann, FDA, CDRH Webinar: Over-the-Counter (OTC) Hearing Aids Proposed Rule and Personal Sound Amplification Products (PSAPs) Draft Guidance, at slide 8 (Dec. 7, 2021).

<sup>14</sup> *See infra* Section II.c.ii.

loss depending on the scale the manufacturer uses to define “moderate.” Due to the real possibility of significant risks involved with using a hearing aid designed for more serious hearing loss, including increased hearing damage,<sup>15</sup> HIA suggests that FDA cap the upper-limit of the “moderate” hearing loss category at 50 dB - 55 dB HL. This would align with ASHA and WHO standards so that manufacturers appropriately design OTC hearing aids for patients only with hearing loss below these levels.

Again, HIA recognizes that the statute bases eligibility for OTC hearing aids on patient perception, but because patient perception is subjective and somewhat unreliable, HIA believes that FDA should adopt a “measured” mild to moderate standard—as an internal-industry correlate to “perceived” hearing loss—so that all manufacturers design for the same patient demographic.<sup>16</sup> This approach would facilitate matching actual hearing aid performance with patient needs so that all hearing aids would be safe for patients in the perceived mild hearing loss category and effective for patients in the perceived moderate. Further, based on this “measured” hearing loss definition, FDA could build a more specific profile of the presentation of hearing loss contemplated under the mild to moderate standard to provide more information to patients regarding the type of subjective symptoms that identify “perceived” mild to moderate hearing loss. A fixed standard may help to provide additional examples and more meaningfully articulate relevant factors to better inform patients in assessing their own hearing loss so they may ascertain whether they fit into the proper patient population for OTC hearing aids.<sup>17</sup>

### iii. Self-Assessment

As noted, the definition of “OTC hearing aid” provides for the use of “tests for self-assessment of hearing loss,” but such tests are not further defined. For example, an OTC hearing aid may “include tests for self-assessment,” but it is not clear whether standalone self-assessment kiosks or online tools are contemplated under the OTC hearing aid controls, or whether the term “includes” requires that such tools are integrated into the device itself to be considered a permissible “test for self-assessment” under the proposed regulation.

Because it is unclear what types of tests are contemplated—and in fact these tests could even implicate audiometers subject to 21 C.F.R. § 874.1050—and because self-assessment is so critical to the success of OTC hearing aids, HIA proposes that FDA include a definition of “tests for self-assessment,” indicating what type of tests are permissible for use in and with OTC hearing aids, in the OTC hearing aid controls regulation set forth in proposed 21 C.F.R. § 800.30. HIA suggests that “tests for self-assessment” is defined as **any test or procedure that can be shown to provide appropriate audibility to signals for the user** without limitation to tests that are integrated into the device itself as to ensure the wide availability of such tests. HIA also asks

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<sup>15</sup> See *infra* Section II.c.i.

<sup>16</sup> It’s important to note that, as discussed in “Technological Specifications” section, self-reported hearing loss is often inaccurate. While HIA recognizes that self-assessment is a critical element of the OTC hearing aid, steps must be taken to ensure that patients that have self-reported—but not clinical—hearing loss are not harmed by the use of OTC hearing aids. Thus, while there should be a minimum definition of hearing loss, the specifications for any OTC hearing aid should be tailored to the lowest levels of hearing loss to prevent developing worsened hearing loss. See *infra* Section II.c.i.

<sup>17</sup> Elements of “perceived” mild to moderate hearing impairment are discussed in the “Labeling” section in accordance with the NPRM. See *infra* Section II.e.

that FDA set forth any controls or regulations applicable to these products to ensure that they are adequate to advise patients of the suitability of an OTC hearing aid. HIA specifically requests that FDA clarify whether screening tests would be regulated as audiometers or subject to other controls, as well as the application of related controls to “smart phone apps” that provide the same features.<sup>18</sup>

**b. Premarket Notification Through a 510(k) is Necessary to Protect Patients.**

FDA emphasizes the need for hearing aids to be safe and effective throughout the NPRM, but as FDA itself has recognized, “while quality system compliance and enforcement is important for assuring device safety, it is not sufficient.”<sup>19</sup> Indeed, this is clear in light of the multiple companies that have thus far failed to comply with applicable provisions relating to hearing aids—companies for example selling hearing products as “PSAPs” but promoting them for hearing loss or as OTC hearing aids.<sup>20</sup> For this reason, HIA recommends that FDA require premarket notification (510(k)) for any (and all) OTC hearing aid, regardless of whether the hearing aid is self-fitting hearing. Absent an explicit requirement for 510(k)s, it is foreseeable that some companies will sell hearing aids that are not safe, not effective, or unsafe *and* ineffective.

FDA has proposed detailed specifications for OTC hearing aids, including extensive labeling requirements and technical requirements (discussed below), but the only way to ensure compliance with such requirements is through a combination of premarket review and enforcement. Enforcement, while necessary, is insufficient. History has demonstrated the limits of enforcement in assuring market safety, which often results in FDA prioritizing enforcement action only when patient injury has already occurred.<sup>21</sup> The Federal Trade Commission (“FTC”) explained in a 1977 report the pitfalls of this approach in the hearing aid industry, citing “the

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<sup>18</sup> FDA, in the Agency’s Mobile Medical Applications guidance, states that “[s]oftware functions that use tools within the mobile platform (e.g., speaker) to produce controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders (*i.e.*, an audiometer)” are not eligible for enforcement discretion as a Mobile Medical Application. FDA, Guidance for Industry: Policy for Device Software Functions and Mobile Medical Applications, at 25 (Sept. 27, 2019).

<sup>19</sup> FDA, Medical Device Safety Action Plan, Docket No. FDA-2018-N-1315 at 8, <https://www.fda.gov/media/112497/download> (Apr. 17, 2018).

<sup>20</sup> As explained by the Hearing Loss Association of America, while this NPRM was in development, “bad actors have stepped in to fill this vacuum and begun to advertise OTC hearing aids on television and on the internet, even though there are no products that can claim to be OTC hearing aids . . . .” Press Release, HLAA, HLAA’s Concern for Consumers Reaches the FDA, <https://www.hearingloss.org/hlaas-concern-for-consumers-reaches-the-fda/> (Jan. 8, 2021).

<sup>21</sup> For example, FDA just reclassified three types of lancets from class I exempt to class II subject to premarket notification and one from class I exempt to class II premarket approval due to “new information” on safety risks. Medical Devices; General and Plastic Surgery Devices; Reclassification of Blood Lancets, 86 Fed. Reg. 66,180, 66,182 (Nov. 22, 2021) (“From January 1, 2015, to May 31, 2021, FDA received over 3,100 reports for blood lancets, most of which are device malfunctions.”); *see also* General and Plastic Surgery Devices; Reclassification of Certain Surgical Staplers, 86 Fed. Reg. 56,195 (Oct. 8, 2021) (“FDA notes that, as discussed in the proposed order, malfunctions and misuse associated with surgical staplers for internal use *have resulted in serious adverse events, including deaths*. FDA determines that reclassifying surgical staplers for internal use from class I to class II, establishing special controls, and requiring premarket review will help ensure a reasonable assurance of safety and effectiveness for these devices.” (emphasis added)). Without adequate controls, FDA will not achieve its goal of ensuring the safety and effectiveness of hearing aids.

need for additional regulatory efforts to protect consumers, the industry, and those dealers upon whose good reputations the actions of the less ethical or unethical and less competent or incompetent may reflect,” as “unlawful practices have continued in spite of some fairly substantial efforts made by various interests to curtail them.”<sup>22</sup>

Indeed, FDA has known since the early 1970s that the hearing aid market cannot rely on enforcement alone. Prior to restricting distribution of hearing aids and adopting hearing aid-specific regulation, FDA recognized both that the “sale of a hearing aid that is ineffective, and possibly unsafe, for its intended use are major problems in the present hearing aid delivery system,” and that “the labeling of many hearing aids . . . generally contained numerous false or misleading statements, lacked precise otologic indications for use, and omitted necessary warning and cautionary statements, including warnings against use in those pathological conditions in which use may be dangerous.”<sup>23</sup> Inspection and enforcement on a case-by-case basis, FDA concluded, would not be feasible “because there are more than 1,200 models of hearing aids.”<sup>24</sup> The same stands true today, and lack of proactive Agency oversight could raise all of these issues once again. FDA cannot reasonably expect that enforcement will serve to protect patients in an industry that has *needed* to rely on regulatory enforcement for consumer protection for almost 60 years but has seen little enforcement action over the last five years.<sup>25</sup>

Should FDA decline to require premarket review, economic principles and real-life examples suggest that the market would be flooded with substandard hearing products. Under Gresham’s law, “bad money drives out good” based on an asymmetry of information.<sup>26</sup> If all bad products are passed off as good, a buyer will pay only the price of the bad product to reduce the risk of overpaying. Therefore, the bad product ends up purchased more than the good product.

This exact scenario happened in the hearing-adjacent Personal Sound Amplification Product (“PSAP”) market, as exemplified by the well-designed but comparatively costly PSAP Soundhawk.<sup>27</sup> While the Soundhawk had been called “the best performing PSAP,” it was more expensive than competitors; ultimately, even though it was markedly better than its competitors, it failed commercially due to the price point and is no longer marketed.<sup>28</sup> This is a very real concern if the market is flooded with similar lower priced “bad” hearing aids. Indeed, this would curtail access to the “good” hearing aids while bad experience would drive potential patients from the market and further propagate that “dresser drawer” phenomenon, jeopardizing the well-

<sup>22</sup> FTC, *Report of the Presiding Office on Proposed Trade Regulation Rule for the Hearing Aid Industry*, at 56 (Aug. 1, 1977), [https://www.ftc.gov/system/files/documents/reports/report-presiding-officer-proposed-trade-regulation-rule-hearing-aid-industry/r511006\\_report\\_of\\_the\\_presiding\\_officer\\_on\\_the\\_proposed\\_trade\\_regulation\\_rule\\_for\\_the\\_hearing\\_aid.pdf](https://www.ftc.gov/system/files/documents/reports/report-presiding-officer-proposed-trade-regulation-rule-hearing-aid-industry/r511006_report_of_the_presiding_officer_on_the_proposed_trade_regulation_rule_for_the_hearing_aid.pdf).

<sup>23</sup> Hearing Aid Devices, 41 Fed. Reg. 16,756, 16,757 (Apr. 21, 1976).

<sup>24</sup> *Id.*

<sup>25</sup> The pattern of bad behavior among “OTC” hearing aid manufacturers has been well-documented by state Attorneys General. *See supra* note 7-8.

<sup>26</sup> Mario Seccareccia, *Gresham’s Law*, in The Encyclopedia of Central Banking (Louis-Philippe Rochon and Sergio Rossi, eds. 2015).

<sup>27</sup> The Soundhawk was advertised as \$299.

<sup>28</sup> Chase Smith et al., *PSAPs vs Hearing Aids: An Electroacoustic Analysis of Performance and Fitting Capabilities*, 23(7) Hearing Review 18 (June 14, 2016).

being of patients.

Requiring that a manufacturer supply data demonstrating substantial equivalence to a predicate device is an appropriately calibrated measure that will help to ensure that consumers will purchase safe and effective OTC hearing aids. Given that the NPRM contains detailed guidance on both labeling and technical specifications, it should not be unduly burdensome for manufacturers to provide documentation to establish substantial equivalence. Requiring manufacturers to supply this information to FDA will have the salutary effect of ensuring that each manufacturer has satisfied the applicable requirements.

Though HIA recognizes that FDA has exempted air-conduction hearing aids from premarket notification requirements since 2000 and wireless air-conduction hearing aids since 2011, those devices were intended to be used only at the direction of a learned intermediary, such as a hearing health professional. When a hearing aid is appropriately fit, programmed, verified, and validated by a hearing health professional, the professional verifies that the gain and output are appropriate for the hearing aid user's hearing loss so that optimal benefit is obtained and additional hearing loss is not caused by wearing the hearing aids. Following the measurement of exact hearing thresholds, the hearing health professional uses a frequency-specific, threshold-based formula to prescribe gain and real ear measurements of exact sound levels in the end user's ear canal to adjust and verify that the gain provided in the ear canal is adequate for audibility of sounds—particularly speech sounds—and that output does not result in uncomfortable levels and/or exceed prescriptive targets. Thus, the hearing health professional verifies that a given hearing aid is both safe and effective for an individual patient, reducing the need for FDA premarket review.

In prescribing 510(k)-exempt hearing aids, the licensed hearing health professional serves as a gatekeeper by ensuring that any given hearing device selected is safe and effective for a patient. Without the requirement for a learned intermediary, however, risks of patient harm or use of ineffective product due to non-compliant devices and inappropriate use increase substantially. It thus becomes even more important that FDA devise—and review compliance with—standards applicable to OTC hearing devices such that these devices can be used successfully without assistance from a hearing health professional. Here, FDA serves as the patients' first and only line of oversight. FDA can execute its role to protect patients only by reviewing OTC hearing aids prior to market entry. As these devices transition from prescription to OTC, the risks involved in their use only *increase*.

