Before the
UNITED STATES FEDERAL TRADE COMMISSION
Washington, DC 20580

In the Matter of	)	
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Hearing Health and Technology – Workshop	)	Project No. P171200
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COMMENTS OF THE CONSUMER TECHNOLOGY ASSOCIATION

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I. INTRODUCTION

Over 30 million Americans suffer from hearing loss.[1] And while that number will surely rise in the coming years due to an aging population, current medical device hearing loss products are failing to adequately address the medical needs of those consumers who are impacted by hearing loss. Hearing aids are the primary device used to mitigate hearing loss, and recent estimates show that as many as 86% of people who might benefit from hearing aids do not use them.[2] There are several potential causes for the under-utilization of hearing aids, such as a reluctance to admit hearing loss, or the social stigma sometimes associated with hearing aid use, but one of the most significant causes is the high price of hearing aids. As we discuss further in these comments, the high price of hearing aids is due in large part to overregulation both at the federal and state level and the concentration of market power within a small group of manufacturers. With most insurance plans refusing to cover the cost of hearing aids and prices easily reaching thousands of dollars per device, it is tragic but not surprising that many

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1 NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, HEARING HEALTH CARE FOR ADULTS: PRIORITIES FOR IMPROVING ACCESS AND AFFORDABILITY 21 (Dan G. Blazer et al. eds., 2016), *available at* https://www.nap.edu/catalog/23446/hearing-health-care-for-adults-priorities-for-improving-access-and [hereinafter the 2016 National Academies Report].

2 *Id.*

Americans are forced to forgo purchasing a device that could significantly improve their quality of life. For people with hearing loss, an affordable device could mean the difference between engaging in everyday conversation no matter the environment or struggling to hear or participate; or, the difference between someone pursuing a new career path or settling for a job where they know they take alternative steps to manage their disability. These differences can have a profound affect not only on the individual who suffers from hearing loss, but for society as a whole due to public health implications and the potential impacts on unemployment or underemployment.

Fortunately, new solutions to mitigate hearing loss are within reach. Over the past few years, the consumer technology industry has made rapid advances in hearing assistive technology, and many consumer electronics products described as "Personal Sound Amplification Products" or PSAPs by the Food and Drug Administration ("FDA") now rival, and even surpass, the quality of certain types of traditional hearing aids. However, distribution of these devices to consumers has been stymied by FDA regulations. If the FDA moves to ease these restrictions, it can unleash the power of the consumer electronics industry and significantly expand Americans' access to hearing assistive technology.

As the trade association representing the U.S. consumer technology industry, the Consumer Technology Association ("CTA")[3] strongly supports regulatory changes that will expand access to hearing assistive technology products. CTA also recognizes that consumers will need guidance in order to navigate a new category of hearing assistive devices. To that end, CTA

[3] The Consumer Technology Association (CTA)™ is the trade association representing the $292 billion U.S. consumer technology industry, which supports more than 15 million U.S. jobs. More than 2,200 companies – 80 percent are small businesses and startups; others are among the world's best known brands – enjoy the benefits of CTA membership including policy advocacy, market research, technical education, industry promotion, standards development and the fostering of business and strategic relationships. CTA also owns and produces CES® – the world's gathering place for all who thrive on the business of consumer technologies. Profits from CES are reinvested into CTA's industry services.

has developed a new technical standard that will guide manufacturers and also make it easy for consumers to identify and compare hearing assistive devices and find the product that best fits their needs.

CTA thanks the Federal Trade Commission for its attention to this important issue and is pleased to provide the following comments on the Commission's April 18, 2017 Hearing Health and Technology workshop.

II. RESPONSES TO FEDERAL TRADE COMMISSION QUESTIONS

1. What information about hearing technology and related health care services is available to consumers who may be shopping for these goods and services? How useful do they find this information?

