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RE: Over-the-Counter Hearing Aids and Federal Preemption of Consumer Protections Under State Law

Dear Ms. Amin:

As the national trade association representing manufacturers of hearing aids, assistive listening devices, component parts, and power sources, the Hearing Industries Association ("HIA") has long been committed to the safety and effectiveness of hearing aids, as well as ensuring consumer protection and satisfaction for all hearing aids wearers. HIA appreciates the commitment of FDA to maintaining these same high-quality standards for OTC hearing aids, as the proposed OTC model will not necessarily represent a major shift in technology, but primarily a new mechanism of distribution. HIA understands the statutorily-mandated need to revisit federal and state regulations to accommodate the new OTC hearing aid category. At the same time, HIA strongly believes that the important consumer protections currently provided by state regulations must be maintained.

Section 709 of the FDA Reauthorization Act (FDARA) states that:

> No State or local government shall establish or continue 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 over-the-counter hearing aids (as defined in section 520(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), as amended by subsection (a)) through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations promulgated under this subsection, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids.

Given the complexities of addressing the preemption provision included under FDARA, HIA conducted a review of hearing aid laws and regulations of the fifty states plus the District of Columbia to understand the potential impact on existing state regulatory structures and – importantly – on consumer protections. From this research, there are five primary areas of consumer protection that stand out: (1) licensing; (2) receipt requirements; (3) return period; (4) promotion and advertising; and (5) assistive technology device warranties. To assist the Agency as it works to promulgate proposed OTC rules, we have provided analysis and illustrative examples of each area of consumer protection which states have deemed important in regulating the hearing aid market, and provided recommendations where appropriate.

As FDA promulgates proposed regulations for an OTC hearing aid category, the Agency should preserve existing state consumer protections, as discussed below, and in some instances attach these critically important consumer protections to the device itself to codify these state-level protections at the federal level. It would truly be unfortunate if efforts to increase accessibility and lower costs resulted in the loss of the important state consumer protections that now exist, which could lead to less utilization of hearing aids.

I. State-Based Consumer Protections

A. Licensure Requirements

FDA maintains regulatory authority over the safety and effectiveness of hearing aids as medical devices, and, as part of that responsibility, regulates their review, labeling, and conditions of sale. At the same time, states, with significant interests in protecting the health, safety, and wellbeing of their citizens, have historically used their licensing authority over the fitting, dispensing, or sale of hearing aids to protect patients from potential problems arising from the purchase and use of hearing aids.[1] Importantly, most state provisions do not regulate the device itself, but rather regulate hearing aids

[1] Additionally, some states also regulate the sale of hearing aids outside of licensing statutes, through commercial codes, business, and trade laws.

through the licensee as provided under state hearing aid sales and practice statutes. As such, many important consumer protections that apply to hearing aids flow through the licensee. For example, as part of licensing requirements, license-holders must comply with receipt and disclosure requirements; mandatory return periods; promotion and advertising restrictions; and other important consumer protections. However, given the pendency of the forthcoming Over-the-Counter ("OTC") hearing aid rules, HIA is concerned that the preemption of state rules could undermine these important consumer protections because licensed personnel will not be involved in hearing aid sale and distribution. The undermining of consumer protections is not the result Congress intended. As explained in the 2018 Consensus Paper issued by the hearing care professional provider groups and endorsed by HIA, FDA and the FTC should ensure that consumers continue to be protected and put in place adequate processes and resources to enforce these protections.[2]

Many states have articulated and codified their interest in maintaining strong consumer protections for hearing aids through state practice acts, including regulation of the practice of the licensee and the device itself by requiring certain disclosures with a sale, provision of return periods and warranties, and using licensing laws to ensure protection against deceptive advertising for consumers. Succinctly, the introduction to Florida's licensing statute "recognizes that a poorly selected or fitted hearing aid not only will give little satisfaction but may interfere with hearing ability and, therefore, deems it necessary in the interest of the public health, safety, and welfare to regulate the dispensing of hearing aids in this state." This is equally true for OTC hearing aids. Florida, in recognizing the crucial balance between access and consumer protection, further notes that "restrictions on the fitting and selling of hearing aids shall be imposed only to the extent necessary to protect the public from physical and economic harm, and restrictions shall not be imposed in a manner which will unreasonably affect the competitive market."[3]

While states may include these consumer protections under their individual professional licensing structures, they clearly recognize the importance of ensuring transparency in the purchasing process, providing consumers with all relevant information when purchasing a medical device, and – importantly – recourse if the device does not provide a benefit. Additionally, while hearing loss is not specific to one age group, hearing loss disproportionately affects the older, more vulnerable adult population. The application of strong consumer protections for all hearing aid devices is essential, regardless of mode of distribution. After all, by creating an OTC hearing aid category, Congress intended to increase access in a manner that benefits consumers, not harms them.