The default for Class II devices is a 510(k) requirement, and FDA has not pointed to any reason why a non-self-fitting OTC hearing aid should be exempt. And, according to FDA guidance, there are no such reasons. FDA, in determining whether a Class II device should be 510(k) exempt, considers four factors:

- (1) Whether the device has a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials;
- (2) Whether characteristics of the device necessary for its safe and effective performance are well-established;

(3) Whether changes in the device that could affect safety and effectiveness will either:

- a. be readily detectable by users by visual examination or other means such as routine testing, before causing harm, e.g., testing of a clinical laboratory reagent with positive and negative controls; or
- b. not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and

(4) Whether any changes to the device would not be likely to result in a change in the device's classification.<sup>29</sup>

Under these factors, a non-self-fitting OTC hearing aid does not meet the criteria for exempting a Class II device from the need for a 510(k). As noted, there is a history of false or misleading claims associated with so-called OTC hearing aids. Moreover, because OTC hearing aids do not yet exist, the characteristics necessary for safe and effective performance in the intended patient population are not well-established. Further, changes to the device will not be detectable by the intended inexperienced patients and could increase the risk of injury. Finally, changes to the device could easily render the product a self-fitting hearing aid, which would be a change from Class II exempt to Class II non-exempt. There is no basis, therefore, to exempt non-self-fitting OTC hearing aids unless and *until* there is a history of safe use without the assistance of a hearing health professional.

Further, it would be inconsistent with FDA's regulations to *not* require a 510(k) when a device transitions from prescription to OTC. Under FDA regulation, a 510(k) exemption is limited only to "reasonably foreseeable characteristics of commercially distributed devices;" devices that deviate from these characteristics, expressly including devices "intended for lay use where the former intended use was by health care professionals only," require a 510(k).<sup>30</sup> Indeed, "FDA has found that the directions for use necessary for health care professionals to use a device safely and effectively can be significantly different from the directions for use necessary for lay users to use that same device safely and effectively" and for that reason determined that "a device labeled for prescription use only to a device that is labeled for OTC use typically could significantly affect the safety or effectiveness and would likely require submission of a new 510(k)." <sup>31</sup> FDA required 510(k)s to switch, for example, a cleared anti-snoring device, the SnoreRx, to OTC, as well as a cleared cervical cap, the Stork OTC Conception Assistance Kit.<sup>32</sup>

FDA recognizes in the NPRM that labeling changes "to comply with the proposed OTC Hearing Aid Controls may exceed the limitations of exemption, for example because the device was formerly intended for use by healthcare professionals only." 86 Fed. Reg. at 58,172. But it is not clear from this language whether FDA intends that any and all OTC hearing devices, even non-self-fitting, adopting revised labeling to meet the 21 C.F.R. § 800.30 controls for OTC

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<sup>29</sup> FDA, Guidance for Industry and CDRH Staff: Procedures for Class II Device Exemptions from Premarket Notification (citing 63 Fed. Reg. 3,142 (Jan. 21, 1998)) (Feb. 19, 1998).

<sup>30</sup> See e.g. 21 C.F.R. § 874.9.

<sup>31</sup> FDA, Guidance for Industry: Deciding When to Submit a 510(k) for a Change to an Existing Device, at 17 (Oct. 2017).

<sup>32</sup> FDA, 510(K) Summary: SnoreRx, K170285 (Aug. 28, 2017); FDA, 510(K) Summary: The Stork OTC, K140186 (July 11, 2014).

devices would require a 510(k) to be marketed OTC. It is further unclear how the 510(k) requirement applies to hearing aids currently sold as “DTC” that transition to OTC, as such products never were intended for use by healthcare professionals only but nonetheless were not considered “OTC” by the Agency.

If every marketed OTC hearing aid exceeds the limitations of the exemption, as this language implies, it follows that *every* OTC hearing aid coming on the market would need to submit a 510(k). And that is precisely what HIA recommends. To remove all uncertainty, HIA recommends that FDA adopt a 510(k) requirement for any OTC hearing aid.

HIA proposes that 21 C.F.R. § 800.300(g) house the 510(k) requirement and 21 C.F.R. § 874.3305(b)(1) and (2) incorporate by reference (proposed changes italicized, bolded, and underlined for clarity):

*Legacy hearing aid.* Class I for an air-conduction hearing aid that is not a wireless or self-fitting device **and is not an OTC hearing aid.** **Prescription** legacy hearing aids are exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. **Over-the-counter hearing aids under 21 C.F.R. § 800.30(b) are not exempt from premarket notification procedures in subpart E of part 807 of this chapter.**

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*Wireless hearing aid.* Class II (special controls) for a **prescription** air-conduction hearing aid that incorporates wireless technology in its programming or use. A **prescription** wireless hearing aid that is not a self-fitting hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. **A wireless hearing aid may also be an Over-the-Counter hearing aid. Over-the-counter hearing aids under 21 C.F.R. § 800.30(b) are not exempt from premarket notification procedures in subpart E of part 807 of this chapter. Self-fitting hearing aids are subject to paragraph (b)(3).**

FDA could revisit the requirement that each new or significantly modified OTC hearing aid obtain 510(k) clearance after several years of experience evaluating OTC hearing aids through the 510(k) process and postmarket performance monitoring.

HIA however recognizes that review of such 510(k)s might be burdensome for the Agency. To that end, FDA could implement an alternative system in which only the first 510(k) from a given manufacturer would require a 510(k). Such a “first-time” 510(k) requirement for a medical device from a given manufacturer is not unprecedented, provided, as stated in 21 C.F.R. § 807.81(a)(3)(ii), that the manufacturer does not make changes that could significantly affect the safety or effectiveness of the device. In 2017, FDA adopted this approach for the review of

immunological genetic health risk assessment systems. Under 21 C.F.R. § 866.5950, a qualitative in vitro molecular diagnostic system analyzing DNA for genetic risk of disease development is a “one-time FDA reviewed” device and is exempt from premarket notification “when it has previously received a first-time FDA marketing authorization.” 21 C.F.R. § 866.5950(a), (b). This approach, a “partial limitations of exemptions,” is particularly effective where an exemption may not be appropriate for all devices in a particular group to provide reasonable assurances of safety and efficacy.<sup>33</sup>

FDA could adopt the same approach here. Specifically, FDA could add the 510(k) requirement to 21 C.F.R. § 800.30 and revise 21 C.F.R. § 874.3305(b)(1) and (2) to read:

*Legacy hearing aid.* Class I for an air-conduction hearing aid that is not a wireless or self-fitting device **and is not an Over-the-counter hearing aid. Prescription** legacy hearing aids are exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. **Over-the-counter hearing aids under 21 C.F.R. § 800.30(b) are partially exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. A premarket notification is required for an Over-the-counter legacy hearing aid when it is introduced into commercial distribution for the first time by a person required to register under 21 C.F.R. § 807.81(a)(3).**

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*Wireless hearing aid.* Class II (special controls) for a **prescription** air-conduction hearing aid that incorporates wireless technology in its programming or use. A **prescription** wireless hearing aid that is not a self-fitting hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. **A wireless hearing aid may also be an Over-the-Counter hearing aid. Over-the-counter hearing aids under 21 C.F.R. § 800.30(b) are partially exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. A premarket notification is required for an Over-the-counter wireless hearing aid when it is introduced into commercial distribution for the first time by a person required to register. Self-fitting hearing aids are subject to paragraph (b)(3).**

Under this proposal, that first-time 510(k) would serve as confirmation that the initial hearing device complies with FDA requirements for OTC hearing aids. This one-time regulatory process would allow FDA to provide the regulatory oversight to confirm that a company’s OTC hearing aid can, in fact, meet the needs of patients. Limiting this requirement to only the first

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<sup>33</sup> See 83 Fed. Reg. 25,910, 25,913, 25,914 (June 5, 2018).

hearing device from a manufacturer would reduce obstacles to entry for companies, as well as reduce the workload for FDA in reviewing these hearing products. Further, a 510(k) for a self-fitting hearing aid could serve as a first 510(k) for any manufacturer for any OTC product—self-fitting or otherwise—further reducing the Agency’s workload where a manufacturer develops and distributes both. And FDA could further reduce its burden even further by creating templates based on the specifications adopted in the Final Rule; the agency’s experience with COVID-19 tests shows that this approach can benefit both companies and the agency.

**c. FDA Should Revise the Technical Specifications to Include More Safety Protections for Patients.**

Congress, in FDARA, required FDA to adopt regulations that would “provide reasonable assurances of the safety and effectiveness of [OTC] hearing aids.” FDARA § 709. For good reason: If safety and effectiveness parameters are not carefully defined, OTC hearing aids will not only fail to provide their intended benefit but could also cause harm. But FDA’s proposed parameters do not go far enough in ensuring either safety or effectiveness. Should FDA decide to retain the current parameters set forth in the NRPM, HIA has serious concerns that patients will face real safety risks. And these risks go beyond the “dresser drawer” problem—even a hearing aid that meets these prescribed parameters has the potential to further damage a patient’s hearing, potentially resulting in noise-induced hearing loss.

**i. Output and Gain**

Several major U.S. hearing health professional associations, with endorsements from several other industry groups, assembled a group of clinical hearing experts, acoustic scientists, and educators to publish and submit to FDA a Consensus Paper recommending standards for OTC hearing aids.<sup>34</sup> The NRPM does not reference this document.

Instead, the NRPM proposes to integrate *consumer* technology standards. HIA believes that the proposed consumer technology standards are not adequate to protect patients *with hearing loss* and urges FDA to replace the consumer technology standards with the standards outlined in the Consensus Paper. Specifically, HIA agrees with the Consensus Paper proposal—which again represents the position of multiple medical experts—that (i) the maximum output (OSPL90) for the OTC hearing aid category be no greater than 110 dB SPL<sup>35</sup>, and (ii) a gain limit be defined at 25 dB<sup>36</sup> based on the National Acoustic Laboratories NAL-NL2 formula, which is the most widely used formula world-wide for the calculation of gain for adult patients.<sup>37</sup> These amplification standards were developed for treating hearing loss rather than merely increasing volume. These proposed standards have been utilized by multiple manufacturers for over a decade and have proven to be not only safe but also extremely effective.

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<sup>34</sup> American Speech-Language-Hearing Association (ASHA) et al., Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness, Consensus Paper From Hearing Care Associations (August 2018), <https://www.asha.org/siteassets/uploadedfiles/consensus-paper-from-hearing-care-associations.pdf>.

<sup>35</sup> As measured in a 2 cc coupler OSPL90, per ANSI S3.22-2014.

<sup>36</sup> 2 cc coupler high frequency average (HFA) full on gain, as measured at an input level of 50 dB SPL per ANSI S3.22-2014.

<sup>37</sup> Gitte Keidser et al., The NAL-NL2 Prescription Procedure, *Audiology Research* 1(e24), 88 (2011).

However, in the NPRM, FDA adopted the Consumer Technology Association (“CTA”) Standard of ANSI/CTA-2051, entitled “Personal Sound Amplification Performance Criteria.”<sup>38</sup> But HIA notes that these standards are intended for PSAPs, which, in FDA’s own words, “have different intended uses, and are therefore subject to different regulatory controls.”<sup>39</sup> FDA very clearly states in the NPRM that “FDA does not consider [PSAPs] to be ‘devices’” and that “PSAPs are not subject to medical device regulations, nor would the proposed requirements of this rulemaking apply to such PSAPs.” 86 at Fed. Reg. 58,154. Though FDA recognizes the distinction between a PSAP and a medical device, the NPRM nevertheless states, with no discussion or explanation, “that this standard”—specifically intended under the standard only to provide “target values for consumer products that provide personal sound amplification and/or enhancement to a user”<sup>40</sup>—“is also relevant for OTC hearing aids. . . .” 86 Fed. Reg. at 58,161.

HIA encourages FDA to reconsider the use of the CTA standards, as they are intended for a *healthy* patient population with *clinically normal* hearing. Hearing loss patients are not these patients; many hearing loss patients are at risk of further hearing loss because of their existing deficit and represent a more vulnerable population than the prototypical examples of PSAP users, such as hunters or birdwatchers, that typically rely on PSAPs.<sup>41</sup> See 86 Fed. Reg. at 58,154, n.4. Patients with hearing loss are seeking a medical device, not a sound amplifier or speaker. The CTA standards are “the *minimum* technologic criteria needed for hearing aid efficacy.<sup>42</sup> Requiring only the bare minimum would not ensure effectiveness and likely would further exacerbate the “dresser drawer” problem.

FDA tries to justify the use of the CTA standards by pointing to the Occupational Noise Exposure standard from NIOSH that includes the same output limit recommendations as the CTA standards. *Id.* But again, these standards and recommendations are developed for people *without hearing loss* and certainly not for full-time use by a vulnerable or elderly patient population with medically verifiable hearing loss patients. In adopting the CTA standard, FDA has rejected—again without explanation—a standard developed specifically for a medical device for patients with hearing loss in favor of one created for consumer products intended for intermittent use by individuals with normal hearing.<sup>43</sup> HIA strongly believes that reliance on the CTA standards for the intended hearing loss patient population is inappropriate and dangerous.

As HIA believes that the CTA standards that FDA intends to adopt are not sufficient to ensure the safety and efficacy of an OTC hearing aid *specifically intended for patients with hearing loss*, HIA encourages FDA to revisit the Consensus Paper. FDA proposes in the NPRM

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<sup>38</sup> Personal Sound Amplification Performance Criteria, ANSI/CTA-2051, Consumer Technology Association (Jan. 2017) (“ANSI/CTA-2051”).

<sup>39</sup> FDA, Guidance for Industry: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products, at 4 (Oct. 20, 2021) (“Draft PSAP Guidance”).

<sup>40</sup> ANSI/CTA-2051, (Scope) at 1 (Jan. 2017).

<sup>41</sup> See also Draft PSAP Guidance at 9.