Consumers may learn about hearing technology and related health care services through a variety of sources, such as medical professionals, hearing health professionals, word of mouth from family and friends, acquaintances with hearing problems, and advocacy organizations such as the Hearing Loss Association of America ("HLAA"). However, despite this variety of sources, many consumers still find it daunting to navigate the hearing technology marketplace. As the National Academies of Sciences, Engineering, and Medicine stated, "[c]urrently, there are few independent information sources available to consumers that would allow easy comparisons across hearing aids and hearing assistive technologies."[4]

The dearth of helpful information for consumers can be attributed in part to three significant factors. First, the FDA defines PSAPs in a way that effectively prohibits PSAP manufacturers from describing how their products help mitigate mild to moderate hearing loss. Consequently, consumers that might benefit from the hearing assistive properties of PSAPs may be unaware of these products.

[4] 2016 National Academies Report, *supra* note 1, at 288.

Second, the high degree of vertical integration in the traditional hearing aid market limits consumers' access to unbiased information. Many hearing aid distributors are either owned by or are locked in to one of the big six hearing aid manufacturers through favorable distribution agreements. As a result, many distributors are incentivized to favor a particular brand of hearing aids, and they may not give consumers an objective assessment of their options.

Lastly, there is a lack of standardization of the terminology describing hearing technology products. The 2016 National Academies Report found that "the lack of standardized terminology between manufacturers about the features and capabilities of these technologies makes comparisons even more challenging."[5] The lack of standards, combined with the FDA's restrictions on the claims that can be made about PSAPs, has created a confusing hearing technology marketplace. Steps to alleviate the current state of consumer confusion are discussed in the remainder of these comments.

Each of these three significant factors creating a dearth of information for consumers about PSAPs is discussed in more detail below.

5 *Id.*

2. How are hearing aids and other forms of hearing technology commonly distributed and sold? To what extent are new sellers of hearing devices, as well as new methods of distribution and sales, affecting the range of goods, services, and prices available to consumers?

Traditional Hearing Aids

Restrictive federal and state regulations have made purchasing a hearing aid a complicated and expensive process that is inaccessible to many American consumers. The FDA currently defines a hearing aid as "any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing."[6] Devices that fall into this category are subject to a variety of FDA regulations that cover manufacturing practices, labeling, and pre-purchase medical evaluation requirements. [7] Many states also impose restrictions on the sale of hearing aids. For example, in California it is unlawful to engage in the practice of fitting or selling hearing aids without having a valid license,[8] which are only available to persons who submit an application to the Hearing Aid Dispensers Board, pay a fee, and pass both a written and practical examination.[9] In Florida, it is unlawful to sell or distribute hearing aids through the mail to the ultimate consumer.[10] And Missouri prohibits sales of hearing aids through the mail without prior fitting and testing by a

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6 21 C.F.R. §801.420.

7 *See e.g.*, 21 C.F.R. § 820 (describing the various requirements of the Quality System Regulation); 21 C.F.R. § 801.420(b-c) (describing the labeling and user instructional brochure requirements for hearing aids); 21 C.F.R. §801.421(a)(1) (prohibiting a hearing aid dispenser from selling a hearing aid unless the prospective user has provided the dispenser with a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated (within the past six months) and the patient may be considered a candidate for a hearing aid); C.F.R. §801.421(a)(2) (allowing a prospective hearing aid user to waive the medical evaluation requirement if certain requirements are met).

8 CAL. BUS. & PROF. CODE § 2538.20 ("It is unlawful for an individual to engage in the practice of fitting or selling hearing aids, or to display a sign or in any other way to advertise or hold himself or herself out as being so engaged without having first obtained a license from the board.").