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[2] Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness. Consensus Paper from Hearing Care Associations. August 2018. The Consensus Paper was issued by the American Academy of Audiology (AAA), Academy of Doctors of Audiology (ADA), American Speech-Language and Hearing Association (ASHA), and International Hearing Society (IHS), and includes five recommendations for the FDA to ensure safety and efficacy of the new OTC hearing aid category. Those recommendations include product requirements, inside- and outside-of-the-box labeling requirements, risk classification and 510(k) requirements, and strong consumer protection laws. The Consensus Paper was endorsed by HIA.
https://www.audiology.org/sites/default/files/advocacy/federal/documents/ConsensusPaper_OTC_HA.pdf

[3] Fla. Stat. § 484.0401

The states have determined that consumers who buy hearing aids need protections as purchasers that are separate and apart from the device-related protections already provided by FDA. However, depending on how FDA crafts the preemption regulations mandated under FDARA, there is the possibility that many of these consumer protections will be preempted along with state licensing provisions for the new OTC hearing aid category. Because those protections flow through the licensee rather than apply directly to the device, the creation of the OTC hearing aid category – which bypasses state licensing requirements – will obviate these consumer protections. Indeed, maintaining traditional state licensing protections for hearing aids purchased from licensees, while exempting OTC devices, would result in fewer protections for the consumer purchasing OTC, while mandating stricter and more costly consumer protections (i.e. professional penalties) to state-license holders. This would create a dichotomous system wherein only consumers who buy from state license-holders receive the benefits of existing pro-consumer regulation and oversight, whereas consumers who buy an OTC product, are left unprotected. Should FDA preempt the entire state licensing system for hearing aids, then these state protections will cease to exist altogether, to the detriment of consumers.

To address this issue, as FDA considers the preemption of state laws and regulations for an OTC hearing aid category, the Agency should preserve important consumer protections for the OTC category by attaching them to the device itself to codify these protections at the federal level. In the alternative, the Agency should explicitly state the authority of states to do so if FDA chooses instead to leave additional consumer protections to the states (outside of licensing provisions).

As the Agency applies the preemption provision, HIA encourages FDA to consider – regardless of distribution model – the importance of consumer protections that many states apply to traditional hearing aids through licensing provisions. These provisions (including receipt requirements, return periods, and promotion and advertising) do not restrict or interfere with access, and can apply outside of a licensing structure, providing a crucial layer of protection for consumers of hearing aids as medical devices – whether obtained through the traditional model or under the new OTC hearing aid category. Additionally, we urge FDA to narrowly tailor its preemption language to ensure that all hearing aids maintain consumer protections that are currently codified inside and outside of the licensing structure, including State assistive device warranty laws, deceptive trade laws, and other consumer protections.

B. Receipt Requirements

While not federally mandated, forty-six states and the District of Columbia require that some type of written receipt, bill of sale, or purchase agreement accompany the sale of any hearing aid.[4] The purpose of such requirement is based in consumer protection: it is intended to ensure that the purchaser has been fully informed, in writing, of the terms of the sale, of the details of the product purchased, and of any available recourse, such as a return period, applicable warranties and guarantees. Because these consumer protections in no way diminish access and are so important to the category of product – regardless of whether the device is a traditional or OTC hearing aid – HIA encourages FDA to consider

[4] A hearing aid, as defined by FDA, is as any wearable product intended to aid or compensate for impaired hearing. *See* 21 C.F.R. § 801.420 (defining hearing aid).

adopting receipt requirements on a federal level for the new OTC hearing aid category, or, in the alternative, make clear that existing or future state laws and regulations requiring certain disclosures are not preempted by the implementation of OTC hearing aid regulations.

