May 2, 2017

Chairman Michael Burgess and Ranking Member Gene Green
U.S. House of Representatives Energy and Commerce Committee
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

RE: Examining Improvements to the Regulation of Medical Technologies

Dear Chairman Burgess and Ranking Member Green:

The Hearing Industries Association (HIA) appreciates the opportunity to provide testimony on the hearing before the Subcommittee on Health entitled "Examining Improvements to the Regulation of Medical Technologies." HIA is the national trade association of manufacturers of hearing aids, assistive listening devices, component parts, and power sources. HIA's membership consists of 17 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. These companies invest over $600 million per year on hearing aid research and development. Our members collectively employ more than 6,000 engineers and scientists who develop sophisticated hearing aids and algorithms to process sound so that it resembles natural hearing with minimal power consumption.

HIA has substantial interest in the policies proposed in the **Over-the-Counter Hearing Aid Act of 2017 (H.R. 1652)**, which are being considered by the Subcommittee today. The bill is designed to improve the accessibility and affordability of hearing aids by requiring FDA to establish an over-the-counter category for hearing aids. Before Congress proceeds in adopting the proposed legislation to create an OTC sales model for hearing aids, caution is warranted. Although promoting the goals of affordability and

accessibility are important, they should be secondary to assuring the safety and efficacy of hearing aids through the FDA's review processes and promoting the clinical interests of the patient. There are no studies demonstrating a person can accurately self-diagnose and self-manage the degree or cause of hearing loss, which would be required for successful implementation of an OTC sales channel for hearing aids. HIA recommends that the current draft of H.R.1652 should be amended to allow OTC sales for mild hearing loss only, as the consequences of ineffective treatment in this segment are relatively low.

The hearing industry is rapidly innovating, leading patients to receive more advanced technology at the same cost as a few years ago. Over the past decade some of our members have successfully miniaturized hearing devices through nanotechnology and flex circuitry, developed Bluetooth and wireless features for content streaming, and linked hearing aids with smart phones to maximize performance in a wide variety of listening environments. Smart hearing aids have won multiple awards from several groups as a result of these innovations.[1] Despite these impressive technological advances, hearing aid technology has become more affordable, with some HIA members manufacturing hearing aids that can be purchased for as little as $500 with the necessary professional services included.[2]

The hearing aid market is not the stagnant and outdated market that some recent reports would have one believe.[3] The new practical functions and enhanced features of today's hearing aids are associated with increased satisfaction rates and usage.[4]

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[1] HIA, Hearing Aid Industry Report (2017) (awarded the Consumer Technology Association's CES "Best of Innovation Awards"; SXSW Interacting Innovation Awards & Edison Awards; Bluetooth Breakthrough Awards; German Design Awards; Good Design Awards; Red Dot Awards; and several others).

[2] *See* Costco for a variety of hearing aids made by various manufacturers, including ReSound, Siemens (Costco's Kirkland brand), and others, starting at $499, including professional services, https://www.costco.com/hearing-aid-styles.html.

[3] *See* President's Council of Advisors on Science and Technology, Letter to President Obama, 2 (Oct. 2015) ("PCAST Report"), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf.

[4] Harvey B. Abrams, PhD, and Jan Kihm, MS, *An Introduction to MarkeTrak IX: A New Baseline for the Hearing Aid Market*, Hearing Review (May 15, 2015), http://www.hearingreview.com/2015/05/introduction-marketrak-ix-new-baseline-hearing-aid-market/.

Consumer satisfaction with current hearing aids is high and growing, with a 91 percent satisfaction rating for those obtained since 2014; 77 percent for hearing aids obtained between 2010 and 2013; and 74 percent for hearing aids obtained prior to 2010.[5] Furthermore, overall satisfaction has increased from 74 percent in 2008 to its current level of 81 percent.[6] Based on more than 30 years of data from MarkeTrak – a tracking survey of the hearing aid market – overall satisfaction with hearing aids is at its highest level ever. Better products and better experiences with hearing care professionals contribute to the improving satisfaction rates.