9 CAL. BUS. & PROF. CODE § 2538.24-26.

10 FLA. STAT. § 484.054.

hearing instrument specialist licensed under Missouri law.[11] As a result of the burdensome regulatory environment, hearing aids are primarily dispensed through medical offices, audiologists, or hearing instruments specialists.[12]

In addition to being limited to these narrow distribution channels, hearing aids are made even more inaccessible by the widespread practice of "bundling." When consumers seek to purchase a hearing aid, they are often presented with a single bundle that includes a hearing loss assessment, an assessment of hearing aid candidacy, a functional communication assessment, hearing aid fitting and programming, accessories, and other related services, such as maintenance for a period of time.[13] A 2014 study found that over 80% of hearing care professionals use the bundling model.[14] While bundling may be convenient for some consumers who desire to purchase all of these services at one time, for other consumers this method of distribution locks them into a single provider and requires them to purchase services they may not need or want. Additionally, by obscuring the price of individual components and services, bundling also makes it harder to engage in price comparisons for the variety of hearing aid and service options. Other Forms of Hearing Technology

Over the past few years, there has been a rapid increase in the availability of Personal Sound Amplification Products. Like most consumer electronic products, PSAPs are sold through a variety of distribution channels, including online retailers, drug stores, and electronics stores.

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11 MO. ANN. STAT. § 346.110.

12 2016 National Academies Report, *supra* note 1, at 181.

13 *Id*. at 242.

14 Letter from the President's Council of Advisors on Science and Technology to President Barack Obama, Aging America & Hearing Loss: Imperative of Improved Hearing Technologies 3 (Oct. 26, 2015) [hereinafter PCAST], *available at* https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf.

The President's Council of Advisors on Science and Technology ("PCAST") found that many consumers with hearing loss can benefit from PSAPs.[15] This is not surprising, given that the technology used in these products may be similar, if not identical, to that used in hearing aids.[16]

Unfortunately for consumers suffering from hearing loss, the FDA has not encouraged the promotion of PSAPs to help them alleviate their condition. Instead, it has taken steps to prevent PSAPs from being used to treat hearing loss. In a 2009 guidance document, the FDA specifically defined a PSAP as "a wearable electronic product that is not intended to compensate for impaired hearing, but rather is intended for non-hearing impaired consumers to amplify sounds in the environment for a number of reasons, such as for recreational activities."[17] As a consequence, PSAPs cannot be marketed to hearing impaired consumers to help them improve their medical condition. Any promotional materials that suggest the use of PSAPs for hearing impaired customers would subject the product to the regulatory requirements imposed on hearing aids.[18] Because of these regulatory restrictions, PSAPs cannot be sold as a means of addressing mild to moderate hearing loss and many consumers suffering from such symptoms are unaware of them even though PSAPs offer hearing benefits at a lower cost. The regulatory restrictions

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15 *Id*. at 7.

16 *Id*.

17 FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY AND FDA STAFF: REGULATORY REQUIREMENTS FOR HEARING AID DEVICES AND PERSONAL SOUND AMPLIFICATION PRODUCTS (2009), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm127091.pdf. The guidance proposed by the FDA in 2013 includes a very similar PSAP definition. FOOD AND DRUG ADMINISTRATION, REGULATORY REQUIREMENTS FOR HEARING AID DEVICES AND PERSONAL SOUND AMPLIFICATION PRODUCTS: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2013), *available at* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM373747.pdf ("a PSAP is a wearable electronic product that is not intended to compensate for impaired hearing, but rather is intended for non-hearing impaired consumers to amplify sounds in certain environments, such as for hunting or other recreational activities.").

18 *Id*.

that prevent less expensive technologies, which are perfectly suited to alleviate mild to moderate hearing loss, from reaching consumers are a significant cause of the continued high cost and burdensome distribution structures facing consumers in the hearing aid market. Simply put: the regulatory roadblock has created a lack of effective competition.

3. How are innovations in hearing technology – including hearing aids, personal sound amplification products (PSAPs), and other devices and platforms – changing the competitive landscape and expanding the range of viable options to ameliorate hearing loss? What other innovations and developments are on the horizon?