In states that require a receipt, bill of sale, or purchase agreement accompany the sale of a hearing aid, there are several common disclosures that must be included. Those disclosures are: (1) licensee's signature and license number, (2) business address of the seller, (3) device specifications (i.e. make, model, and serial number of the device), (4) full terms of sale (i.e. purchase price, services), (5) condition of device (i.e. whether the device is "reconditioned" or "reused"), (6) terms of any guarantee or warranty, (7) specific duration of any trial period or right to return/cancel the sale, and (8) an instructional brochure.

The receipt, bill of sale, or purchase agreement provides notice to the purchaser of not only the identifying information of the 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 licensee, at the time of delivery of the hearing aid, to provide the purchaser with a receipt containing: the seller's signature; business address; license or certification number; brand, model, manufacturer identification code, and serial number of the hearing aid; specific condition of the hearing aid; length of time the hearing aid is guaranteed; 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).[5] Under Virginia law, each hearing aid shall be sold through a purchase agreement that includes: licensee's business address, license number, business phone number, signature; a clear statement of whether a hearing aid is "used" or "reconditioned" and any terms of warranty; the name, model, and serial number of the device; full purchase price; payment terms; any nonrefundable fees; disclosure of the statutory right to return period; and disclosure that the licensee is not a physician and any representations made are not a medical examination, opinion, or advice.[6] In Minnesota, any oral statements made by audiologists or certified dispensers regarding warranties, refunds, and services on hearing aids must be written into the contract of sale. The audiologists or certified dispenser must also provide the purchaser with a consumer rights brochure at the time of sale and notate in the contract of sale that this brochure has been provided.[7]

Certain states require the inclusion of additional items in a receipt, bill of sale, or purchase agreement. For example, in addition to the standard disclosures listed above, Arizona law also requires that the bill of sale include language verifying that the purchaser has been informed about audio switch technology and proper use of said technology, and must also inform the purchaser of Arizona's telecommunications equipment distribution program providing assistive telecommunications devices to residents with hearing loss.[8] Likewise, Connecticut requires every receipt, contract, or order for a hearing aid to include conspicuous disclosure that any purchaser who leaves a deposit of $100 or more with a seller is entitled

[5] Fla. Stat. § 468.1245.
[6] 18 V.A.C 80-20-220.
[7] Minn. Stat. § 148.5197.
[8] Ariz. Rev. Stat. § 36-1909.

to cancel that order if the purchaser is unable to inspect the hearing aid at the seller's place of business within 45 days and that the purchaser has the right to cancel the purchase for any reason at any time within 30 days after receiving the hearing aid.[9] 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. As such, these provisions are critical to protect consumers, many of whom are vulnerable due to age or cognitive impairment.

Because states primarily impose receipt requirements through the licensee (again, included under comprehensive practice statutes that govern all aspects related to hearing aids), certain existing receipt requirement laws and regulations would not carry over from traditional hearing aids to the new OTC category, as the sale of OTC hearing aids will not be limited to licensed individuals. But, notwithstanding the license status of the seller, it is important for hearing aid patients – including OTC hearing aid patients – to have a clear record of sale that includes:

1) Address of the seller
2) Device information (i.e. make, model, serial number)
3) Condition of device (i.e. "new," "reconditioned," "reused")
4) Terms of any guarantee or warranty
5) Right to return or right to cancel an order (discussed in the next section)
6) Notice that the purchaser has been provided an instructional brochure

States have decided that these protections are necessary for hearing aid users; FDA should not eradicate those protections when establishing a new category of hearing aid. Whether patients use OTC or traditional hearing aids is irrelevant to their need for such protections given the risks associated with the use of an inappropriate hearing device. Additionally, there is much that is unknown about the products that will enter the OTC market or how they will be marketed, and FDA and the FTC should take the opportunity to ensure strong state consumer provisions that have protected individuals with hearing loss continue.

HIA recommends that FDA include consumer protections, including receipt requirements, in its regulatory framework for OTC products. Alternatively, HIA suggests that FDA clearly preserve state authority to impose consumer protections so long as they do not restrict or interfere with access to OTC hearing aids or require the involvement of a licensed person.

C. Return Period

Thirty states, plus the District of Columbia, have laws or regulations specifying a time period for a purchaser to return a hearing aid. The return period (also referred to in other terms, such as a "trial period," "right to return," or the "right to cancel") is an important consumer protection put in place to prevent consumers from purchasing a hearing aid product that does not provide a benefit, does not meet expectations, or fits incorrectly.