HIA appreciates the Subcommittee's interest in pursuing legislation to promote the affordability and accessibility of hearing aids through the Over-the-Counter Hearing Aid Act of 2017 (H.R. 1652). But affordability and accessibility must not come at the cost of safety or effectiveness. Hearing aids are, after all, medical devices intended to treat a disease or condition. To that end, HIA believes that all hearing aids, regardless of method of sale, should be required to comply with the general controls established by the Food and Drug Administration (FDA).

If enacted, the Over-the Counter Hearing Aid Act of 2017 would create a new OTC delivery channel for hearing aids. While OTC purchases may result in increased access and affordability, the evidence suggests the proposed OTC delivery channel may be effective only for a subset of hearing loss patients. Creating a new OTC distribution channel will not change the technology, but only a new mechanism for delivering the product. The relevant question is whether consumers can diagnose their own hearing loss and program their own hearing aids to best address their specific type and level of hearing loss or whether professional assistance is needed.

With adequate FDA controls in place, HIA believes that OTC may be suitable to address mild hearing loss only. The consequences of ineffective treatment for mild hearing loss are low, whereas the risks of failure and further delay in treatment for moderate hearing loss are significantly greater. Such treatment failure leaves the

[5] *Id.*
[6] *Id.*

individual at greater risk of isolation, depression, falls, dementia and other conditions related to untreated hearing loss.

I. Congress and FDA should limit any potential OTC Hearing Aid Sales to the Treatment of Mild Hearing Loss. H.R. 1652 Should be Amended to Allow OTC Sales of Hearing Aids for Patients with Mild Hearing Loss Only.

Hearing aids are the treatment of choice for the vast majority of adults with hearing loss, and they play a critical role in improving communication function and quality of life. The scientific literature shows that untreated hearing loss is associated with social isolation, loss of independence, depression, dementia, and increased risk of falls.[7] Though hearing loss is a common corollary to aging, its impact can be serious.

Hearing loss is a multifactorial condition, which requires a complex and skill-based approach to its treatment. There is a significant sensorineural component to hearing loss suffered by the vast majority of adults. Increasing audibility alone is often not sufficient to resolve their complex communication issues.[8] In addition to diminished audibility, hearing loss often involves diminished frequency resolution (difference in pitch), diminished temporal resolution (timing), or diminished loudness perception (range between softest and loudest sounds). Some hearing loss is also situational: discussions of hearing loss include not just idiosyncratic etiologies, but different levels of loss and audibility in differing settings. Hearing aids incorporate advanced signal processing algorithms that are designed to address the complex interactions between a damaged sensory organ, the desired input speech signal, and interfering environment sounds. Consequently, expertise in the selection, fitting and programming of these devices, as well as counseling patients in the likely benefits and limitations of amplification, is often critical for optimizing treatment outcomes.[9]

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[7] Seniors Research Group, *The Consequences of Untreated Hearing Loss in Older Persons*, Nat'l Council on the Aging (May 1999); Stig Arlinger, *Negative Consequences of Uncorrected Hearing Loss—A Review*, 42 Int'l J. of Audiology 2S17 (July 2003); NAS Report, *supra* n.13, 273-74.

[8] Julia Calderone, *Hearing Loss: No More Suffering in Silence?*, Consumer Reports (Feb. 2, 2017), http://www.consumerreports.org/hearing-aids/hearing-loss-no-more-suffering-in-silence/.

[9] Larry 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*, 26 Am. J. Audiology 53 (Mar. 2017).