The Current Hearing Aid Market Lacks Competition and Innovation

In its current state, the hearing aid market is characterized by high prices for consumers, a small number of competitors, and a lack of innovation. In 2013, the average price of a bundled pair of hearing aids was $4,700.[19] Prices for some higher-end devices can reach up to $6,000.[20] Importantly, most hearing aids are not covered by Medicare or private insurance. As a result, these high prices are borne entirely by consumers in most circumstances. One survey found that 50% of consumers cited the lack of insurance coverage for hearing aids as a barrier to their acquisition of a hearing aid.[21]

While high end-user prices are often expected for technologically advanced medical devices with high production costs, this does not appear to be the case for hearing aids. A 2010 study found that the components for some hearing aids cost less than $100.[22] Also, some evidence suggests that hearing aid manufacturers have not focused their efforts on significantly improving the core hearing assistance capabilities of hearing aids. In its 2015 report the PCAST noted that while the incorporation of common consumer technologies such as Wi-Fi and Bluetooth connectivity and smartphone interfaces can raise the price of premium-model hearing

19 2016 National Academies Report, *supra* note 1, at 243.

20 *Id*. at 243.

21 PCAST, *supra* note 14, at 2.

22 *Id*.

aids by $500-$1,000, premium and basic hearing aid models still offer comparable levels of hearing improvement.[23]

The high prices and lack of innovation can be attributed in part to the lack of competition in the hearing aid market. Over the past few years, just six companies have controlled 98% of the global hearing aid market.[24] Furthermore, these companies have vertically integrated to strengthen their hold on all aspects of the market. The 2016 National Academies report found that "[t]he hearing aid industry has been characterized as having 'considerable vertical integration, with manufacturers controlling the design, development, manufacturing, and distribution of their products, nearly to the point of sale.'"[25] If a hearing aid dispenser is not outright owned by one of the big six manufacturers, it may have a favorable contract with a single manufacturer that creates an incentive to favor that particular brand.[26] Recent surveys found that about 20% of audiologists and hearing aid dispensers sell only one brand.[27] These surveys also found that even if multiple brands are offered, dispensers still recommend a single brand to 75-80% of their patients.[28] The significant degree of vertical integration can harm competition by making it difficult for a new player to break into consumer distribution channels and it ultimately can harm consumers by allowing the established big six manufacturers to charge high prices without fear of being undercut by new entrants.[29]

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23 *Id*.

24 *Id*.

25 2016 National Academies Report, *supra* note 1, at 243.

26 PCAST, *supra* note 14, at 3.

27 *Id*. at 3.

28 *Id*.

29 *See* Robert Pitofsky, Former Chairman, Vertical Restraints and Vertical Aspects of Mergers--A U.S. Perspective (Oct. 16, 1997) (describing the potential harmful effects of vertical integration),

The Lower Cost of PSAPs Can Significantly Expand Consumer Access to Hearing Assistive Devices

The term PSAP encompasses a wide variety of devices that amplify hearing. While many of these products were not initially designed to replace hearing aids, their functional capabilities often overlap with hearing aids. For instance, PSAPs can help users listen to TV, have conversations over the phone or in person, or listen to speakers in noisy or large venues. PSAPs are also often versatile devices that can be adjusted to individual hearing using a smartphone application. These apps can allow the user to control volume or cut out background noise. Despite the FDA's rule that PSAPs should not be used to assist hearing impaired consumers, many consumers are beginning to use PSAPs to mitigate hearing impairment.[30]

PSAPs have the potential to make hearing assistive technology much more affordable for consumers than it is today. A *Consumer Reports* study found that the price of PSAPs ranges from $25 to $500.[31] The significantly lower prices of PSAPs can in part be attributed to the fact that the PSAP market is much more competitive than the traditional hearing aid market. The 2014 CTA PSAP consumer survey found that no single brand had a considerable market share – the most common brand had an 8% market share and over 15 competing brands had market shares between 2% and 5%.[32]

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available at https://www.ftc.gov/public-statements/1997/10/vertical-restraints-and-vertical-aspects-mergers-us-perspective.