<sup>42</sup> Comments of Frank Lin, Docket No. FDA-2021-N-0555 at 2 (Jan. 7, 2022).

<sup>43</sup> Though the Consensus Paper from Hearing Care Associations was sent to FDA more than three years ago, the NPRM neither references nor even recognizes the recommendations developed by the hearing health professionals treating patients with hearing loss on a daily basis. HIA believes that it is inappropriate to propose adopting a standard designed for consumer products for use by healthy individuals without considering or addressing the Consensus Paper crafted specifically to address the needs of individuals with hearing loss.

“a maximum OSPL90 output level of 115 dB sound pressure level (SPL) as a general rule to balance consumer safety with device performance” with a limit of 120 dB SPL for an OTC hearing aid that implements input-controlled compression and a user-adjustable device volume control and no gain limit. 86 at Fed. Reg. 58,161. FDA reasons that these proposed output limits are adequate “to prevent injuries from exposure to loud sounds when amplified by OTC hearing aids while still allowing a sufficient dynamic range of outputs, called ‘headroom,’ to provide effective amplification for users with perceived mild to moderate hearing loss.” *Id.* FDA further justifies this limit by warning that “too low an output reduces device effectiveness and can lead to poor device performance, including clipping and distortion. In turn, poor performance would reduce consumer satisfaction and use of the devices.” *Id.* FDA continues “We believe that the proposed output limits balance the above considerations for these devices, so the limits are therefore appropriate for OTC hearing aids.” Again, FDA cites no data or studies to support any of these assertions, and the only justification the Agency provides is a reference to the CTA standard and a statement that the NASEM report did not specifically recommend a limit on gain; thus, with no further analysis, FDA essentially condones the administration of more therapy or treatment than needed.

With respect to the maximum gain, there is no gain limit defined *per se* in ANSI/CTA-2051. Instead, ANSI/CTA-2051 simply states “[t]he manufacturer shall report the maximum available high-frequency gain.” ANSI/CTA-2051 at 11. Consequently, FDA proposes not to limit the hearing device gain, reasoning that “the proposed maximum output limit (together with the other proposed requirements) will provide reasonable assurance of safety and effectiveness without limiting the device gain also.” 86 Fed. Reg. at 58,162.

HIA believes the maximum output limit at 115 dB SPL or 120 dB SPL coupled with the absence of a gain limit fails to “balance consumer safety with device performance.” *See* 86 Fed. Reg. at 58,161. The output level does not solve the issue of “poor device performance” as any hearing aid can drive the gain to the output limit and therefore lead to “poor device performance.” Poor device performance may be the outcome of the signal processing of hearing aids that do not effectively control and process gain, loudness control, spectral analysis, frequency response, directional microphones, noise reduction, and feedback cancellation. Among these, gain control plays a critical role to properly present the intensity of the sound that is appropriate for the patient’s degree of hearing loss. The goal of “balanc[ing] consumer safety with device performance” would not be achieved by simply increasing the output limit. Without a gain limitation for an appropriate fitting of mild to moderate hearing loss, a manufacturer could still introduce OTC hearing aids that not only have “poor device performance” but also have *an added safety risk*: additional hearing loss from over-amplification.

Indeed, the lack of gain limitation threatens prolonged duration to high sound levels.<sup>44</sup> It is well-established that individuals exposed to high levels of sound for long durations are at a significant risk of developing noise-induced hearing loss.<sup>45</sup> Overexposure to loud sound from

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<sup>44</sup> Anurag R. Goel et al., Long-Term Effects of Hearing Aids on Hearing Ability in Patients with Sensorineural Hearing Loss, *J Am Acad Audiol.*; 32(6):374-378 (Jun. 2021).

<sup>45</sup> For a recent review, *see* Trung N. Le et al., Current insights in noise-induced hearing loss: a literature review of the underlying mechanism, pathophysiology, asymmetry, and management options, *J Otolaryngol Head Neck Surg.*; 46(1):41 (May 23, 2107).

either portable listening devices or hearing aids can cause both temporary and permanent hearing loss by damaging structures within the cochlea, including outer hair cells, the stria vascularis, and the supporting cellular structures.<sup>46</sup> The Occupational Safety and Health Administration guideline provides that prolonged exposure to sound levels above 90 dBA presents risks for noise-induced sensorineural hearing loss.<sup>47</sup> In light of this guideline, individuals who use OTC hearing aids with no gain limit and 120 dB SPL maximum output levels (with or without input compression) as proposed by the draft OTC hearing aid rule are at a significant risk for developing noise-induced hearing loss.

Labeling mitigation would not adequately address these safety concerns. FDA posits that such risks are mitigated because a patient who experiences higher-than-expected volume levels, such as at the symphony, could respond by taking off or reducing the volume of the hearing device. FDA estimates that patients would have 28 seconds to react to such occasional peaks and proposes to include in product labeling a cautionary statement for patients that “[y]ou should turn down the volume or remove the device if the sound output is uncomfortably loud or painful.” 86 Fed. Reg. at 58,162. But this only shifts the burden to the patients to act quickly to protect themselves from exposure to extremely loud sound. This assumes the patient *can* recognize or adjust the hearing aid when sounds are too loud, which is a particularly troubling assumption when the NPRM does not require input-controlled compression and a user-adjustable volume control for all OTC hearing aids. FDA cites to no evidence demonstrating that patients can or will recognize when sounds are too loud. Further, many people with mobility, dexterity and cognitive challenges are unable to remove or adjust hearing aids at all, much less within 28 seconds. Thus, the hearing device itself should provide this protection.

Even if labeling includes a cautionary statement, there is no guarantee or even high likelihood that the average patient will read or understand the user guide—especially if the user guide is not available in their preferred language, if they have other cognitive decline issues, physical limitations that make it hard to respond quickly, or, as in FDA’s example of the symphony, are engrossed in the experience and forget to implement what they read in the labeling months—or years—earlier.<sup>48</sup> Allowing manufacturers to design devices that present a safety risk, and then expecting consumers to react promptly to mitigate that risk, is not consistent with the statutory goal of consumer protection.

Indeed, reliance on labeling mitigation also poses problems as it assumes that damaging sound pressure levels are necessarily uncomfortable and will be recognized by patients thereby

<sup>46</sup> Cory D.F. Portnuff, Reducing the risk of music-induced hearing loss from overuse of portable listening devices: understanding the problems and establishing strategies for improving awareness in adolescents, *Adolesc Health Med Ther.* 7:27-35 (Feb. 10, 2016); Earl E. Johnson, Safety limit warning levels for the avoidance of excessive sound amplification to protect against further hearing loss, *Int J Audiol.*, 56:829-836 (July 07, 2017). Note that the Consensus paper discussed the implication of the Johnson article at length. Johnson recommended an overall output level lower than 111 dB SPL as a safe level for a moderate degree of hearing loss.

<sup>47</sup> See Occupational Safety and Health Administration (OSHA), Occupational Noise Exposure, <https://www.osha.gov/noise>. See also NIOSH, Hearing Loss Prevention: Risks, <https://www.cdc.gov/niosh/programs/hlp/risks.html>.

<sup>48</sup> FDA, Guidance for Industry: Applying Human Factors and Usability Engineering to Medical Devices, at 19-20 (“These strategies are not the most preferred, though, because they rely on the user to remember or refer back to the information, labeling might be unavailable during use, and knowledge gained through training can decay over time.”) (2016).

prompting them to take action. But that assumption is not reasonable; the hearing damage that has affected millions of Americans, as explained, due to both occupational noise exposure and consumer electronics refutes the notion that patients recognize or take action when exposed to unsafe sound levels. In OTC hearing devices, the risk of exposure to unsafe sound levels is exacerbated by the fact that frequency specific hearing thresholds are not (necessarily) the basis for the fitting. As a result, normal populations of delicate outer hair cells could be subjected to extreme sound pressure levels by unlimited gain devices with imprecise frequency tuning. Labeling precautions therefore may be helpful where patients harm is acute but would do nothing to address the risks arising from chronic exposure.

FDA therefore appears to underestimate the safety concern posed by the combination of extended wear times, a high output level and unlimited gain, but this concern is well supported by ample scientific evidence in the literature. For instance, several investigators demonstrated that a long-term use of personal listening devices with maximum output levels from 91-121 dB increased the risk of noise-induced hearing loss.<sup>49</sup> A recent study by Goel et al. (2021) showed a permanent threshold shift (*i.e.*, worsening hearing thresholds) in patients wearing professionally fit hearing aids for five years, in comparison to a control group that did not wear hearing aids during that time.<sup>50</sup> These findings highlight that the long-term effects—positive or negative—of wearing hearing aids *that are professionally fit* has not been fully understood yet. Goel et al. stated that “patients not captured in this model may experience clinically significant deterioration within 5 years of amplification, *particularly those with hearing aids that do not have prescriptive maximum power output (MPO) settings*. In addition, there are likely patients exposed to unsafe sound levels despite a prescribed safe MPO, including those who manually increase amplification due to preference for increased volume, spend significant time in environments with high ambient noise levels, and experience random technology error.”<sup>51</sup> Where patients have no guidance from a hearing health professional, reduction of MPO settings would help by decreasing the total sound exposure and threat of noise-induced hearing loss.

Note that the subjects in the Goel et al. study had 25 dB HL of the baseline pure-tone average (PTA) at 500, 1,000, and 2,000 Hz, corresponding to “mild” hearing loss. As such, many of these individuals likely had a residual outer hair cell (OHC) function, which are far more vulnerable to acoustic overstimulation than the inner hair cells (IHC).<sup>52</sup> To address this risk in patients, audiologists typically set the gains in a very conservative way so that higher gains are reserved for hearing loss progression. But with no limitation on gain for OTC hearing aids, many patients naturally will gravitate towards higher gain because the sounds will be more audible. Too much gain before a patient needs it further damages hearing, and the risk of such

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<sup>49</sup> Mario R. Serra et al., Recreational noise exposure and its effects on the hearing of adolescents. Part I: an interdisciplinary long-term study, *Int J Audiol.* 44(2):65-73 (Feb 2005); Jian-Hua Peng et al., Risk of damage to hearing from personal listening devices in young adults, *J Otolaryngol.* 36(3):181-5 (June 2007); Brian J. Fligor and L. Clarke Cox, Output levels of commercially available portable compact disc players and the potential risk to hearing, *Ear Hear.* 25(6):513-27 (Dec 2004).

<sup>50</sup> Anurag R. Goel et al., Long-Term Effects of Hearing Aids on Hearing Ability in Patients with Sensorineural Hearing Loss, *J Am Acad Audiol.* 32(6):374-378 (Jun. 2021). With such developments, a hearing professional would typically prescribe a lower gain and gradually increase as needed.

<sup>51</sup> *Id.* (emphasis added).

<sup>52</sup> Yuh-Shyang Chen, Changes of hair cell stereocilia and threshold shift after acoustic trauma in guinea pigs: comparison between inner and outer hair cells. *ORL J Otorhinolaryngol Relat Spec.* 65(5):266-74 (Sept./Oct. 2003).

damage is further compounded by the high maximum output levels proposed in the Nprm. In other words, the proposed rule allows OTC hearing aids to provide unlimited and powerful gain, as well as maximum output levels significantly beyond that which would be medically prescribed for a patient with clinically-diagnosed mild to moderate hearing loss—but without the guardrails of the professional fitting. This poses an unacceptable risk for patients.

Tighter design specifications, rather than labeling reliance, is more consistent with FDA's approach to risk mitigation when more effective ways to address potential harms are available. Where risks can be mitigated by design controls, FDA guidance expressly instructs companies to revise product design rather than rely on labeling. In a 2016 Human Factors guidance, FDA explains that "modifying the device design is usually more effective than revising the labeling," particularly because "labeling might not be accessible when needed . . ." <sup>53</sup> If "no other options are available" or are not "possible or practicable," then labeling may be helpful.<sup>54</sup> But there are other options here: FDA can reduce the maximum output levels and adopt a gain limit to reduce unnecessary risk to patients without sacrificing efficacy. Because design controls can effectively mitigate risks, FDA typically would not permit individual manufacturers to rely on labeling alone to protect patients, and FDA provides no explanation as to why a different approach should apply to OTC hearing aids. FDA therefore should abandon its exclusive reliance on labeling directing patients to reduce use if they notice harm in favor of design controls that *prevent* harm from occurring in the first place.

It is worth noting that hearing aids indicated for mild to moderate hearing loss on the market today—available only through and individually fitted by hearing health professionals—are designed to provide more conservative output parameters than those proposed by the OTC hearing aid rule. For instance, one major hearing aid manufacturer offers two receivers for their receiver-in-canal products that are most suitable for mild to moderate hearing loss. The MPO specifications of these two receivers are 111 dB SPL and 114 dB SPL, respectively. Other manufacturers offer low power receivers for mild to moderate hearing loss with MPO specifications of 113 dB SPL, 110 dB SPL, and 115 dB SPL. Although these low power hearing devices are intended for patients with mild to moderate hearing loss *pursuant to a fitting by hearing health professionals*, they are still *more restrictive* than the parameters proposed by the draft OTC hearing aid rule.

Even if MPO could be technically set to the Nprm's proposed maximum, use at that maximum setting is specifically prescribed by audiologists only rarely for patients with mild to moderate hearing loss. If the proposed rule is adopted as is, patients would have much more freedom to manipulate the hearing device than they would with professionally fitted hearing aids and could reach the maximum setting with little effort. Such an unrestricted degree of freedom in setting OTC hearing aid parameters, without the guardrails of the professional fitting, could be used in a manner that could cause temporary and permanent sensorineural hearing loss. And there is no benefit that would offset that serious risk.