The extent of hearing loss and its impact on different individuals varies. There is no technology or product that can be sold as a "one-size-fits-all" hearing solution for all hearing loss. The FDA defines hearing loss across five categories based on the decibel scale with mild hearing loss ranging from a 20 to 40 decibel hearing loss and moderate hearing loss ranging from 40 to 70 decibels. With two-thirds of all Americans with hearing loss having mild loss and only an estimated 12 percent of these people currently wearing hearing aids,[10] OTC hearing aids could improve adoption rates for Americans with mild hearing loss while presenting a favorable benefit-risk profile. Conversely, an estimated 50 percent of individuals with moderate hearing loss currently use hearing aids.[11] This population, which is already utilizing hearing aids at a substantial rate, is much less likely to be able to self-diagnose and self-manage with OTC hearing aids, and the impact of an erroneous treatment would be much greater.

Mild hearing loss, which is generally defined as difficulty hearing soft speech or sounds,[12] is more amenable to self-treatment through OTC hearing aids than more severe degrees of hearing loss. Treatment of moderate hearing loss involves a more comprehensive audiogram configuration. Further, simple amplification across all frequency ranges is not likely to provide the anticipated clinical benefits, potentially resulting in patient frustration and abandonment by moderate hearing loss patients. Despite the abundance of hearing technology and related hearing health care services information available to potential patients, some of that information may be difficult for patients to understand without a learned intermediary. Adult-onset hearing loss is a complex condition, and the modern hearing aid represents state-of-the-art digital technology with hundreds of possible style-feature combinations. Consequently, consumers generally benefit from conversations with a hearing health professional to

[10] HIA, Final Report, MarkeTrak 9: A New Baseline, Estimating Hearing Loss And Adoption Rates and Exploring Key Aspects of the Patient Journey, slide 39 (Mar. 2015) ("MarkeTrak 9).
[11] There are varying classifications for degrees of hearing loss, and FDA combines "moderate" and "moderately severe" hearing loss into an all-encompassing "moderate" category. This would mean people with very significant 70dB hearing loss would be advised to purchase an OTC device. This is yet another reason why HIA believes that referring people who will know they have a "moderate" hearing loss to purchase an OTC device is not sound policy.
[12] Calderone, *supra* n. 8. There is, however, complexity in this definition, as a patient may have one type of hearing loss in one ear and another in the other ear.

understand the complex nature of their particular hearing loss and associated hearing aid needs. Without this assistance, it is very difficult for the patient to discern which hearing aid will be most effective or which settings or programmable features to select in that hearing aid.

The nature of hearing loss is highly individualized.[13] Combining individual physical characteristics, such as the size, shape, and volume of the ear canal, with non-auditory factors such as cognitive function, motivation, manual dexterity, and family dynamics, creates a unique challenge.[14] Situational hearing loss adds further complexity.[15] Additionally, as described, there is a surplus of information available on hearing aids and health care; parsing through this information to decide which OTC hearing aid is appropriate would likely be challenging for many consumers. For these reasons, moderate or more severe hearing loss is a medical condition that is not readily susceptible to self-treatment. HIA therefore does not support OTC access for moderate or more severe hearing loss, as the risks of abandonment or ineffective treatment are high given the co-morbidities related to untreated hearing loss.

A recent placebo-controlled, double-blind, randomized clinical trial illustrated the advantages of consultations with a hearing health professional in the hearing aid selection and fitting process. The study and associated paper by Larry Humes et al. compared different service-delivery models among participants with hearing loss. The results suggested that there were no significant differences between the two approaches on five of the six outcomes – the exception, however, was the critical measure of satisfaction. Satisfaction significantly increased for those participants who initially received OTC devices following additional treatment under the audiology best practices (AB) model in which the patients received assistance from audiologists.[16] While 81 percent of the

[13] Calderone, *supra* n.12 ("You can have two people with identical audiograms who have very different functionality . . . .") (internal quotations omitted).
[14] American Speech-Language-Hearing Association, Hearing Aids for Adults (last visited Mar. 24, 2017), http://www.asha.org/PRPSpecificTopic.aspx?folderid=8589935381&section=Key_Issues.
[15] Donald J. Schum, PhD, *Situational Performance of Noise Reduction and Directionality*, Audiology Online (May 16, 2011), http://www.audiologyonline.com/articles/situational-performance-noise-reduction-and-830.
[16] Humes et al., *supra* n.9. Of note, the study used only technologically-advanced hearing aids.