[30] *See, e.g.*, Paula Span, No Hearing Aid? Some Gizmos Offer Alternative to 'Speak Up!,' N.Y. TIMES, July 15, 2016, *available at* https://www.nytimes.com/2016/07/19/health/hearing-aid-alternatives.html?_r=1; Patti Neighmond, Is It Time For Hearing Aids To Be Sold Over The Counter?, NPR, April 24, 2017, *available at* http://www.npr.org/sections/health-shots/2017/04/24/524946910/is-it-time-for-hearing-aids-to-be-sold-over-the-counter.

[31] PCAST, *supra* note 14, at 7.

[32] CONSUMER ELECTRONICS ASSOCIATION, PERSONAL SOUND AMPLIFICATION PRODUCTS: A STUDY OF CONSUMER ATTITUDES AND BEHAVIOR 12 (2014).

Not only is the average price for a PSAP far below the average price of a pair of hearing aids ($4,700), PSAP pricing falls squarely within the price range that many consumers would find acceptable. A 2014 survey by CTA that asked consumers how much they would be willing to spend on hearing health over the next year found that those diagnosed with hearing loss were willing to spend an average of $925, those with "a lot or some trouble hearing" were willing to spend $265, and those "with a little trouble hearing" were willing to spend $211.[33] As a result of PSAPs' cost effectiveness, it is likely that more consumers would purchase PSAPs to address their condition if these devices could be marketed to consumers for mild to moderate hearing loss.

[33] *Id.* at 8.

4. To what extent are hearing aids, PSAPs, or "hearables" interoperable with different adjustment or programming tools, as well as other technologies and communications systems? What standard setting efforts are underway and how might standard setting further competition and innovation (or fail to do so)?

As discussed above, PSAPs have the potential to offer consumers affordable access to hearing assistive technology. However, given the wide range of PSAPs that are available, it is critical that consumers have access to accurate and easy to understand information about PSAP capabilities. In order to meet that need, CTA has created the "Personal Sound Amplification Performance Criteria" (ANSI/CTA-2051).[34]

CTA's Personal Sound Amplification Performance Criteria

ANSI/CTA-2051 provides technical performance metrics and associated target values for consumer products that provide personal sound amplification and/or enhancement to a user. Products must meet the stated requirements to be considered compliant with the standard. ANSI/CTA-2051 sets out three categories of standardization:

- Category 1 – Manufacturers must publicly report specified measurements for these technical features. Devices must meet a specified threshold or acceptable range to be compliant with the standard. Category 1 features include:
    - Frequency Response Bandwidth. Frequency Response Bandwidth of a sound reproduction system relates to the portion of the input acoustic spectrum that the device can provide to a user. A consistent methodology for

[34] CONSUMER TECHNOLOGY ASSOCIATION, CTA/ANSI-2051 (2017). CTA is accredited by the American National Standards Institute (ANSI) to write standards for the consumer technology industry. As an ANSI-accredited Standards Development Organization, CTA must follow rules established by ANSI known as the *Essential Requirements* which are intended to ensure an open, transparent standards development process. CTA and ANSI broadly publicize each new standards development project in order to attract participation from any stakeholder with a material interest in the standard's development.

measurement and assessment of the spectrum width provides the consumer a means to compare and evaluate competing systems.

- Frequency Response Smoothness. Frequency Response Smoothness of a sound reproduction system relates to user experience of fidelity or consistent performance across frequency. A limit on maximum deviation is specified to ensure that sufficient smoothness is achieved.
- Maximum Acoustic Output. Maximum Acoustic Output relates to user comfort, in particular to avoid uncomfortably loud sounds. A criterion for maximum output provides a minimum performance standard for user comfort.
- Distortion Control Limits. Distortion relates to user experience of fidelity or faithful reproduction of the sound input. A maximum criterion for distortion provides a minimum performance standard.
- Self-Generated Noise Levels. Self-generated noise relates to noise at the device output that is not present in the input sound. Such noise can potentially mask soft but desirable sounds. A criterion for maximum self-generated noise provides a minimum performance standard.