Further, HIA reiterates how important it is to address these safety concerns because OTC

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<sup>53</sup> FDA, Guidance for Industry: Applying Human Factors and Usability Engineering to Medical Devices, at 11 (2016).

<sup>54</sup> *Id.* at 20, 27.

hearing aids are expected to be worn, like professionally fit hearing aids, for approximately 12 hours per day.<sup>55</sup> As discussed above, noise-induced hearing loss from the overuse of portable listening devices has been reported in the literature, and as a result, there is an increasing awareness that preventive measures are warranted to prevent hearing loss among the users of portable listening devices.<sup>56</sup> Many OTC hearing aid products are expected to have wireless functionality that allows audio streaming for speech and music. Without gain limits, there is no reason to believe that OTC hearing aids would not present the same risks as portable listening devices with respect to the risk of noise-induced hearing loss. Further, once a hearing aid is perceived as a “consumer” product—combining “hearing aid” function *and* streaming function—patients likely will use the hearing device for 12 hours a day or more; FDA should ensure that OTC hearing aids can be used for this purpose safely *before* any damage is done.

Currently, the most popular consumer products utilize conservative gain and output limits.<sup>57</sup> One good example is Apple’s AirPods. Chong-White et al. recently compared headphone accommodations with Transparency mode in Apple’s AirPods Pro to conventional hearing aid amplification. Apple’s AirPods Pro and AirPods Max have three noise-control modes: Active Noise Cancellation, Transparency, and Off. Transparency mode lets outside sound in so users can hear what is going on around them and processes outside sound with frequency-dependency gain and compression just like hearing aids. Apple products also provide the feature called “Live Listen.”<sup>58</sup> With Live Listen, iPhone, iPad, or iPod touch can act like a microphone that sends sound to the user’s AirPods, AirPods Pro, AirPods Max, Powerbeats Pro, or Beats Fit Pro. This is again a very similar functionality that a hearing aid provides to help the users hear a conversation in a noisy area or even hear someone speaking across the room.<sup>59</sup> Chong-White et al. showed that the OSPL90 for AirPods Pro is less than 100 dB SPL. For a conversational input speech level, AirPods Pro provides a gain of 12 to 15 dB.

Apple is one of the most prolific audio product manufacturers in the world. AirPods sales have been increasing markedly over time: 15 million AirPods sold in 2017 and 114 million in 2020,<sup>60</sup> about 27 times greater than the number of sales for hearing aids in the US.<sup>61</sup> Given their market share and the similar functionalities that OTC hearing aids are intended to provide,

<sup>55</sup>L.B. Taubman et al., Accuracy of hearing aid use time as reported by experienced hearing aid wearers, *Ear Hear.* 20(4):299-305 (Aug. 1999); Anna M. Jilla et al., Predictors of Hearing Aid Use in the Advanced Digital Era: An Investigation of Benefit, Satisfaction, and Self-Efficacy, *J Am Acad Audiol.* 31(2):87-95 (Feb 2020).

<sup>56</sup> Cory D.F. Portnuff, Reducing the risk of music-induced hearing loss from overuse of portable listening devices: understanding the problems and establishing strategies for improving awareness in adolescents, *Adolesc Health Med Ther.* 7:27-35 (Feb. 10, 2016); Timon Hussain et al., Early Indication of Noise-Induced Hearing Loss in Young Adult Users of Personal Listening Devices, *Ann Otol Rhinol Laryngol.* 127(10):703-709 (Oct. 2018); Wen Jiang et al., Daily music exposure dose and hearing problems using personal listening devices in adolescents and young adults: A systematic review, *Int J Audiol.* 55(4):197-205 (Jan. 15, 2016); Ainul Huda Sulaiman et al., Hearing Risk among Young Personal Listening Device Users: Effects at High-Frequency and Extended High-Frequency Audiogram Thresholds, *J Int Adv Otol.* 11(2):104-9 (Aug. 2015).

<sup>57</sup>Nicky Chong-White et al., Evaluating Apple AirPods Pro with Headphone Accommodations as Hearing Devices, *The Hearing Review* (Dec. 2021).

<sup>58</sup> Apple, AirPods Pro and AirPods Max Active Noise Cancellation and Transparency mode (May 21, 2021), <https://support.apple.com/en-us/HT210643>; Apple, Use Live Listen with AirPods or Beats (Jan. 11, 2022), <https://support.apple.com/en-us/HT209082>.

<sup>59</sup> *Id.*

<sup>60</sup> Business of Apps. Apple Statistics, <https://www.businessofapps.com/data/apple-statistics/> (current as of 2022).

<sup>61</sup> HIA data shows that over 4.22 million hearing aids were dispensed in the U.S. in 2019.

Apple's conservative approach of setting the audio output and gain limit for Apple's products is notable. The exceptionally high market adoption of AirPods raises questions of whether anything beyond such a conservative approach is necessary. Experience with Apple suggests that implementation of a gain of 25 dB and an OSPL90 of less than 110 dB SPL, as HIA and the Consensus Paper recommends, could facilitate the safe and effective use of OTC hearing aids for patients with mild to moderate hearing loss.<sup>62</sup>

Setting the maximum output for OTC hearing aids at 110 dB SPL is also consistent with FDA's own approach to ensure safe and effective use of tinnitus maskers. To the best of our knowledge, there are no tinnitus maskers cleared with a maximum acoustic output limit at 120 dB SPL. Rather, maximum output levels for tinnitus maskers are typically much less than 120 dB SPL. For example, the maximum overall output level for Starkey's Multiflex Tinnitus Technology (K122876, K201370) and GN Hearing's Tinnitus Sound Generator Module (K180495) is 87 dB SPL and 100 dB SPL, respectively. With the use time for hearing aids typically much longer than that of a tinnitus masker, it is logical that FDA apply the same level of maximum acoustic output limit to OTC hearing aids as are found in these other devices.

Alternatively, HIA recommends, at a minimum, limiting OTC and self-fitting hearing aids to 110 dB SPL. Any devices that allow maximum levels above 110 dB SPL should include a warning, which would also be required in the hearing product labeling, as discussed below.

Based on the foregoing reasons, HIA requests that FDA implement the following:

- The peak (or maximum) 2 cc coupler OSPL90, per ANSI S3.22-2014, be equal to or lower than 110 dB SPL.
  - Any OTC or self-fitting hearing aid above 110 dB SPL should include explicit audible warnings that this high level of output exposes the user to potentially damaging sound levels and a manual override.<sup>63</sup> This approach will better protect users by ensuring that they are aware of this higher level and that it may pose risks to their hearing.
- A high frequency average 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. HIA believes 25 dB is appropriate for a flat loss of 55 dB HL (which is at the high end of the mild to moderate range), input speech level at 50 dB SPL, binaural usage, and incidence of new users.<sup>64</sup>
- Mandated user-adjustable volume control for hearing aids with any maximum output limit, because without it, the user cannot reduce the output as needed, unnecessarily exposing the user to loud sound for a long time.

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<sup>62</sup> Dana Urbanski, et al., Toward a New Evidence-Based Fitting Paradigm for Over-the-Counter Hearing Aids, *Am J Audiol*, 30(1):43-66 (Mar. 10, 2021), [https://pubs.asha.org/doi/10.1044/2020\\_AJA-20-00085](https://pubs.asha.org/doi/10.1044/2020_AJA-20-00085); Thomas J. Tedeschi, et al., Real World Evidence on Gain and Output Settings for Individuals with Mild-to-Moderate Hearing Loss, *The Hearing Review* (Jul. 14, 2020), <https://hearingreview.com/inside-hearing/research/real-world-evidence-on-gain-and-output-settings-for-individuals-with-mild-to-moderate-hearing-loss>.

<sup>63</sup> This request is reiterated in the Labeling section.

<sup>64</sup> For details, see the Consensus paper, *supra* note 34, at 8-11.

## ii. Hearing Assessment Tools

Under the statutory language set forth in FDARA § 709, OTC hearing aids are to be made available to patients with “perceived” mild to moderate hearing loss. While the statute defines the intended use population in that fashion, it is critical that OTC hearing aids go only to consumers who actually have hearing loss and can benefit from them. In that vein, it is important to note that HIA remains concerned about reliance purely on subjective self-diagnosis. Studies suggest that “self-reported” hearing assessment often is not representative of audiometric hearing loss.<sup>65</sup> And a 2017 CDC report explained that “23.5% of persons who self-reported excellent or good hearing (irrespective of noise exposure reported) had bilateral or unilateral notches,” and consequently, “[h]earing loss often progresses for years before being self-perceived or diagnosed.”<sup>66</sup> These findings suggest caution should be used in relying exclusively on self-reported hearing measures.

Thus, while it is important to expand accessibility and affordability by removing barriers to access for persons with hearing loss, it is also imperative that the screening measures used to characterize candidacy are accurate for the intended user group. FDA has elected to rely exclusively on labeling for self-diagnosis, but, as FDA has recognized, “[a]ddressing use-related hazards by modifying the device design is usually more effective than revising the labeling or training.”<sup>67</sup> This suggests that FDA should consider elements that may, in addition to labeling, facilitate a better understanding of perceived hearing loss. FDA should anticipate that at least some manufacturers will provide hearing assessment tools to aid in self-assessment. FDA should recommend that these tools may be used and integrated into the labeling. Specifically, HIA requests that FDA recommend to consumers the use of methods of assessing hearing loss that are more accurate than labeling, including:

- Hearing assessment kiosks, typically found in drugstores, supermarkets, or other public areas;
- Online screening measures, including screening threshold tests; and
- Smartphone-based measures, speech-in-noise levels, and ease of use by aging populations.

HIA anticipates that such tools will be used regardless of FDA recommendations and therefore believes that FDA should address how such tools may be used and advise as to whether those tools will be subject to any regulatory controls. Further, HIA requests that FDA provide further

<sup>65</sup> Janet S. Choi et al., A Comparison of Self-Report and Audiometric Measures of Hearing and Their Association With Functional Outcomes in Older Adults, *Journal of Aging and Health*. 2016;28(5):890-910 (Nov. 9, 2015), <https://doi.org/10.1177%2F0898264315614006>; Silvia Ferrite et al., Validity of self-reported hearing loss in adults: performance of three single questions, *Rev Saude Publica*. 2011;45(5):824-830 (Oct. 2011), <https://doi.org/10.1590/S0034-89102011005000050>.

<sup>66</sup> Centers for Disease Control and Prevention (CDC), Vital Signs: Noise- Induced Hearing Loss Among Adults- United States 2011-2012 (Feb. 7, 2017), [https://www.cdc.gov/mmwr/volumes/66/wr/mm6605e3.htm?s\\_cid=mm6605e3\\_w](https://www.cdc.gov/mmwr/volumes/66/wr/mm6605e3.htm?s_cid=mm6605e3_w); C.G. Le Prell et al., Evidence of hearing loss in a “normally-hearing” college-student population, *Int J Audiol* 50(Suppl 1):S21–31 (Mar. 2011); Christine Rota-Donahue & Sandra Levey, Noise-Induced Hearing Loss in the Campus, *Hear J* 69:38–9 (June 1, 2016).

<sup>67</sup> FDA, Guidance for Industry: Applying Human Factors and Usability Engineering to Medical Devices, at 11 (2016).

guidance on whether the use of these tools render hearing products “self-fitting” or subject to additional regulation (like an audiometer).<sup>68</sup>

### **iii. EMC and Material Safety**

HIA appreciates and agrees with FDA’s requirements for electrical and thermal safety demonstrations for wireless air-conduction hearing aids but believes some further clarification is appropriate. The NPRM proposes “[t]o revise the special control currently in § 874.3305(b)(1) for consistency with the special control currently in § 874.3325(b)(3)” and explains that though this control “would require demonstration of electrical safety and thermal safety, we believe that generally manufacturers of wireless air-conduction hearing aids regulated under § 874.3305 have been evaluating these safety aspects for their devices and therefore, this proposed revision would have little to no impact on these manufacturers.” 86 Fed. Reg. at 58,170. HIA asks that FDA to clarify whether the FDA recognized standard No. 19-4 ANSI AAMI ES60601-1:2005/(R)2012 can be used with IEC 60601-2-66:2019 for purposes of evaluating electrical safety of OTC hearing aids. The same question arises with respect to a demonstration of thermal safety with regard to standard No. 19-4 ANSI AAMI ES60601-1:2005/(R)2012 in combination with particular standard IEC 60601-2-66:2019.

These questions arise because IEC 60601-2-66:2019 is not included on the FDA recognized standards list even though it is used and recognized in many other countries around the world. If it is permissible (and HIA recommends that FDA accept it), it could be cited in the special controls set forth in 21 C.F.R. § 874.3305 as well as in § 800.300.