[9] Conn. Gen. Stat §20-402a.

Accordingly, the majority of states, representing nearly 70 percent of the U.S. population, has recognized the importance of ensuring a hearing aid is suitable for an individual's needs and therefore determined that disclosure of the right to return a hearing device, including all of the applicable conditions, is an essential consumer protection. Such a right is based on the recognition that hearing aids are not one-size-fits-all technologies, and that consumers are less likely to buy hearing aids if, upon using them, the product does not provide the desired results. These considerations are important for consumers regardless of whether they purchase a hearing aid from a professional or OTC. Arguably, the return period is even more important with OTC hearing aids because in most cases, consumers will not have an opportunity to try the product before purchase.

In Virginia, a purchaser or lessee of a hearing aid is entitled to return a hearing aid for any reason (provided it is in satisfactory condition) within 30 days of the date of delivery. The purchaser is entitled to a full refund or replacement, less a reasonable charge for medical, audiological, and hearing aid evaluation services provided.[10] Colorado is similarly situated; it provides a minimum 30-day rescission period in which the buyer has the right to cancel – for any reason – by giving written notice, which entitles the buyer to a full refund for an undamaged device under Colorado's deceptive trade practices statute.[11] Likewise, Massachusetts regulations require a 30-day trial period that starts after the date of receipt. The purchaser can cancel the purchase by either returning the hearing aid or submitting a notice of cancellation by certified mail to the seller and physically returning hearing aid within 10 days. Massachusetts, like many states, includes in its regulations a tolling provision such that the trial period may be stayed pending hearing aid repairs or adjustments.

Minnesota law provides a 45-calendar day minimum guarantee and a buyer right to cancel upon receipt of the hearing aid. If a hearing aid is returned, the seller has 30 days to provide the refund with a cancellation fee limited to no more than $250. Likewise, California provides that all new and used hearing aids must be accompanied by a written warranty with language stating that the hearing aid is specifically fit for the needs of the buyer, and, should the hearing aid for any reason not meet the needs of the buyer, it may be returned within at least 45 days for adjustment or replacement, or a refund.[12]

Maine includes an additional protection for purchasers to return a hearing aid for medical reasons. While Maine provides for a 30-day trial period, entitling the purchaser to a full refund other than the costs of any ear molds and lab fees, a consumer can cancel within 60 days of delivery under certain circumstances. [13]

[10] Va. Code § 54.1-1505.
[11] Col. Rev. Stat. § 6-1-701.
[12] Cal. Civ. Code § 1793.02.
[13] M.R.S. Title 32, § 17305.

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)[14] data suggests that hearing aid users are not confident in their ability to assess their hearing loss or select an appropriate device. Specifically, MT10 asked survey respondents about their level of comfort with certain tasks related to hearing aids, including: (1) assessing their hearing loss, (2) selecting an appropriate hearing aid for their needs, (3) getting started using the hearing aid (i.e. inserting), (4) using the feature to adjust settings, (5) cleaning/maintaining the hearing aid, and (6) troubleshooting. Respondents expressed the least amount of confidence in two areas where OTC purchasers will receive no support: assessing their hearing loss and selecting an appropriate hearing aid. Given this response, preserving a right to return for all hearing aid consumers is clearly of paramount concern. Preserving the right to return is also an essential part of promoting access. With so many consumers lacking confidence in their ability to assess their own hearing loss or select a hearing aid, the loss of the right to return the hearing aid makes it less likely they will decide to explore or acquire hearing aids, even it if is available OTC.

Even an OTC hearing aid may still be a costly investment, both financially and psychologically.[15] Without the guidance of a hearing professional, consumers are taking a significant risk that a given product does not meet their needs or provide the necessary benefits. An inability to return a device that does not provide a benefit may serve as a barrier to addressing their hearing loss in the first instance. Preempting state return laws may also deter patients from seeking professional help after already investing in hearing aids that can neither be used nor returned. An unsuccessful experience with a hearing aid that cannot be returned may wrongly convince consumers that hearing aids are not a viable option for them.