- Category 2 – Manufacturers must publicly report specified measurements for these technical features but no required threshold is mandated. Category 2 features include:
  - High Frequency Gain Provided. The manufacturer shall report the maximum available high-frequency gain.

- Battery Life. Battery life is directly related to user experience, expectations, and operating cost. Establishment of a common metric for battery life allows customers to more accurately evaluate and compare devices.
- Latency. Latency relates to user experience of temporal fidelity or time alignment of the reproduced sound with the original. The critical aspect of latency relates to the perception of one's own voice when speaking, whereby the signal from the device interacts with one's voice heard naturally through bone and air conduction. Excess latency tends to inhibit speech.
- RF-Immunity. The manufacturer shall report RF Immunity for wireless device compatibility in both microphone (M) and, if present, telecoil (T) coupling modes.

- Category 3 – Manufacturers must publicly report the presence of these technical features but no specific value/metric for measurement of these features is included in the standard and no threshold must be met. Category 3 features include:
  - Fixed or Level Dependent Frequency Equalization (Tone Control). Manufacturers shall report if device tone controls are present and, if so, how they operate. Some tone controls enable a user to adjust the frequency response which is then fixed independent of level. Others change the frequency response versus input level without user interaction, i.e., automatically according to the manufacturer's algorithm. Combinations of the above also exist.

- Level Dependent Gain/Compression. Manufacturers should provide qualitative information identifying the functional compression/automatic gain of the device. This description should classify the compression/automatic gain characteristic(s) of the device as Multiband, Single Band, or none (Linear) and whether it is Wide Dynamic Range Compression and/or Limiting.
- SNR Enhancement. Directional and remote microphones can enhance the level of a desired sound source (e.g., a preferred talker) relative to background noise or the sound from other sources in the environment.
- Noise Reduction. Beyond the techniques described above, other noise-reduction algorithms exist that attempt to mitigate the deleterious effects of noise while minimizing degradation of a desired signal.
- Feedback Control. The manufacturer will indicate whether feedback control/cancellation signal processing is included.
- Personalization. Personal response characteristics which modify the device functionality that may be of benefit to the user include, but are not limited to: a user's hearing thresholds as a function of frequency, hearing performance in various conditions of noise, speech intelligibility in noise, localization resolution, or head-related transfer function specification.
- Device Coupling to the Ear. The manufacturer shall report the fit of the device to the user's ear using the following definitions: open fit, closed fit, and adjustable fit.

- Wireless Connectivity. The manufacturer shall report all modes of wireless connectivity supported by the device, for example: none, telecoil, Bluetooth, DECT, Wi-Fi, etc.

While ANSI/CTA-2051 was only published in January 2017, CTA expects that it will became a widely adopted metric that will increase competition and consumer access to hearing assistive technology by making it easy to identify and compare high quality PSAPs. Instead of being forced to choose a PSAP based on vague marketing statements like "exceptional sound quality," "next generation chip," or "high frequency amplification," consumers will have easy access to concrete data about a device's capabilities and performance metrics.

CTA Has a Successful Track Record of Creating Industry Standards for Consumer Electronic Devices

Over the past several decades, CTA and its predecessor organizations have created hundreds of standards covering a wide range of consumer technology products, including audio systems, television data, video systems, DTV interfaces, portable handheld and in-vehicle electronics, health and fitness technology, consumer electronics networking, modular communication interfaces for energy management standards, and residential systems.