With respect to material safety, HIA also requests that FDA revise the rule to more clearly integrate ISO10993-1:2018 into the proposed rule to provide further clarity. FDA states in the NPRM that “[w]e are proposing that the eartip be encased by atraumatic materials, that is, materials that prevent injuries to the skin and bone, for example, because they are very flexible. The use of atraumatic materials reduces the chance that daily use or accidental contacts will cause damage to the delicate skin or bone of the ear.” 86 Fed. Reg. at 58,165.<sup>69</sup> Separately, in addition to ensuring that materials of eartips are atraumatic and flexible enough to prevent injuries to the skin and bone, manufacturers must evaluate the biological safety of all parts of OTC hearing aid devices that come into contact with skin per the FDA recognized standard ISO10993-1 Fifth edition 2018-08, 2-258. HIA suggests integrating this standard into the special controls section of 21 C.F.R. § 874.3305, as well as in § 800.300. HIA believes that ISO10993-1:2018 allows manufacturers to evaluate the biocompatibility of hearing aids in line with the FDA draft guidance document entitled “Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin,” which supports the use of available information and literature on materials to justify the omission of biocompatibility tests to reduce animal use in

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<sup>68</sup> As noted, the Agency’s Mobile Medical Applications guidance expressly states that such hearing screening apps would not be subject to enforcement discretion. FDA, Guidance for Industry: Policy for Device Software Functions and Mobile Medical Applications, at 25 (Sept. 27, 2019).

<sup>69</sup> The term atraumatic is not defined in this context. HIA believes that FDA intends the term to mean flexible or soft so as not to cause pain but requests further clarification if this understanding is incorrect.

testing.<sup>70</sup>

#### iv. Assembly

HIA believes that obtaining evidence that shows patients can correctly use OTC hearing aids is an integral part of ensuring that OTC hearing aids are safe and effective. Indeed, FDA has on many occasions stressed the importance of usability studies to show that the intended use population can appropriately use the device.<sup>71</sup> Given the size and diversity of the OTC hearing aid population, HIA views this type of testing as essential here.<sup>72</sup> Therefore, HIA believes that FDA should require evidence of usability studies conducted to ensure that prospective users of OTC hearing aids will be able to assemble and insert hearing devices without the assistance of a professional.

Undoubtedly, some OTC hearing aids, especially those that are receiver-in-canal style, will require some customization and assembly, and that assembly may be challenging for patients. For example, a receiver-in-canal hearing aid may require the individual to select an appropriately sized receiver cable and an appropriately sized earbud/ear tip, but it can be difficult to select appropriately-sized tubes and domes and assemble them correctly. It is often challenging for hearing-impaired patients to do so even during a hearing aid fitting and therefore likely will remain challenging to do so without a hearing health professional.

To ensure that *all* users—not only sophisticated patients—can put the hearing device together, FDA should require manufacturers to conduct usability studies to ensure that patients can assemble and insert hearing devices without the assistance of a professional. Hearing aid assembly is complex, and there may be challenges. Manufacturers may find that assembly is simpler for patients with an in-the-ear design than a receiver-in-canal one, and challenges may be overcome by providing customers with a better-designed (*i.e.*, a pre-assembled) receiver-in-canal. Discrepancies in the rate of success with hearing aid assembly suggest that video instructions may yield higher success rates than written ones.<sup>73</sup> In any event, given that consumer assembly is a prerequisite to the use of the device, FDA should adopt special controls

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<sup>70</sup> FDA, Guidance for Industry: Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin, at 2 (Draft, Oct. 15, 2020).

<sup>71</sup> See e.g. FDA, Guidance for Industry: Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development, at 12 (Draft, Feb. 2016) (“If the product design remains unchanged but the applicant seeks to add a new user population, then as applicable, a new use-related risk analysis and new HF Validation study should be performed.”); FDA, Guidance for Industry: Applying Human Factors and Usability Engineering to Medical Devices, at 21 (Feb. 2016) (“The most important consideration for test participants in human factors validation testing is that they represent the population of intended users.”).

<sup>72</sup> FDA advises that devices be subject to human factors testing in participants that are representative of the range of characteristics within the intended user group. “[I]f a device is intended to be used by both professional healthcare providers and lay users, FDA views these as distinct user populations.” FDA, Guidance for Industry: Applying Human Factors and Usability Engineering to Medical Devices, at 22 (Feb. 2016).

<sup>73</sup> Elizabeth Convery et al., A Self-Fitting Hearing Aid: Need and Concept, Trends in Amplification, Trends Amplif. 2011;15(4):157-166 (2011), <https://journals.sagepub.com/doi/pdf/10.1177/1084713811427707>; Larry E. Humes et al., The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial, Am J Audiol. 2017;26(1):53-79 (Mar. 1, 2017), [https://pubs.asha.org/doi/10.1044/2017\\_AJA-16-0111](https://pubs.asha.org/doi/10.1044/2017_AJA-16-0111).

mandating that manufacturers obtain data through usability studies confirming that their devices can, in fact, be successfully assembled, and such data should be submitted in a 510(k).

#### v. Exposure

Another concern relates to whether there are safety risks faced by a person with little (or no) measurable hearing loss who perceives difficulty with one or more of the four symptoms referenced in the mandated OTC labeling and purchases an OTC device. *See* 86 Fed. Reg at 58,178 (listing difficulty hearing conversations, difficulty using a telephone, fatigue due to listening, and need for increased volume as signs of perceived hearing loss). A significant body of research indicates that adults exposed to high levels of sound for long durations are at a significant risk of hearing loss. Overexposure to sound can cause both temporary and permanent hearing loss by damaging structures within the cochlea, including outer hair cells, the stria vascularis, and the supporting cellular structures.<sup>74</sup> As discussed above, persons with minimal or no measurable hearing loss who use hearing devices with no gain limit and 120 dB SPL output are at risk for noise-induced sensorineural hearing loss when they are listening at high output levels, as are individuals exposed to levels above 90 dB.<sup>75</sup>

Studies by Serra et al., Peng, et al., and Fligor and Cox report that in young adults, long-term use of personal listening devices with maximum output levels from 91-121 dBA increases the risk of noise-induced hearing loss.<sup>76</sup> Because many OTC hearing aids will have wireless functionality that allows audio streaming for speech and music, OTC hearing aids should be required to include technological safeguards, such as an automatic shut-off feature or volume decrease with a manual override, as well as labeling, to ensure safety and efficacy for hearing devices that are expected to be worn up to 12 hours per day. This method has been recommended by the WHO, which suggests that, in addition to written warnings, the device provide a visual and audible/vibratory warning and cue for action every time the user reaches 100% of the allowable output.<sup>77</sup> These hearing aids should include additional warnings that, at completion of a set time period (hours), the patient has exceeded a safe usage period and that there is a danger of permanent hearing loss. Upon either of these warnings, the patient would need to manually override the warning—a feature that should not be available in non-self-fitting devices but only in FDA-cleared self-fitting OTC hearing devices.

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<sup>74</sup> Cory D.F. Portnuff, Reducing the risk of music-induced hearing loss from overuse of portable listening devices: understanding the problems and establishing strategies for improving awareness in adolescents, *Adolesc Health Med Ther.* 2016;7:27-35 (Feb. 10, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4754097/>.

<sup>75</sup> Centers for Disease Control and Prevention (CDC)/ NIOSH Hearing Loss Prevention: Risks, <https://www.cdc.gov/niosh/programs/hlp/risks.html> (last visited Jan. 17, 2022); Occupational Safety and Health Administration (OSHA), Occupational Noise Exposure, <https://www.osha.gov/noise> (last visited Jan. 17, 2022).

<sup>76</sup> Mario R. Serra et al., Recreational noise exposure and its effects on the hearing of adolescents. Part I: An interdisciplinary long-term study, *Int J Audiol.* 2005;44(2):65-73 (Feb. 2005), <https://www.tandfonline.com/doi/abs/10.1080/14992020400030010>; Jian-Hua Peng et al., Risk of damage to hearing from personal listening devices in young adults, *J Otolaryngol.* 2007;36(3):181-185 (June 2007), <https://pubmed.ncbi.nlm.nih.gov/17711774/>; Brian J. Fligor and L. Clarke Cox, Output levels of commercially available portable compact disc players and the potential risk to hearing, *Ear Hear.* 2004;25(6):513-527, (Dec. 25, 2004), <https://pubmed.ncbi.nlm.nih.gov/15604913/>.

<sup>77</sup> Int'l Telecommunication Union, Guidelines for safe listening devices/systems, Rec. ITU-T H.870 at 41 (Aug. 2018); World Health Organization/WHO-ITU, Safe Listening Devices and Systems, at 13 (2019).

**d. QSRs are a Cost-Effective Measure to Maintain Safety and Effectiveness of OTC Hearing Aids.**

In the NPRM, FDA requests input on “potential revisions to the applicable QS requirements for OTC hearing aids.” 86 Fed. Reg. at 58,165. HIA supports the application of a complete set of QSR elements. None of the risks inherent in the use of hearing aids are reduced by adopting an over-the-counter distribution model, and nothing in this new distribution model suggests that QSRs are not necessary. Instead, the elimination of the learned intermediary arguably makes it even more important that FDA apply the complete QSR regulations to OTC devices, as OTC hearing aids lack the safeguard afforded by the extra level of safety and effectiveness provided by the hearing health professional’s expertise in selecting, fitting, and maintaining hearing aids. Without this safeguard, it is essential that OTC hearing aids remain subject to the QSRs in their entirety. There is no public health rationale for providing purchasers of OTC hearing aids with devices that are not subject to the same quality standards as prescription hearing aids.

Quality control is necessary to ensure the manufacture of reliable, safe, and effective hearing aids. Hearing aids are complex systems with complicated software and hundreds of components, including digital processors, microphones, receivers, battery components, and wireless chips that are routinely adapted and reengineered to provide ever more innovative devices for people with hearing loss. The QSRs provide an invaluable framework for controlling and managing the design and manufacturing processes to ensure quality while allowing manufacturing to occur at the current state of the art.<sup>78</sup> FDA oversight through QSRs helps promote adherence to pro-quality principles.

QSRs are even more important if FDA decides that most OTC hearing aids do not require 510(k) clearance, as a quality system is integral to providing reasonable assurance of safety and effectiveness. 86 Fed. Reg. at 58,165 (“Further, because hearing aids are medical devices, a quality system for medical devices specifically, as opposed to a quality system for consumer electronics more generally, is necessary to provide reasonable assurance of safety and effectiveness. This is because medical device quality systems address regulatory concerns regarding safety and effectiveness that systems for consumer electronics do not.”). Eliminating both premarket review and all FDA requirements governing product quality would be inconsistent with FDA’s avowed goal of ensuring the safety and effectiveness of OTC hearing aids. 86 Fed. Reg. at 58,150 (“In creating a regulatory category for OTC hearing aids and amending existing rules, we intend to provide reasonable assurance of safety and effectiveness for these devices.”).

As FDA itself noted, “hearing aids are medical devices,” and therefore “a quality system for medical devices specifically, as opposed to a quality system for consumer electronics more generally” is better-tailored to addressing “regulatory concerns regarding safety and effectiveness.” *Id.* at 58,165. HIA agrees. Though HIA appreciates that “FDA wishes to minimize regulatory burdens,” as explained above, the regulatory elements are fundamental building blocks of product quality. The lack of reported injuries with hearing aids reflects that

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<sup>78</sup> See generally 61 Fed. Reg. 52,602 (Oct. 7, 1996).

the QSRs have played an important role in maintaining the safety of hearing aids.

In analyzing whether to exempt OTC hearing aids from QSRs, FDA should consider the reasons the Agency implemented the QSRs in the first place. For example, FDA explained in rulemaking that “a significant proportion of device recalls were attributed to faulty design of product” and “approximately 44 percent of the quality problems that led to voluntary recall actions during this 6-year period were attributed to errors or deficiencies that were designed into particular devices and may have been prevented by adequate design controls.”<sup>79</sup> Software data further “indicated that over 90 percent of all software-related device failures were due to design-related errors, generally, the failure to validate software prior to routine production.”<sup>80</sup> None of these concerns, which certainly apply to hearing aids, are alleviated by an over-the-counter distribution model.

Consequently, HIA recommends that FDA require the full complement of QSRs for all hearing aid manufacturing—OTC or otherwise—including formal design control procedures, personnel training, production and process controls, compliance monitoring, corrective and preventative action requirements, and document controls. *See generally* 21 C.F.R. Part 820. Through its comprehensive control of devices, the QSRs help to ensure that device manufacturers address the multiple sources of device failures. Because most hearing aids are wireless class II devices, “their failure could adversely affect public health,” and “[e]ven firms with excellent past records put their consumers at future risk if their [controls] are inadequate.”<sup>81</sup> Thus, QSRs are not merely preferable but *necessary* for safe and effective manufacturing of these complex devices.

HIA further emphasizes that the “regulatory burden” of compliance with QSRs is not as significant as it might seem. HIA has surveyed members with regard to the burden of QSRs; these data reflect that, on average, the cost of QSR compliance is approximately 20 cents for a \$1000 hearing aid.<sup>82</sup> Patients may also see long-term savings accrue from robust quality systems, as the longevity of quality-controlled devices is expected to exceed that of devices without such requirements. Even if compliance with QSRs adds \$1 to the cost of a \$500 hearing aid—ten-fold the rate found in the HIA survey—these negligible savings would not be worth the risks imposed by cutting quality standards. And, as FDA explained in the QSR rulemaking, “literature on quality systems consistently states that firms implementing such systems, which begin with design controls, report cost savings in the long-run.”<sup>83</sup>

The presence of numerous hearing aid manufacturers already in the market reflect the minimal burden: As of November 2021, 78 establishments are currently FDA registered for manufacturing of wireless hearing aids under product code OSM and over 100 establishments for non-wireless under product code ESD—all of which are subject to the full panoply of QSR requirements. Clearly, experience shows that the QSRs can readily be incorporated into hearing

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<sup>79</sup> *Id.* at 52,602.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.* at 52,645.