participants who were assigned to the AB group said they would keep their hearing aids, only 55 percent of the participants in the OTC group said the same.[17] At the end of the initial six-week trial, 44 of 53 (83%) in the AB group actually purchased their hearing aids compared to only 1 of 51 (2%) in the OTC group. Following the six-week trial, 49 participants in the OTC model participated in an additional four-week trial that included professional adjustments to their OTC hearing aids before deciding to purchase. Notably, after four weeks of assistance from an audiologist, the percentage of willing purchasers in the OTC group jumped significantly.[18]

It should be stressed that the research participants in both the AB and OTC groups received baseline audiologic evaluations and the same high-end, commercially-available digital hearing aids – conditions that *will not* occur in the real world of OTCs. The authors wrote, "the observation that the CD participants self-select hearing aids that are somewhat under-powered may explain some of the inferior outcomes observed in this group compared to the AB participants."[19] And while HIA agrees that affordable and accessible hearing aids are clearly in the best interests of the consumer. HIA also believes that the best hearing aid for a consumer is the one that is worn. HIA therefore believes that the risks of under-treatment or failed treatment leading to the potential abandonment of more effective hearing loss treatment are far greater for people with moderate hearing loss than those with mild hearing loss.

Even for patients with mild hearing loss, self-treatment will not be a panacea. Some speculate that increased self-treatment will act as a gateway for consumers who will struggle with hearing in certain situations by reducing cost barriers to hearing aid purchases and related medical visits.[20] But this is an untested hypothesis, at least in the United States.[21] With the same evidence, one could conclude that ineffective self-

[17] This group was not fully representative of an OTC group, e.g., the patients were evaluated by a hearing professional against study inclusion/exclusion criteria.
[18] *Id.*
[19] *Id.* at 75.
[20] Comments of CTA, Docket No. FDA-2013-D-1295, 5 (May 6, 2016).
[21] In South Korea and Japan the results were the opposite. Both countries allow OTC hearing aids, and both countries have low adoption and satisfaction rates.

treatment may lead some to frustration and further delay in getting effective therapy based on a belief that if an OTC hearing aid does not work, no hearing aid will work. And this possibility is of particular concern because of the variable nature of hearing loss – it is much more complicated than simply amplifying sounds – and the complexity and critical importance of proper and customized programming and fitting of the device (collectively known as "fit" in the industry). It is expected that many patients will not be successful with self-fit OTCs.[22]

Limiting OTC sales to mild hearing loss will not have a significant impact on patient access for hearing aids for individuals with moderate hearing loss. In recent years, the hearing aid distribution model has evolved, making hearing aids available to consumers through new channels at affordable costs.

Most notable is the addition of "big box" stores to the hearing aid market. Warehouse stores, like Costco and Sam's Club, have implemented "Hearing Aid Centers" to offer the full array of hearing health services at value pricing. Big box stores now account for at least 10 percent of the private United States hearing aid market, and their market share continues to grow.[23] All of these stores provide safe and effective FDA-compliant hearing aids while providing increased economical access. These stores have been able to bring down costs for consumers while providing professional services, warranties, and advanced technology. Other types of distributors, such as pharmacy chains, have announced they are considering entering the market to provide professionally-fit hearing aids as well.[24]

Additionally, the internet has opened up other avenues of sales that increase access to services and lower prices of both goods and services. For example, the internet has

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[22] National Academies of Sciences, Engineering, Medicine, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability* 35 (June 2, 2016) ("NAS Report"); *see also* Humes et al., *supra* n.9 ("CD service-delivery model [self-selected pre-programmed high-quality hearing aids via an OTC model] was efficacious, with similar effect sizes. However, CD group had a significantly ($p < .05$) lower satisfaction and percentage (CD: 55%; AB: 81%; P: 36%) likely to purchase hearing aids after the trial).