States have determined that patients should be afforded the opportunity to return a device, and there is no evidence that Congress intended to preempt the important consumer protections embedded in the return period. Indeed, the preemption provision was intended to address state laws that *interfere* with or *restrict* consumer access to hearing aids; return periods do no such thing. Preserving the return period for hearing aids actually promotes access by guaranteeing consumers the right to return a product that does not work for them so that they may find a product that does. Establishing a broad preemption provision that encompasses these consumer protection laws would have the perverse effect of discouraging the purchase of OTC hearing aids – a result directly contrary to Congress' goals in enacting the legislation. Additionally, given the multiple pathways to access OTC hearing aids, including by mail and online, consumers need to have options to return their product. Indeed, as the country

[14] MarkeTrak 10 (MT10) is an online survey commissioned by the Hearing Industries Association every three to four years with comprehensive findings on the estimated incidence of hearing loss within the U.S., household income and education related to hearing aid use, satisfaction with hearing instruments, new user rates by age, physical health effects of hearing loss, and more. MT10 was an online survey to 20,072 households in October 2018. This representative sample, 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.

[15] MarkeTrak 10 found that the average person is aware they have a hearing impairment for approximately 12 years. Once aware, it takes an average of four to five years to see a hearing care professional. Even then, it may take a person an additional 6 years to take the next step to obtain a hearing aid. Powers, T. and Rogin, C. "MarkeTrak 10: Hearing Aids in an Era of Disruption and DTC/OTC Devices." *Hearing Review*, August 2019, 13.

continues to grapple with COVID-19, many industries have shifted to electronic platforms and providing online resources and products, including the medical space. Going forward, as consumers seek to reduce COVID-19 exposure, they may be more likely to buy hearing aids over the internet – a marketplace potentially more prone to fraud and deception – and need to know they can return their product. For this reason, HIA requests FDA draft the provision relating to preemption so that it does not preempt state-mandated right to return, or, alternatively, implement a federal right to return for the entire device category. Otherwise, the proliferation of online sellers of hearing aids will mean a reduction in consumer ability to obtain redress if a hearing aid does not provide a benefit.

D. Promotion and Advertising

Another area in which we urge caution in implementing the preemption provision for an OTC category is promotion and advertising. Both the federal government and states have demonstrated a strong interest in protecting consumers from deceptive advertising, including false advertising, fraudulent statements, and misrepresentations in the promotion and advertising of hearing aids. Given the limited enforcement resources at the federal level, states provide essential enforcement and oversight with respect to consumer fraud and false advertising.

Strong oversight and enforcement will be needed. In the years since FDARA passed, there has been a proliferation of companies advertising "OTC hearing aid," even though the category does not yet exist. The problem became so pervasive that FDA issued a 2018 letter to manufacturers, clarifying that Section 709 of FDARA is not self-implementing and that no OTC hearing aid category exists *until* the final regulations are issued.[16] Even with this explicit guidance, unscrupulous advertisements for "OTC hearing aids" and other claims continue. In one egregious example, a single company not only advertised OTC hearing aids, but also marketed their products to children, advertised their product as treatment for severe hearing loss (when OTC products are specifically for adults with perceived mild-to-moderate hearing loss), promoted their devices as treatment for conditions beyond hearing loss, and included unsubstantiated efficacy claims.[17] Given that putative OTC manufacturers and distributors are already flagrantly violating FDA's regulations and policies, and given FDA's limited enforcement resources, the already-vulnerable hearing aid patient population is at risk. This suggests that, at a minimum, the state consumer protections for traditional hearing aids are necessary once an OTC category is established.

As discussed in the prior sections addressing "receipt requirements" and "return period," the concern about preemption of many state promotion and advertising requirements arises to the extent licensing is preempted, as states regulate promotion and advertising of hearing aids through their licensing framework. If such a licensing scheme is preempted, states will not have the authority to enforce those promotion and advertising requirements specific to hearing aids that flow through the licensee when

[16] Letter from FDA to Hearing Aid Manufacturers (July 24, 2018). https://www.fda.gov/media/114844/download
[17] Letter from HIA to FDA (June 12, 2019) requesting FDA action for illegal and dangerous promotion of OTC hearing aids, which are targeting children, severe hearing loss, and specific medical conditions in violation of the Food, Drug, and Cosmetic Act and in contravention of FDA's letter of July 24, 2018.

hearing aids are sold OTC.[18] Therefore, HIA urges FDA to avoid preempting the existing licensing structure for traditional hearing aids. Doing so will preserve the existing protection. In addition, in coordination with the FTC, FDA should extend consumer protections in promotion and advertising to the new OTC hearing aid category, who would otherwise not have specific hearing aid protections.[19] In connection with the final rules, we encourage FDA to issue a guidance document addressing improper promotion. As FDA develops its preemption provisions, HIA urges FDA to consider the essential partnership with states in enforcement of such regulations, and the critical role states play in oversight of hearing aids to protect their citizens.