<sup>82</sup> Testimony of David Fabry, HIA, Docket No. FDA-2015-N-4602 (Apr. 21, 2016); Comments of HIA, Docket No. FDA-2015-N-4602 (June 30, 2016). HIA recognizes that this survey data is several years old but notes that there have been no changes to QSR regulations or requirements since HIA performed this survey in 2016.

<sup>83</sup> 61 Fed. Reg. at 52,645.

aid manufacturing. And there is no evidence to suggest that requiring adherence to FDA regulations, including QSRs, or existing standards by future OTC manufacturers would have a negative impact on competition or consumer access.

As the Agency recognizes, “the quality system described in part 820” is “straightforward to implement” and flexible. Manufacturers can “develop and follow procedures and fill the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device.”<sup>84</sup> While the framework provides “essential elements” to ensuring safety and efficacy, QSRs do not dictate how manufacturers design and produce their products.<sup>85</sup> The specific ways in which QSRs are implemented largely is left to the discretion of the manufacturers.

QSRs represent an integral part of the general controls for any device presenting more than negligible risks. It is for this reason that FDA only exempts certain class I devices for which “the public health benefits gained did not exceed the costs of implementation,” but maintains them for class II and class III devices “because their failure could adversely affect public health.”<sup>86</sup> These general controls are designed to protect all users of devices, including ones sold over-the-counter.

As a modification to existing QSRs, HIA suggests that FDA integrate ISO 13485:2016 for hearing aids, which provides a harmonized international standard for medical device quality management. HIA recognizes that FDA is already “undertaking other separate efforts to minimize regulatory burdens for manufacturers by proposing the harmonization of part 820 with an international consensus standard,”<sup>86</sup> Fed. Reg. at 58,165, and HIA encourages these efforts. HIA further appreciates that the issues surrounding implementation of ISO 13485:2016 extend far beyond the hearing aid context. Nonetheless, HIA takes this opportunity to emphasize the global nature of and efforts to address hearing loss. The application of an international standard quality standard for OTC hearing aids would reduce any theoretical QSR barriers to entry for global companies, encourage additional market entry by international manufacturers, and modernize quality controls—all while providing assurances of safety and effectiveness standards.

**e. HIA Recommends Revisions to, and Usability Studies of, the Proposed Mandatory OTC Labeling.**

FDA relies heavily on labeling to ensure safe self-selection and use by the intended patient population. Importantly, because hearing health professionals will not be involved in selection or fitting of hearing devices, consumers will depend solely on the labeling to convey all necessary information regarding the safe and effective use of the device. Due to the reliance on labeling, FDA requires that all OTC devices include adequate directions for safe use with

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<sup>84</sup> FDA, Quality System (QS) Regulation/Medical Device Good Manufacturing Practices (Sept. 27, 2018), available at <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices>.

<sup>85</sup> *Id.*

<sup>86</sup> 61 Fed. Reg. at 52,645.

labeling specifically for the “layman;” prescription devices are exempt from this requirement.<sup>87</sup> FDA therefore must ensure that all directions for OTC hearing aids are “adequate.” To this end, HIA recommends revisions to strengthen and clarify the proposed labeling, as well as usability studies to ensure that patients can understand the extensive and complex labeling set forth in the proposed rule.<sup>88</sup>

To start, HIA points out that FDA omitted from proposed 21 C.F.R. § 800.30(c)(3) the requirement set forth in current 21 C.F.R. § 801.420(b)(2) to include the model name or number and the year of manufacture for both OTC and prescription hearing aids. FDA stated in the NPRM that proposed § 800.30(c)(3) and § 801.422(c)(3) provide “the requirement for the labeling on an [OTC or prescription] hearing aid itself, specifically, name of the manufacturer, model name or number, serial number, and year of manufacture . . . .” 86 Fed. Reg. at 58,175. However, only the serial number is required in the proposed 21 C.F.R. § 800.30(c)(3) and § 801.422(c)(3). *See* 86 Fed. Reg. at 58,182, 58,189. HIA recommends that FDA incorporate the requirement for the model name and number and year of manufacture into each regulation in the Final Rule.

### **i. Outside Labeling**

The proposed OTC hearing aid outside packaging labeling, set forth in proposed 21 C.F.R. § 800.30(c)(1), includes information necessary for purchasing the device. *See* 86 Fed. Reg. at 58,177. This information is of paramount importance, as it serves as the basis for enabling a patient to determine whether the OTC hearing aid inside the box is suitable for him or her. Consumers may base the decision to buy—or not buy—an OTC hearing aid on the information on the outer labeling. Similarly, they may base their decision whether to seek professional consultation on that information. For these reasons, the proposed outer packaging labeling includes a warning that OTC hearing aids are not for users under 18 years of age; a description of the symptoms of mild to moderate hearing loss; considerations for seeking a consultation with a licensed hearing health professional; and “Red Flag” conditions. *Id.*

HIA believes that additional details may be helpful in informing patient decisions with respect to purchasing OTC hearing aids. Specifically, HIA suggests the following modifications to 21 C.F.R. § 800(c)(1)(i):

- (B) Symptoms suggesting perceived mild to moderate hearing loss:**

The four scenarios included in proposed labeling may not only describe mild to moderate hearing loss but also may be present in persons with more severe hearing loss. For purposes of specificity, HIA suggests that the proposed OTC hearing labeling include more examples. Specifically, HIA proposes to *add* as examples of

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<sup>87</sup> 21 U.S.C. § 352(f); 21 C.F.R. §§ 801.5, 801.109.

<sup>88</sup> As referenced in Comments to this Docket by the American Academy of Audiology, poor understanding of medication labeling has been shown to contribute significantly to hospitalizations. Jennifer P. King et al., Developing consumer-centered, nonprescription drug labeling a study in acetaminophen. *Am J Prev Med.*, 40(6):593-8 (Jun. 2011).

perceived mild to moderate hearing loss:

- *Muffling of speech and other sounds;*
- *Difficulty hearing whispered conversations, dripping water, leaves rustling, or birds chirping;*
- *Difficulty understanding words, especially background noise or in a crowd;*
- *Difficulty hearing or understanding soft or high-pitched voices;*
- *Difficulty hearing consonants, especially the “S” and “F” sounds;*
- *Often misunderstanding what others say and responding inappropriately; and*
- *Frequently asking others to speak more slowly, clearly, and/or loudly.*

● **(C) Advice of availability of professional services:**

The existing proposed labeling provides examples of environments where the hearing loss may be more significant than mild to moderate, such as “cannot hear conversations in a quiet environment” or “trouble hearing loud sounds.” 86 Fed. Reg. at 58,178. HIA suggests that in addition to advising a patient to seek help in such a situation, the labeling should inform the patient to *return the device*, in an effort to address the “dresser drawer” phenomenon (see 86 Fed. Reg. at 58,160) and see a *licensed* hearing health professional if the patient has tried unsuccessfully to treat hearing loss with an OTC device. Therefore, HIA’s proposed revised labeling would state (proposed changes italicized, bolded, and underlined):

“This device may not be useful for more significant hearing loss or complicated hearing needs. If you cannot hear conversations in a quiet environment, or you have trouble hearing loud sounds—for example, loud music, motor vehicles, power tools, noisy appliances—this device may not help you hear better. If you try this device and continue to struggle with or remain concerned about your hearing, you should **return the device and** seek a consultation with a **licensed** hearing healthcare professional.”

## ii. Inside Packaging Labeling

With respect to the proposed inside packaging labeling, HIA suggests that FDA require patients be advised that additional supplies (e.g., domes, tips, batteries, wax guards) may be necessary and purchased for additional cost.

HIA also recommends revising specific language in proposed 21 C.F.R. § 800.30(c)(2)(i) as follows (proposed changes italicized, bolded, and underlined):

- **(B) “Red flag” conditions:** The proposed “Red flag” conditions advise patients to

consult with a licensed physician “prior to purchasing this device.” 86 Fed. Reg. at 58,179. This direction is confusing, as the hearing product has already been purchased. HIA suggests replacing that direction with:

You should promptly consult with a licensed physician, preferably an ear specialist if, at any time after purchasing this device, you have any of the following . . .

HIA recommends revising 21 C.F.R. § 800.30(c)(2)(iii) as follows:

- **(C) Advice to seek professional services:** The inside packaging labeling advises patients to seek medical help in the event of certain red flag conditions. HIA recommends including a statement that, should patients experience any muffled sounds, ear pressure (or “popping”) or aural fullness, ringing in ears, and/or changes in hearing after wearing the device, the patient cease using the OTC device immediately and seek professional assistance. The revised labeling would state:

**Note: If you remain concerned, consult a licensed professional.**

If you try this device and experience any muffled sounds, ear pressure (or “popping”) or aural fullness, ringing in ears, and/or changes in hearing when the device is not in use, cease using it immediately and seek professional assistance. If you continue to struggle with or remain concerned about your hearing, you should consult with a licensed hearing healthcare professional.

- **(D) Note about user expectations:** HIA believes that this section should include a statement that the specific device may not be sufficient or appropriate to address the needs of a given patient. Further, HIA recommends the addition of a clear warning pertaining to the use of OTC hearing aids above 110 dB SPL. The revised labeling would include:

**Note: Expectations about what a hearing aid can do**

**This hearing aid may not be appropriate to address the needs of all patients.**

A hearing aid will not restore normal hearing and may not completely eliminate difficulty hearing over in noise. Further, a hearing aid will not prevent or improve a hearing impairment resulting from a medical condition(s).

For many people, the use of a hearing aid may be more satisfactory with training or counseling because the device is

only one part of hearing habilitation.

Also, if you have hearing loss in both ears, use of hearing aids for both ears (bilateral hearing aids) may provide more benefit than just one hearing aid, especially in demanding listening situations—for example, noisy environments.

**Use of hearing aids at maximum outputs above 110 dB SPL increases the chance of harmful sound levels in the ear and additional hearing loss.**

The importance of strong labeling for patients cannot be emphasized enough. As FDA explains in a 2001 guidance document, patient labeling is the mechanism used to “inform[] patients or their lay caregivers about proper use, risks, and benefits of the device in language they can understand,” as well as their understanding of the device, its operation, care, and maintenance, and safety issues.<sup>89</sup> Where the patient “is not involved in the choice of the device,” such labeling may not be as important, but it is critical when the intended user is not familiar with the device and information.<sup>90</sup> For this reason, manufacturers seeking 510(k)s for devices to be used by consumers—even prescription devices—routinely provide data showing that consumers do understand and can follow the proposed labeling, and 510(k)-exempt manufacturers keep this data on file.<sup>91</sup>

Here, patients will rely on FDA’s proposed labeling to determine whether a hearing aid is indeed necessary, and, as noted, difficulties in self-assessing and self-reporting hearing loss are well-established.<sup>92</sup> Patients have noted concerns about their abilities to do so, as data suggests that hearing aid users are not confident in their ability to assess their hearing loss or select an appropriate hearing device.<sup>93</sup> Yet, in proposing the OTC hearing aid labeling, FDA did not cite any usability data it has compiled regarding patient understanding of how to use OTC hearing aids or the risks.<sup>94</sup>

Without human factors validation, HIA is concerned that the symptoms cited in labeling for mild to moderate hearing loss may not be sufficient for patients to accurately assess their hearing loss. Though HIA recognizes that the statutory standard of “perceived mild to moderate hearing loss” is subjective, self-assessment is difficult, and FDA must establish that the proposed

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<sup>89</sup> FDA, Guidance for Industry: Medical Device Patient Labeling, at 6 (Apr. 2001).

<sup>90</sup> *Id.* at 9.

<sup>91</sup> *Id.* at 45.

<sup>92</sup> Centers for Disease Control and Prevention (CDC), Vital Signs: Noise- Induced Hearing Loss Among Adults—United States 2011-2012 (Feb. 7, 2017),

[https://www.cdc.gov/mmwr/volumes/66/wr/mm6605e3.htm?s\\_cid=mm6605e3\\_w](https://www.cdc.gov/mmwr/volumes/66/wr/mm6605e3.htm?s_cid=mm6605e3_w) (A recent study reported by the CDC reported that “[h]earing loss often progresses for years before being self-perceived or diagnosed” and references two additional studies: C.G. Le Prell et al., Evidence of hearing loss in a “normally-hearing” college-student population, *Int J Audiol* 50(Suppl 1):S21–31 (Mar. 2011) and Christine Rota-Donahue & Sandra Levey, Noise-Induced Hearing Loss in the Campus, *Hear J* 69:38–9 (June 1, 2016)).

<sup>93</sup> MarkeTrak 10 (MT10), *infra* note 102.

<sup>94</sup> HIA submitted a request under the Freedom of Information Act for any analyses FDA may have performed assessing the proposed labeling of hearing aids, but the Agency responded that it could not identify any relevant documents. This suggests that FDA has not, in fact, performed or assessed usability testing.

labeling is sufficient to assist in such an assessment. As FDA recommends for any device labeling, both the Agency (for the proposed labeling language) and manufacturers (for specific additional labeling) should conduct individual in-depth interviews, focus group interviews, self-administered questionnaires, usability testing, and readability testing to verify potential lay users' comprehension of the medical device patient labeling and their ability to follow the instructions in the medical device patient labeling in order to operate the device.<sup>95</sup> Device labeling only supports safety and effective use of a device "if designed adequately," but that design must be validated.<sup>96</sup> Given the pivotal role labeling will play in device selection and usage, FDA must ensure that *any* labeling is validated through human factors studies. FDA has provided no reason why these usability studies can or should be waived for OTC hearing aids.