[23] *US Hearing Aid Unit Sales Increased by 8.7% in 2016*, Hearing Review (updated Feb. 9, 2017), http://www.hearingreview.com/2017/01/us-hearing-aid-unit-sales-increased-8-7-2016/.

[24] *See, e.g.*, Laura Northrup, *CVS Will Experiment With Selling Glasses and Hearing Aids in Some Stores*, Consumerist (Oct. 5, 2015), https://consumerist.com/2015/10/05/cvs-will-offer-glasses-and-hearing-aids-in-stores-as-pilot-project/.

made it easier to locate and identify service providers, and patients in underserved areas can consult with hearing health professionals on the phone or through webcasts to address issues with hearing aids. And some companies have adopted a direct-to-consumer model of sales through the internet.[25] This model requires the submission of an audiogram conducted by a hearing health professional or a programming kit at an additional cost, but proper fit remains an issue. Other companies, like Hearing Planet, are researching ways to make online consultations work as technology continues to evolve. These new sales and distribution models are indeed having a positive impact on the accessibility of hearing aids.

These caveats notwithstanding, HIA supports the endeavor to reduce the barriers to access hearing loss treatment. Regardless of the method of sale, HIA members will continue to design and innovate to improve the quality of life of individuals with hearing loss. HIA urges the Committee to amend H.R. 1652 to protect patients from the potential shortfalls of self-treatment by amending the bill to permit OTC sales of hearing aids for mild hearing loss only.

II. HIA Strongly Supports the Continued Regulation of Hearing Aids as Medical Devices by the FDA.

Any product "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease" or "to affect the structure or any function of the body of man or other animals, and which does not achieve [any of] its primary intended purposes through chemical action" is a medical device under the Federal Food, Drug, and Cosmetic Act (FDCA).[26] FDA classifies devices based on their level of risk.[27] Currently, air conduction hearing aids are classified as a Class I device, the lowest risk classification.[28] Those that incorporate wireless or bone conduction

[25] *See, e.g.*, iHear Hearing Solutions, http://ihearmedical.com/hearing-solutions#comparisonChart.
[26] FDCA § 201(h), 21 U.S.C. § 321(h).
[27] *Id.*; *see also* FDCA § 513, 21 U.S.C. § 360c.
[28] 21 C.F.R. § 874.3300(b); FDA, What does it mean for FDA to "classify" a medical device? (last updated Dec. 28, 2015), https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194438.htm.

features are considered Class II, or moderate risk devices.[29] Class II devices require greater regulatory controls to provide reasonable assurance of safety and effectiveness. Approximately 88 percent of hearing aids sold in the United States in 2016 contained wireless features and were therefore categorized as Class II devices. Regardless of classification, all hearing aids are subject to the Quality System Regulations (QSRs),[30] as well as other general controls, such as establishment registration, device listing, labeling requirements, reporting, and correction and removal notification requirements. FDA regulations also require all medical device labeling or promotional claims to be supported by valid evidence.

HIA strongly supports FDA regulation of hearing aids as medical devices and believes all FDA labeling requirements, electromagnetic capability (EMC) standards, and any standards implicating safety should be retained for OTC hearing aids.

Additionally, HIA strongly believes that FDA review of a marketing application for a manufacturer's initial hearing aid device would help ensure device safety and effectiveness. FDA can establish guidance documents that would clearly state the data needed to support this 510(k), facilitating entry into the market. Subsequent hearing aids by the manufacturer would be 510(k) exempt and could be marketed without FDA review, absent changes that under FDA's regulation would require a 510(k).