Several of CTA's standards have also played a critical role in ensuring that consumer technology products are accessible for sensory-impaired users. For instance, ANSI/CTA-608, *Line 21 data Services*, is the standard for providing and using closed captioning services. The standard describes the specifications for creation, transmission, reception, and display of caption data, plus the relationship of Caption Mode data to other data. ANSI/CTA-608 remains the closed caption standard for analog television. The newer ANSI/CTA-708, *Digital Television (DTV) Closed Captioning*, standard, which was first published in 2008, is the closed caption standard for digital television. Over the past several decades, these standards have helped

countless hearing impaired users enjoy television. Another successful CTA standard is ANSI/CTA-2041, *Standard for a Round Tactile Indicator*, which was published in 2012. This standard defines the size, shape and placement of a tactile indicator ("nib") to assist users who are blind or visually impaired in determining the location of numeric keys on handheld remote controls for consumer electronics products.

5. To what extent might existing federal and state regulations be modified or streamlined to better accommodate new technologies and business models, consistent with promoting competition and innovation while meeting legitimate consumer protection objectives?

The FDA Should Formally Amend the Hearing Aid Medical Evaluation Requirement

The FDA's requirement that a consumer undergo a medical evaluation (or sign a waiver of that evaluation) before obtaining a hearing aid[35] is an outdated regulation that should be formally withdrawn. While the requirement was originally intended to ensure that serious hearing health problems did not go undiagnosed, the 2015 PCAST letter report found that the serious conditions the regulation is concerned with are exceedingly rare.[36] The PCAST ultimately concluded that for non-surgical air-conduction hearing aids, "the requirement for a medical examination (or a written waiver of such examination) provides little patient benefit, while acting as a barrier to access for the millions of Americans needing hearing assistance."[37] Similarly, the 2016 National Academies Report found "no evidence that the required medical evaluation or waiver of that evaluation provides any clinically meaningful benefit."[38]

In December 2016, the FDA published nonbinding guidance stating "the FDA does not intend to enforce the medical evaluation (21 CFR 801.421(a)) or recordkeeping (21 CFR 801.421(d)) requirements prior to the dispensing of certain hearing aid devices to individuals 18 years of age and older."[39] While this is a step in the right direction, the guidance is not binding

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35 21 C.F.R. § 801.421(a).

36 PCAST, *supra* note 14, at 5.

37 *Id*.

38 2016 National Academies Report, *supra* note 1, at 5.

39 FOOD AND DRUG ADMINISTRATION, IMMEDIATELY IN EFFECT GUIDANCE DOCUMENT: CONDITIONS FOR SALE FOR AIR CONDUCTION HEARING AIDS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2016), *available at* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM531995.pdf.

on the agency and industry remains confused about the legal requirements at issue, since the regulation remains on the books. To remove any remaining regulatory uncertainty that would continue to impede competition, the FDA should formally eliminate the medical evaluation requirement from its regulations.

The FDA Should Establish a New Category of OTC Wearable Hearing Devices

The FDA should create a new category of over-the-counter ("OTC") hearing aids that can be marketed as assisting with hearing loss and sold without a medical evaluation in a manner similar to other consumer electronics. Because many PSAPs would fall into the new category of OTC hearing aids, and therefore be able to market themselves as assisting with hearing loss, CTA believes that the creation of an OTC hearing aid category will significantly increase the availability of hearing assistive technology to consumers suffering from hearing loss. Both the 2015 PCAST letter and 2016 National Academies Report recommended the creation of an OTC hearing aid category.

In order to facilitate continued innovation and avoid unnecessary regulatory burdens, the OTC hearing aid category should not be subject to all of the medical device regulations that currently apply to traditional hearing aids. For instance, air-conduction hearing aids (which are similar to many PSAPs) are currently classified as Class I medical devices (the least regulated device category) and are subject to record keeping and complaint process requirements, as well as the Quality System Regulation ("QSR") which governs manufacturing practices. While strict QSR requirements make sense for medical devices or pharmaceuticals that can have life-threatening consequences for patients, they can be unnecessarily burdensome for devices that are meant to address mild to moderate hearing loss.[40] In lieu of QSR, OTC hearing aids should be

[40] PCAST, *supra* note 14, at 6.

subject to a consensus American National Standard, such as the PSAP standard that CTA recently published.[41] Such a standard would be less burdensome for manufacturers and innovators, while still ensuring that consumers are able to identify high quality devices that meet their needs. Both the 2016 National Academies Report [42] and 2015 PCAST letter[43] suggested that the CTA PSAP standard could potentially be applied to OTC hearing aids.