Finally, HIA requests clarity as to the proposed implementation period. Should most OTC hearing products fall under the category of self-fitting or exceed the exemption under 21 C.F.R. § 874.9—which will not be clear until the publication of the Final Rule—FDA will need to review hundreds of 510(k)s within that 240-day window. Consequently, there may be products on the market as of the rule effective date pending 510(k) review. HIA requests that FDA clarify how it will approach enforcement with respect to those products for which a 510(k) is pending at the expiration of that 60-day or 240-day period as applicable. FDA could and should exercise enforcement discretion here. Further, HIA asks that FDA clarify its expectations as to existing product upon publication of the Final Rule. In other words, HIA requests that FDA explain whether manufacturers will be expected to remove from the market existing product that requires a 510(k) during that 60-day window or merely refrain from introducing new product to market until the products are brought into compliance. 86 Fed. Reg. at 58,171 ("For hearing aids that . . . have been offered for sale but are required to submit a new 510(k) under 21 CFR 807.81(a)(3), compliance with the new or revised requirements applicable to the hearing aid, and obtaining 510(k) clearance if applicable, must be achieved before marketing the device on or after the effective date of the final rule."). This is particularly a concern, as FDA's goal to review 510(k)s in fiscal year 2022 is 108 calendar days, suggesting that FDA may not review pending 510(k)s within that 60-day window.<sup>97</sup>

HIA further suggests that FDA consider the inclusion of reduced labeling information inside the box, as long as the full Instruction for Use is available electronically. The product packaging could include detailed instructions guiding users to the relevant information. Electronic dissemination of labeling would allow manufacturers to bring labeling into compliance more quickly.

### **III. Preemption of State Laws Will Have Unintended Consequences that Hurt Consumers.**

As required by FDARA § 709, the NPRM addresses the issues of conflicting state laws

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<sup>95</sup> *Id.* at 44.

<sup>96</sup> FDA, Guidance for Industry: Applying Human Factors and Usability Engineering to Medical Devices, at 19 (2016).

<sup>97</sup> FDA, MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 at 2, <https://www.fda.gov/files/about%20fda/published/MDUFA---Performance-Goals-and-Procedures--Fiscal-Years-2018-Through-2022.pdf> (Dec. 2, 2016).

by preempting any state law that interferes with “commercial activity.” Specifically, FDARA § 709 precludes any state or local government from establishing or continuing in effect “any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of [OTC] . . . including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access [OTC] hearing aids.” FDARA §709(b)(4). To that end, the NPRM proposes to broadly preempt any state rules, including licensing requirements, specifically related to hearing aids (assuming they differ from the federal laws), thereby permitting the distribution of OTC hearing aids without any specialized training or licensing. 86 Fed. Reg. at 58,167-68. However, should a licensed professional publicize such licensure, all state requirements for licensees then apply. *Id.*

#### **a. Consumer Protections**

Though HIA appreciates the difficulty with which FDA must address a myriad of state regulations, FDA’s decision not to adopt consumer protections will have deleterious effects. Existing state hearing aid regulations provide extensive protections for consumers that will be preempted. Pursuant to FDA recommendation, states historically have required licensing for the fitting, dispensing, and sometimes sale of hearing aids, and, through those licensing provisions require consumer protection from potential problems arising from the purchase of hearing aids.<sup>98</sup> Indeed, these consumer protections, including receipt requirements, mandatory return policies, and assistive technology device warranties, are imposed specifically through state professional licensing laws and regulations. If these licensing provisions are preempted, HIA is concerned that, without analogous consumer protection provisions integrated into federal regulations, these consumer protections will be lost.

HIA encourages FDA to recognize—regardless of distribution model—the importance of consumer protections and establish a plan to preserve them for OTC purchasers. These provisions (specifically including receipt requirements, return periods, and warranties) do not interfere with access and can apply outside of a licensing structure, providing a crucial layer of protection for hearing aids patients—whether they use prescription or OTC hearing aids. FDA does recognize this point, stating that “we believe that a State or local requirement for retailers (persons who sell to end users) to accept returned OTC hearing aids would likely promote—rather than restrict or interfere with—commercial activity involving the devices by reducing the financial risk to purchasers” and, “[a]s such, generally, State or local requirements for returns would continue to apply provided they do not conflict with the final rule based on this rulemaking.” 86 Fed. Reg. at 58,160. However, HIA emphasizes that if licensing requirements do not apply to the sale of OTC hearing aids, neither do the return requirements in most states, as consumer protection requirements are contained in the professional licensing statutes and regulations that will be preempted.

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<sup>98</sup> See e.g., 225 ILCS 50/1 (“The purpose of this Act is to protect the deaf or hard of hearing public from the practice of dispensing hearing instruments that could endanger the health, safety and welfare of the People of this State. The Federal Food and Drug Administration has recommended that State legislation is necessary in order to establish standards of competency and to impose stringent penalties for those who violate the public trust in this field of health care.”).

Return requirements, for example—one of the most important consumer protections and one that HIA believes must be preserved to avoid the “dresser drawer” phenomenon, *see* 86 Fed. Reg. at 58,160—have been implemented in thirty-one states and the District of Columbia, but those requirements only apply to licensed hearing health professionals. Maine, for instance, mandates a 30-day “trial period” for hearing aids (or 60-day medical return), but that trial period is imposed only through professional regulations governing hearing aid dealing and fitting practice standards. Specifically, Maine law states “If within this trial period the purchaser notifies the dealer-licensee of the purchaser’s wish to cancel the transaction, *the dealer-licensee shall make a full refund* of the purchase price . . . .”<sup>99</sup> Even more expressly, Ohio law specifically states that “[a] *hearing aid dealer or hearing aid fitter licensed* under Chapter 4747 of the Revised Code, a physician . . . or an audiologist licensed under Chapter 4753 of the Revised Code who enters into a consumer transaction with a consumer *shall provide a refund* to the consumer if the hearing aid is returned to the dealer, fitter, physician, or audiologist not later than thirty days after its original delivery.”<sup>100</sup> Minnesota law likewise requires only that an “*audiologist or certified dispenser must provide* the buyer with a 45-calendar-day written money-back guarantee.”<sup>101</sup> In these states—and others with similar if not as explicit language—such return requirements would not be applicable to an OTC transaction by an unlicensed or undeclared licensed hearing health professional.

Given that purchasers will receive no support in assessing their hearing loss and selecting an appropriate hearing aid, return requirements arguably are *more* important for OTC patients than prescription. Without the guidance of a hearing health professional, patients are taking a risk that a given hearing product does not meet their needs or provide the necessary benefits.<sup>102</sup> An inability to return a hearing aid that does not provide a benefit may serve as a barrier to addressing their hearing loss, as even an OTC hearing aid remains a costly financial and psychological investment. Further, as the country continues to grapple with COVID-19 and as many industries have shifted to electronic platforms, remote purchases of hearing aids through the internet—a marketplace potentially more prone to fraud and deception—should be anticipated. Inadvertently preempting these consumer protection laws by preempting licensing requirements would have the perverse effect of discouraging the purchase of OTC hearing aids—a result directly contrary to Congress’s goals in enacting the legislation. The loss of the right to return the hearing aid makes it less likely that hearing loss patients will decide to explore or acquire hearing aids, even if it is available OTC.

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<sup>99</sup> Me. Rev. Stat. tit. 32, § 17305.

<sup>100</sup> Oh. Rev. Code § 1345.30.

<sup>101</sup> Minn. Stat. § 148.5198.

<sup>102</sup> It is important to recognize that a state-mandated return period plays an important role in encouraging consumers to take the difficult step in buying hearing aids. MarkeTrak 10 (MT10) data suggests that hearing aid users are not confident in their ability to assess their hearing loss or select an appropriate hearing device. Specifically, MT10 asked survey respondents about their level of comfort with certain tasks related to hearing aids, and respondents expressed the least amount of confidence in three areas where OTC purchasers will receive no support: Assessing their hearing loss, selecting an appropriate hearing aid, and troubleshooting problems.

HIA commissioned Az Marketing Research Inc. to conduct our most recent survey, an online survey to 20,072 households in October 2018. This representative sample, which is balanced and weighted to key U.S. census characteristics, reached 55,650 individuals of which 3,132 individuals reported hearing difficulty. Of this target population, 969 were hearing aid owners and 2,163 were hearing aid non-owners.

Similarly, forty-six states and the District of Columbia require a written receipt, bill of sale, or purchase agreement to accompany the sale of a hearing aid. This practice ensures that patients have been fully informed, in writing, of the terms of the sale, of the details of the hearing product purchased, and of any available recourse, such as a return period, applicable warranties and guarantees. The receipt, bill of sale, or purchase agreement provides notice to the purchaser of not only the identifying information of the hearing device, but also instructions for seeking assistance with device issues and the applicable return period.

As one example, Florida currently requires a licensee to disclose an itemized list of pricing related to the hearing aid and accompanying services and requires the seller (licensee), at the time of delivery of the hearing aid, to provide the purchaser with a receipt containing: the seller's signature and information, hearing aid details, specific condition of the hearing aid, length of any guarantee, and disclaimers that the hearing aid will not restore normal hearing nor will it prevent further hearing loss (required on both the packaging and contract).<sup>103</sup> Virginia law requires that each hearing aid be sold through a purchase agreement that includes seller (licensee) details, warranty terms, device identification, payment terms, nonrefundable fees, disclosure of the statutory right to return period, and disclosure that the seller is not a physician and that consultation is not a medical examination, opinion, or advice.<sup>104</sup> Minnesota requires that any oral statements made by a licensee regarding warranties, refunds, and services on hearing aids must be written into the contract of sale, along with a notation that a consumer rights brochure has been provided as required by law.<sup>105</sup> In these cases, the receipt, bill of sale, or purchase agreement (as required under state law) is the primary method of conveying consumer rights and protections to purchasers of hearing aids.

These protections are so important that FDA should provide a mechanism by which to preserve them upon preemption of state laws. HIA recommends that FDA itself adopt consumer protections, specifically requiring a hearing aid sale to be accompanied by a receipt and information relating to a warranty, as well as a mandatory return or trial period, in proposed 21 C.F.R. § 800.30 controls for hearing aids as a condition of sale under paragraph (g). Though such a step may be unusual for FDA, nothing in the FDC Act precludes such an exertion of authority. Far from it: Congress granted FDA broad authority to “describe the requirements under which the sale of over-the-counter hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.”<sup>106</sup> Construction of this expansive language to include consumer protection requirements, set forth by “the oldest comprehensive consumer protection agency in the U. S. federal government,”<sup>107</sup> clearly is reasonable.<sup>108</sup>

Alternatively, should FDA believe that such controls fall outside the scope of its authority to regulate the safety and effectiveness of medical devices, HIA proposes that FDA collaborate with FTC under its Memorandum of Understanding to create consumer protections that attach to

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<sup>103</sup> Fla. Stat. § 468.1245.

<sup>104</sup> 18 Va. Admin. Code § 80-20-220.

<sup>105</sup> Minn. Stat. § 148.5197.

<sup>106</sup> FDARA § 709.

<sup>107</sup> FDA, FDA History (June 29, 2018), <https://www.fda.gov/about-fda/fda-history>.

<sup>108</sup> See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 468 U.S. 837 (1984) (deferring to an Agency's reasonable interpretation of a delegating statute).

all sales of hearing aids.<sup>109</sup> FDA previously has taken the position that FTC has the authority to regulate medical devices, stating that the FDC Act does not “in any way limit, any other authority of FTC related to the regulation of the sale of devices, such as the authority provided to FTC under section 5 of the Federal Trade Commission Act to prevent unfair or deceptive acts or practices.”<sup>110</sup> FTC, looking specifically at the hearing aid market, further explained the basis for its authority to mandate a trial period for hearing aids in 1983, concluding that “there is an inherent risk of no significant benefit in every hearing aid sale,” and thus “every sale without a trial period is unfair,” which allows FTC to regulate pursuant to section 5 of the FTC Act.<sup>111</sup> Though FTC ultimately dropped its proposal to regulate hearing aids—specifically through the adoption of a mandatory trial period—it did so not because it lacked statutory authority to regulate but because a study at that time “convinced commission officials that the rule is unnecessary.”<sup>112</sup> Preempting the state laws that have protected consumers for decades represents a dramatic change in circumstances and make such rules more necessary than ever.

If FDA preempts these consumer protections at the state level and does not establish comparable federal protection, purchasers of OTC hearing aids will have less recourse than they currently do, which could inhibit sales. Stripping consumers of protection certainly was not the outcome Congress contemplated when it enacted the OTC hearing aid provisions.

### **b. Dichotomous Regulatory Systems**

HIA recognizes that FDARA requires FDA to preempt state licensing requirements for OTC hearing aids, but HIA is concerned about the effects of a dichotomous regulatory scheme for proclaimed licensees and other sellers on both patients and industry. The NPRM explains that FDARA will not preclude states from “regulating professional services such as speech pathology, audiology, or fitting” or the continuation of such professional services generally” but explains that any licensing requirements are preempted as applied to OTC devices. 86 Fed. Reg. at 58,166. However, any “person that purports to be a specially licensed professional or establishment would be subject to applicable State and local requirements,” potentially including “periodic professional examination or mandating the availability of testing equipment.” 86 Fed. Reg. at 58,167. In such a scenario, as soon as a licensed professional references credentials, all of the state licensing requirements once again take effect.