Furthermore, the FDA should incorporate consumer comprehension into its analysis of OTC hearing aids. It is imperative to ensure that consumers can understand the directions and conditions for OTC hearing aids. FDA studies have shown that consumer comprehension is a major barrier to the effective use of all medical devices. If a complex medical device is to be available to consumers without a learned intermediary, it is essential to the safe and effective use of the device that consumers can adequately understand and follow the directions on the labeling. FDA routinely requires consumer

[29] FDA, What does it mean for FDA to "classify" a medical device? (last updated Dec. 28, 2015); 21 C.F.R. § 874.3305(b).
[30] *See* 21 C.F.R. Part 820.

comprehension studies of OTC drug products and home-use medical devices.[31] FDA can set clear expectations for how these studies should be done. FDA can also provide guidance on the data needed for effective home testing that is the *sine qua non* for OTC hearing aids.

III. Any OTC Distribution Model Must Protect Patients by Assuring that Personal Sound Amplifiers Are Not Marketed as Products for the Treatment of Hearing Loss.

Only devices intended to treat hearing loss are considered hearing aids, which excludes Personal Sound Amplifiers (PSAPs). PSAPs are intended only for non-hearing impaired consumers. They are designed to accentuate sounds in specific listening environments, such as bird watching or hunting, but they are not intended for everyday use or to correct hearing loss.[32] As recognized by the National Academy of Sciences (NAS), "PSAP manufacturers and distributors are not supposed to be offering their products for the purpose of compensating for hearing loss. This legal and regulatory distinction between hearing aids and PSAPs might not be readily apparent to users, and it might not be fully respected by PSAP sellers who explicitly or implicitly offer their products to compensate for hearing loss."[33] But because PSAPs are not intended to diagnose, treat, cure or mitigate disease and do not alter the structure or function of the body, they are not devices as defined in the FDCA. As such, FDA has very limited regulatory authority over PSAPs, and PSAPs are not subject to regulatory controls or premarket notification.

The distinction between a hearing aid and a PSAP is an important one for protecting patients. The products are not interchangeable and cannot be considered as

[31] FDA, FDA CDRH Public Workshop: Guidance on Medical Device Patient Labeling (Sept. 29, 2015), https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM465733.pdf; FDA, Device Labeling Guidance #G91-1 (Mar. 8, 1991), https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm; FDA, Guidance for Industry: Label Comprehension Studies for Nonprescription Drug Products (Aug. 2010), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM143834.pdf.
[32] FDA, Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Product (Feb. 25, 2009), https://www.fda.gov/MedicalDevices/ucm127086.htm.
[33] NAS Report, *supra* n.22, at 189.

such. The embedded chip technology in a hearing aid is much more sophisticated than that of the standard PSAP currently marketed; directional measurements, compression ratios, frequency manipulations, and feedback management all require sophisticated intervention. PSAPs are designed to amplify only and therefore *cannot* be used to treat sensorineural hearing loss. Because PSAPs are not intended to treat hearing loss, they cannot be fitted or tailored to an individual's specific communication requirements.

Furthermore, because PSAPs are not medical devices, they are not subject to safety and efficacy oversight or regulatory controls.[34] FDA has no authority to require that a PSAP be recalled should patient safety issues arise or PSAPs be ineffective. Nor does a PSAP manufacturer need to inform FDA of a recall. PSAP manufacturers are not even required to submit a report should their product injure a consumer.[35] The Federal Trade Commission (FTC) has said "[i]f your hearing is impaired don't use a PSAP as a substitute for a hearing aid. That may delay the diagnosis of a potentially treatable condition, and cause more damage to your hearing."[36] The NAS Report recommended maintaining the distinction between PSAPs and hearing aids "to ensure that consumers with hearing loss receive the benefits relating to quality, performance, compatibility, and labeling envisioned under the OTC wearable hearing device category."[37]

Consumer electronic products (like PSAPs) and other non-medical devices should remain prohibited from advertising that their products are designed to treat hearing loss. Permitting consumer electronic products to advertise for hearing loss would be akin to complete deregulation of the industry. HIA believes the FTC can play an important role in ensuring consumers receive accurate information about the differences between PSAPs and hearing aids. Since PSAPs are not devices, they are not subject to FDA regulation

[34] Unless the PSAP is an electronic product that emits sonic vibrations and is subject to the electronic product provisions of the FDCA that also apply to non-device products. *See* FDCA §§ 531-542 (21 U.S.C. §§ 360hh-36ss); NAS Report, *supra* n.22, at 180.