As with other consumer protections applying to the fit, dispensing, or sale of hearing aids, there is little evidence that Congress intended to eliminate these provisions or restrict the ability of states to ensure the health, safety, and wellbeing of their citizens. This is particularly true because the hearing aid patient population is typically older and more vulnerable to deceptive tactics.[20] Therefore, continuation of existing strong, enforceable standards is crucial in protecting this vulnerable population, including through existing protections against false claims, deceptive advertising and ensuring OTC distributors or sellers are held to the same standards. We reiterate that, other than the method of access, the risks associated with OTC hearing aids are very likely similar to those of traditional hearing aids, and, as such, FDA should consider consumer protections in promulgating its regulations.

Promotion and advertising regulations are a cornerstone in ensuring consumers have truthful and accurate information when making important decisions pertaining to their hearing health. Oversight over promotion and advertising serves to manage consumer expectations, thereby improving affordability, access, and – importantly – satisfaction with and use of hearing aids, which is the ultimate goal of the new OTC category. As states are essential partners in enforcing promotion and advertising regulations, we urge FDA not to preempt states' authority to enact and enforce deceptive advertising protections (as is the case with traditional hearing aids) to OTC hearing aids, as these provisions do not

[18] For example, Illinois law authorizes the Department of Public Health to revoke or refuse to renew a license or, with approval of the licensure board, impose fines for violations for a licensee's false advertising, misrepresentations, violations of the state's Consumer Fraud and Deceptive Business Practices Act, and violations of FDA and FTC regulations (225 I.L.C.S. § 50.18). Hawaii subjects a licensee to disciplinary action where the licensee conducts misleading or deceptive advertising, or advertising an unavailable model or type of hearing aid for sale to entice the purchaser into the store to purchase another model or type ("bait and switch") (Hawaii Rev. Stat. 451A-13). Hawaii administrative code also includes restrictions on advertising terms like "free" and "no charge," providing rules that the advertisement must list the items that would be free of charge and regulating the print size of such disclosures (Hawaii Admin. Code § 16-83-37).

[19] For example, South Carolina law provides that complaints may be brought against a licensee for unethical conduct including, but not limited to: sale by fraud or misrepresentation; using or causing misleading, deceptive, or untruthful materials; "bait and switch" tactics; representing that medical advice will be available in the process of obtaining hearing aids when that is not true; stating or implying that a hearing aid will restore normal hearing or slow hearing loss; and more (S.C. Code Ann. § 40-25-160).

[20] There are over 38 million Americans 12 years of age or older with hearing loss. Of individuals aged 60-69 years, almost 27 percent have hearing loss. Of individuals aged 70-79 years, almost 55 percent have hearing loss. Of individuals 80 years of age and older, over 80 percent have hearing loss. "How Many People Have Hearing Loss in the United States", Johns Hopkins Cochlear center for Hearing and Public Health, https://www.jhucochlearcenter.org/how-many-people-have-hearing-loss-united-states.html

interfere with or restrict access to OTC products. To that end, FDA should draft its preemption regulations to ensure that states retain the authority to enforce laws relating to the promotion and advertising of all hearing aids, and, in coordination with the FTC, extend consumer protections for the new OTC hearing aid category.

E. Assistive Device Warranties

As already discussed above, Section 709 of FDARA states that "nothing in this section shall be construed to modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law." Given that approximately 22 states have included hearing aids under state trade laws governing warranties for assistive technology devices, FDA should take care to craft the preemption provisions so that they do not undo these important provisions.

In many states, hearing aids fall under the category of "assistive devices" and are subject to assistive devices warranties (alternatively referred to as "lemon laws" in some states). These warranties provide recourse for consumers who purchase nonconforming assistive devices. Typically, assistive technology device laws require an express warranty from the manufacturer that the device will be free from any condition or defect that substantially impairs the value of the device to the consumer. In states with these laws, the express warranty is usually for a period of one year. During that period, the manufacturer is required to make a "reasonable attempt to repair" nonconformities, which are generally defined as defects that impact the use, safety, or value of the device. If the device is not repaired after reasonable attempts, then the consumer may return the device for a full purchase price refund or replacement.