At its most basic, the preemption scheme as proposed sets up two regulatory tracks for the sale of OTC hearing aids: one for licensed professionals and one for retailers. While FDA is clear that state regulations requiring licensing for distribution of hearing aids are expressly preempted, licensees maintaining their prescription practices still will be subject to state regulations, even if they are selling or distributing OTC devices. This is because prescription devices are available only from a licensed professional, and if licensees intend to sell both, they

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<sup>109</sup> See FDA, Memorandum of Understanding between the Federal Trade Commission and the Food and Drug Administration, MOU 225-71-8003 (May 14, 1971).

<sup>110</sup> 42 Fed. Reg. 9286, 9286 (Feb. 15, 1977) (internal citations omitted).

<sup>111</sup> FTC, Hearing Aid Industry Reanalysis of Record and Revised Recommendations, at 285 (Apr. 14, 1983), [https://www.ftc.gov/system/files/documents/reports/hearing-aid-industry-staff-report-reanalysis-rulemaking-record-revised-recommendation-commission/r511006\\_hearing\\_aid\\_industry\\_staff\\_report\\_reanalysis\\_of\\_the\\_rulemaking\\_record\\_and\\_revised.pdf](https://www.ftc.gov/system/files/documents/reports/hearing-aid-industry-staff-report-reanalysis-rulemaking-record-revised-recommendation-commission/r511006_hearing_aid_industry_staff_report_reanalysis_of_the_rulemaking_record_and_revised.pdf).

<sup>112</sup> Randolph E. Schmid, FTC Considers Dropping Proposed Hearing Aid Rule (Aug. 8, 1985).

*must* announce that they are licensed. FDA seems to believe that reference to such credentials is optional, *see* 86 Fed. Reg. at 58,158 (“If a person purports to be a licensed professional or business . . .”), but this is a critical misunderstanding: At least 30 states require licensees, *as a condition of maintaining their license*, to prominently and conspicuously display licenses in their establishments.<sup>113</sup> Licensed professionals in these states therefore, by nature of *having* a license, would be subject to all licensing requirements, “even if such an audiologist or fitter only sold OTC hearing aids.” 86 Fed. Reg. at 58,168. Further, it is not clear whether the reinstated state licensee requirements would extend to the entire establishment or only to the specific licensed professional with credentials on the wall.

Such a scenario, in which licensed professionals are subject to different regulatory requirements than retailers for the sale of the exact same product, puts licensed professionals at a significant competitive disadvantage due to the increased compliance costs and regulatory burdens. Additionally, such a scheme inherently would cause confusion amongst both patients and licensed professionals. But more than that, it simply is nonsensical to impose recordkeeping, fitting, programming, and other requirements on the sale of OTC hearing aids only because the salesperson *also* sells prescription hearing aids and displays a license on the wall.

Further, the re-imposition of licensing requirements upon any declaration of licensing would result in an even more problematic outcome: Creating an additionally dichotomous system wherein only patients who buy OTC hearing aids from state license-holders receive the benefits of existing pro-consumer regulation and oversight, whereas patients who buy the same OTC hearing aids elsewhere are left unprotected. Because, as explained, consumer protections flow through the licensee, patients who purchase from different retailers could be entitled to different consumer protections, which is both confusing and patently unfair to the (typically vulnerable, elderly) patient, who likely will have no understanding of the differing protections based on seller. Moreover, licensees will be forced to charge higher costs to comply with professional requirements, including consumer protections, requiring, in turn, patients to essentially pay a premium for consumer protection. And those higher compliance costs might provide incentives for retailers that currently offer professional services to discontinue them, which, in turn, would make it more difficult for patients to seek help. That is, FDA’s system could deprive consumers of the choice of buying off the shelf or talking to a hearing professional at retailers that would otherwise have both options. None of these scenarios are conducive to patient access.

HIA suggests that, in concert with the adoption of federal consumer protections, FDA preempt licensing requirements as applied to *all* sales of OTC hearing aids, regardless of the licensing status of the seller. In other words, HIA proposes that all sales of hearing aids that meet the special controls for OTC distribution as set forth in proposed 21 C.F.R. § 800.30 should be exempt from requirements arising from that license; licensing requirements remain in place for sales of prescription hearing products.

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<sup>113</sup> See e.g. Ariz. Rev. Stat. § 36-1907 (“A licensee shall conspicuously post a license issued pursuant to this chapter in the licensee’s office or place of business.”); S.D. Codified Laws § 36-24-30 (“The license required by Sec. 36-24-16 shall be kept conspicuously posted in the licensee’s office or place of business at all times. A violation of this section is a Class 2 misdemeanor.”); 28 Pa. Code § 25.208 (“A registrant shall display the dealer’s or fitter’s registration certificate at the place of business listed in the registrant’s application.”).

### c. Preemption Ambiguity

Importantly, HIA is concerned that there is ambiguity in the preemption scheme, and that this ambiguity will create confusion and uncertainty, both from the perspective of the state regulators and the dispensers. While the NPRM provides numerous examples that are helpful in interpreting the application and extent of preemption, those examples are not—nor can they be—comprehensive. There are many unanswered questions about the application of preemption that inevitably will arise, and FDA should provide greater clarity in the Final Rule, as well as establish a mechanism to address both state and industry concerns.

It is not clear, for example, how broad the term “generally applicable” is interpreted: if there is a subset of products regulated under a given law, would FDA consider that “generally applicable” as cited in section III.B of the NPRM? *See* 86 Fed. Reg. at 58,158 (“FDA does not interpret section 520(q)(1)(A)(v) of the FD&C Act or section 709(b) of FDARA as preempting a State’s ability to establish or continue in effect generally applicable State business or professional licensing requirements.”). Twenty-two states include hearing aids under state trade laws governing warranties for assistive technology devices, alternatively referred to as “lemon laws” in some states, which require an express warranty that the device will be free from any condition or defect that substantially impairs the value of the device to the patient. These warranties are critical but often apply only to a subcategory of products, such as hearing aids or wheelchairs;<sup>114</sup> given the limited application of these provisions, it is not clear whether the subcategory would constitute “generally applicable” or would be preempted. The latter outcome, of course, would be to the detriment of purchasers.

Based on the NPRM, it seems like assistive technology device warranties would not be preempted regardless of the fact that they may not be “generally applicable” because they do not interfere with or restrict patient access to OTC hearing aid commercial activity, but the dividing line as to what constitutes “interference” or would result in a “restriction” under the NPRM remains unclear. Indeed, the NPRM recognizes that state requirements for retailers to “accept returned OTC hearing aids would likely promote—rather than restrict or interfere with—commercial activity involving the devices by reducing the financial risk to purchasers” and consequently “local requirements for returns would continue to apply provided they do not conflict with the final rule based on this rulemaking,” regardless of the fact that such return requirements are applicable only to hearing aids. 86 Fed. Reg. at 58,160.

But this assessment of “restrict” or “interfere with” is subjective. Retailers, for example, might conclude that return requirements interfere with *their* distribution of the device, as such requirements make distribution chains more complicated and potentially more expensive. And warranty requirements would, by mandating servicing of an OTC device, interfere with both servicing of OTC devices and commercial activity. Retailers could argue that both discourage the sale of such devices by increasing prices for patients. Conversely, patients, like FDA, would argue the opposite: Return and warranty policies inherently are pro-consumer and thus do not interfere with commercial activity. Thus, the standard for “restrict” or “interfere with” is nebulous, creating significant uncertainty. It is important that FDA provide greater clarity in the Final Rule to avoid subsequent confusion; to that end, HIA suggests that FDA define “restrict or

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<sup>114</sup> *See e.g.* Or. Rev. Stat. § 646A.460 et seq.; Me. Rev. Stat. Ann. tit. 10, § 1500(1); Mo. Rev. Stat. § 407.950(1).

interfere” to mean “**present actual legal or procedural impediment to the exclusion of business disincentives.**”

Further, state law does not distinguish between “OTC” and prescription hearing aids because, before now, no OTC hearing aids existed; thus, state regulations, which apply broadly to “hearing aids” generally, may be preempted as conflicting with, interfering with, or restricting commercial OTC hearing aid activity. For example, many states, such as Rhode Island and New York, require registration (or licensing) for the sale or offer of “hearing aids” generally.<sup>115</sup> In these cases, however, it is not clear whether the entire state law would be preempted or only to the extent that such laws are applicable to OTC hearing devices. In other words, if state laws are not severable, these laws could be preempted as applied to *all* hearing aids, and, in that case, state regulations governing *prescription* hearing aids may also be preempted. If the laws in Rhode Island and New York are not severable, preemption this would leave no licensing or registration requirement, even for prescription hearing aids. Of course, severability depends on the state legislation at issue, and this variability could leave prescription hearing aids in some states subject to no regulation while the same hearing product in other states subject to extensive regulation. And, given the widespread interstate sales and distribution of hearing aids, this could lead to mass confusion in industry and unintentionally introduce extreme inconsistency in state regulation.

There currently are hundreds of state laws and regulations that apply to hearing aids. Because it is impossible for FDA to foresee all disputes about whether any particular state law restricts or interferes with commercial activity, HIA recommends that FDA take a bright-line approach to preemption. That is, HIA suggests that FDA preempt state requirements pertaining directly to the hearing aid device; states could still retain any licensing requirements that are not specific to the hearing device itself (*i.e.*, governing the capabilities, education, and practices for assessing hearing) while prescription hearing devices would remain subject to general state prescription device distribution laws (which, of course, mandate recommendation from a medical professional to distribute any prescription device), with potential modification specifically for prescription hearing aids as the state sees fit. This proposal, however, requires the development and adoption of a federal consumer protection scheme for hearing aids under either the aforementioned FDA or FTC authority; HIA cautions that preemption of all state consumer protections, as discussed earlier, without the adoption of comparable federal consumer protections would be extremely detrimental to patients.<sup>116</sup>

Alternatively, FDA could set up an informal process by which the states and state licensing boards could pose questions to the Agency about regulations that might be preempted for restricting or interfering with federal law. States, before exercising enforcement authority, could consult with FDA about the continued effect of that specific law, and, upon an Agency assessment, request an Advisory Opinion under 21 C.F.R. § 808.5 as to whether a given provision remains enforceable. While this system may create additional burdens for the Agency,

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<sup>115</sup> See e.g., 5 R.I. Gen. Laws § 5-49-2; NY Gen. Bus. Law § 790.

<sup>116</sup> HIA recognizes that this approach may be considered a major change from the NPRM that requires an additional period of Notice and Comment but emphasizes the importance of these protections. Nevertheless, HIA cautions that FDA should refrain from finalizing OTC hearing aid rules without addressing these consumer protection concerns, as these significant issues cannot be left unaddressed.

having a mechanism for prompt feedback would serve to reduce uncertainty for both states and manufacturers. Furthermore, given the extensive review and revision to state law that is necessary for states to continue effectively regulating hearing aids, FDA should adopt a formal transition period providing both states and licensees opportunity to assess and pose questions about the new regulatory landscape. It would also minimize the litigation that would otherwise likely result due to the lack of clear boundaries.<sup>117</sup> These preemption provisions will necessitate changes at the state level. These changes, whether through statute, regulation, or policy, cannot be adopted and implemented in 240 days.

In any case, FDA should coordinate with the FTC as discussed to ensure that patients' interests—particularly with respect to trial periods, warranties, and receipt requirements—remain protected in the absence of state protections. Patients need to know both that hearing devices are safe and effective and that their risk in making such a purchase is protected. Congress has given FDA authority to address these concerns by adopting regulations for hearing aids at the federal level and in so doing, provided leave to ensure the strongest consumer protections apply nationwide. And, as FDA recognizes in the NPRM, consumer protections are essential to ensuring the safety and effectiveness of OTC hearing aids and support, rather than impede, access. 86 Fed. Reg. at 58,160. Thus, FDA and, where necessary, FTC, should ensure that consumers continue to be protected by attaching certain consumer protections to the hearing device, as well as put in place adequate processes and resources to address questions regarding the application of preemption provisions so that interested parties may seek clarity in any necessary updates to their individual regulatory structures.

#### **IV. Conclusion**

In conclusion, HIA suggests that FDA:

- Define terms with more precision, particularly with respect to self-fitting;
- Adopt a 510(k) requirement for all OTC hearing aids, even those that are not self-fitting, to provide assurances of safety and efficacy;
- Modify the proposed technical standards such that, among other things, maximum output is decreased, and maximum gain is established;
- Revise the proposed labeling to provide additional safety instructions and reflect risk;
- Preempt all licensing requirements for OTC hearing aid sales regardless of the seller; and
- Adopt federal consumer protection standards for all hearing aids.

HIA strongly supports the introduction of safe and effective OTC hearing aids in the United

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<sup>117</sup> Licensees already have brought numerous suits concerning federal preemption of state laws, and courts have not been in agreement regarding the outcome. In *Taylor v. Polhill*, for example, the Eleventh Circuit determined that Florida hearing aid licensing and distribution requirements are not preempted by federal law. *Taylor v. Polhill*, 964 F.3d 975 (11th Cir. 2020). Conversely, a 2014 case from the United States District Court for the Eastern District of Texas determined that Texas state licensing laws are preempted by federal law. *METX, LLC v. Wal-Mart Stores Texas, LLC*, 62 F. Supp. 3d 569 (E.D. Tex. 2014). Given the scope of the new law, it is foreseeable that there would be far more litigation in the future.

States. We appreciate the opportunity to provide comments on this NPRM, and we look forward to the publication and implementation of the Final Rule that will allow this objective to be realized.

A handwritten signature in black ink, appearing to read "Kate Carr".

Kate Carr  
President  
Hearing Industries Association