[35] And this is indeed a risk. According to a recent Consumer Reports article, "these devices have the potential to cause additional hearing damage by overamplifying sharp noises, such as the wail of a fire engine" and "[PSAP machines that cost less than $50] don't seem to help much—if at all—and could actually further diminish your ability to hear." Julia Calderone, *Can PSAPs Help Your Hearing?*, Consumer Reports (Feb. 2, 2017), http://www.consumerreports.org/hearing-ear-care/can-psaps-help-your-hearing/.

[36] FTC, Sound Advice on Hearing Aids, 2 (Sept. 2010), http://www.devicewatch.org/reports/ftc_hearing_aids.pdf.

[37] NAS Report, *supra* n.22, at 192.

(although FDA can intervene if PSAP manufacturers do promote their products in a manner that renders them devices). FTC regulation of false or misleading claims, regardless of whether they make medical device claims or general amplification claims, would help protect consumers.

The consumer electronics market operates very differently from the medical device market. As such, there are serious risks associated with the development of PSAPs to treat hearing loss. New consumer electronic technologies are often disseminated at an early stage through beta tests to accelerate, commercialize, and gain feedback, but this model is not appropriate for a medical product. Medical devices are carefully tested for safety and efficacy before being commercialized; consumer product testing is primarily directed toward performance, not safety. And FDA regulates the investigational studies of new devices.[38] Thus, PSAPs need to be treated only as amplification devices, not as substitutes for hearing aids, and this requirement must be enforced. Failure to recognize and enforce these differences would lead to complete deregulation of the hearing industry. FDA should review and finalize its 2013 Draft PSAP Guidance to accomplish these goals.

Complete deregulation of the hearing aid industry should not be considered a viable option. Past experiments with deregulation have shown that the unregulated hearing aid market does not work. Prior to hearing aid regulation, an FDA Task Force in 1976 investigated hearing aids and discovered that many of the hearing devices sold "basically didn't work."[39] In 1985, Colorado experimented with deregulation of hearing aid sales and determined that complaints filed for hearing aids jumped from an average of 14 per year to 100.[40] The most common complaints included refusal to provide legally mandated refunds, problems with fittings and repairs, and contract and fraud issues. Colorado eventually decided to reinstate licensing requirements for hearing aid

[38] 21 C.F.R. Parts 50, 56, and 812.
[39] FDA, Transcript from Streamlining Good Manufacturing Practices for Hearing Aids Workshop, 12 (Apr. 21, 2016) (Statement of Commissioner Robert Califf), https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM502750.pdf.
[40] *Id*. at 183-84.

distribution.[41] Complete deregulation of OTC hearing aids would likely result in a recurrence of the same behaviors and problems. And with the internet, it would be easier to commit fraud and confuse people than before.

Conclusion

HIA appreciates the opportunity to provide testimony at today's hearing. HIA supports the effort to promote innovation in the field of hearing technology and increase access for consumers. HIA believes that new distribution models and new informational resources are already helping to advance these goals. HIA applauds the efforts of the Congress, the FDA and the FTC to work together to ensure more accessible and affordable hearing loss treatment for all.

Once again, HIA emphasizes the importance of safety and efficacy in the hearing aid industry. The health of the patient must be foremost; only after assuring safety and efficacy can the discussion about cost proceed. For this reason, HIA believes that OTC hearing aids subject to the appropriate FDA regulatory controls may be an effective cost-reducing option for those with mild hearing loss, but strongly encourages limiting the category to *only* those with mild hearing loss. HIA urges the Subcommittee to amend H.R. 1652 to permit OTC hearing aid sales to patients with mild hearing loss only.

[41] *Id*. at 185.