Generally, assistive technology devices improve or maintain capabilities of an individual with disabilities. In the District of Columbia, for example, "hearing aids, telephone communication devices for the deaf, and other assistive listening devices" are expressly protected under consumer protection laws as "assistive technology devices."[21] As a result, a hearing aid in the District of Columbia is subject to warranty, which requires a manufacturer to make a reasonable attempt to repair the device or provide a refund.[22]

Similarly, Missouri includes hearing aids under its statutory definition of "assistive device" and requires an express warranty against nonconformities. A "nonconformity" is narrowly defined and excludes conditions of the device as a result of "abuse, neglect or unauthorized modification or alteration of the assistive device by a consumer" or "the result of normal use which may be resolved through a fitting adjustment, preventative maintenance or proper care."[23] Missouri allows four reasonable attempts to repair or the device must be out of service for at least 30 cumulative days to entitle the purchaser to a replacement or full refund, plus refund any collateral costs.[24]

[21] D.C. Code § 28-4031
[22] D.C. Code § 28-4031
[23] Mo. Rev. Stat. § 407.950
[24] Mo. Rev. Stat. § 407.950

Assistive technology device warranties are an important consumer protection and are particularly critical for an OTC category where patients will not receive the same type of personal assistance and guidance through the process. We urge FDA to recognize the importance of these warranties as provided under state law to protect consumers seeking to improve their functional and communicative capabilities and ensure these state laws are not preempted for the OTC category. Disclosures of these types of laws are critical to ensure consumers understand their rights when purchasing a hearing aid and avenues for recourse if they purchase a "lemon." Because these provisions are at risk of preemption under the forthcoming OTC hearing aid rules, we again encourage FDA to implement similar requirements for OTC hearing aids or take care to ensure that existing disclosure requirements are not preempted. Assistive technology device warranties do not interfere or restrict the purchase of or access to OTC hearing aids and are not the type of provision that was intended to be preempted.

II. Conclusion

Congress has given FDA authority to adopt regulations for hearing aids at the federal level and in so doing, provided FDA, in coordination with the FTC, leave to ensure the strongest, most practicable consumer protections apply nationwide; therefore, we urge the Agency to consider the provisions that the vast majority of states have found critical and enacted, including: receipt requirements, return periods, promotion and advertising restrictions, and assistive device warranties. These consumer protections are essential to ensuring the safety and effectiveness of OTC hearing aids. These laws can continue to protect consumers if FDA properly crafts the preemption provisions, thus assuring no conflict between preserving access to OTC hearing aids and preserving state consumer protections created under state law.

Clearly, the impact of preemption may be vast; therefore, we encourage FDA to carefully assess the potential effects of preemption on important consumer protections and the industry, and ensure that its preemption provision does not have unintended consequences and undermine, rather than further, consumer utilization of hearing aids. Over 38 million individuals in the U.S. have some type of hearing loss, which means millions of people will be making a decision when purchasing hearing aids – whether traditional or OTC – that will profoundly affect their audiologic, physical, and mental health.[25] And, unlike the case with most other medical devices, a broad majority of states and Congress have deliberately recognized the importance of this specific device for this population. That is why states have included these consumer protections specific to the dispensing and sale of hearing aids. These state actions, and the longstanding encouragement at the federal level of state involvement in regulating the hearing aid industry, illustrate the importance of preserving state consumer protections for OTC hearing aids.

[25] Over 50? Resolve to Check Your Hearing, (2020), https://betterhearing.org/newsroom/press-releases/over-50-resolve-to-check-your-hearing/

To that end, as FDA promulgates proposed regulations for an OTC hearing aid category, the Agency should preserve existing state consumer protection laws and regulations and attach these important consumer protections to the device itself to codify these protections at the federal level. In the alternative, the Agency should explicitly recognize the authority of states to continue to protect American consumers if FDA chooses instead to leave additional consumer protections to the states.

We are committed to engaging with FDA and welcome the opportunity to answer any questions or concerns you may have.

Sincerely,

Brandon Sawalich
HIA Board Chairman
President and CEO
Starkey

Kate Carr
President
HIA

CC:
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