In conjunction with the creation of a category of OTC hearing aids, the FDA should also withdraw its 2009[44] and 2013[45] guidance regarding PSAPs. In its current form, the FDA guidance classifies all devices that are intended to assist with hearing loss as "hearing aids" that are subject to FDA medical device regulations. All other hearing assistive devices that are not intended to compensate for hearing impairment are considered PSAPs and are essentially prohibited from marketing themselves as having any use in situations traditionally associated with hearing loss (e.g., understanding conversations in a crowded room).[46] Because OTC hearing aids would be marketed as assisting with hearing loss and not be subject to most FDA medical device requirements, the 2009 and 2013 guidance would be rendered obsolete by the new device category and both guidance documents should therefore be withdrawn.

In order for the OTC hearing category to achieve its intended goal of increasing consumer access to hearing assistive technology, the FDA should also preempt state laws and regulations that might interfere with the OTC sale of hearing aids. As noted above, many states have imposed burdensome regulations on the sale of hearing aids that are similar to the existing

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41 CONSUMER TECHNOLOGY ASSOCIATION, *supra* note 34.

42 2016 National Academies Report, *supra* note 1, at 211.

43 PCAST, *supra* note 14, at 6.

44 FDA 2009, *supra* note 17.

45 FDA 2013, *supra* note 17.

46 *Id*.

federal regulations that govern the sale of hearing aids.[47] Several specific state hearing aid regulations are also specifically exempt from preemption in the CFR.[48] To eliminate any confusion about the application of state licensing or medical evaluation requirements for the sale of OTC hearing aids, the FDA regulation that creates the OTC category should eliminate or revise any language that generally or specifically allows for states to create regulations of OTC hearing aids.

CTA also believes that the creation of a distinct OTC hearing category will assist the FTC in policing the marketing claims that are made about PSAPs and OTC hearing aids. Unlike the vague allusions to hearing aid-like functions that some PSAP marketing materials currently use as a result of FDA regulations, clear statements about the hearing health benefits of OTC hearing aids should be easier for the FTC to evaluate. As a result, consumers will be better protected from any potentially inaccurate claims in the PSAP market.

CTA would also like to note that efforts to create an OTC category of hearing aids have made significant progress in Congress in the form of the Over-The-Counter Hearing Aid Act of 2017. The bill, which addresses many of the issues discussed above, enjoys bipartisan support and has recently been attached to the Medical Device User Fee and Modernization Act. CTA has previously expressed its support for this effort.[49] Should this bill become law, CTA would look forward to working with the FDA as it drafts the regulations that will govern the OTC category of hearing aids.

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47 *See, e.g.*, CAL. BUS & PROF. CODE § 2538.20; FLA. STAT. § 484.054; MO. ANN. STAT. § 346.110.

48 *See, e.g.*, 21 C.F.R. § 808.55 (California regulations); 21 C.F.R. § 808.71 (Massachusetts regulations).

49 Consumer Technology Association, "CTA Stands Behind the Over-the-Counter Hearing Aid Act," December 5, 2016, https://www.cta.tech/News/Press-Releases/2016/December/CTA-Stands-Behind-the-Over-the-Counter-Hearing-Aid.aspx.

Congress Should Give the FTC the Power to Make Hearing Health Data More Portable

As discussed in previous sections, the practice of bundling and the vertically integrated structure of the hearing aid market are two significant underlying causes of the high prices consumers face in the traditional hearing aid market. CTA believes that the FTC can help mitigate some of these problems by requiring that audiologists and hearing aid dispensers make patient data more portable.

Specifically, Congress should pass a law instructing the FTC to promulgate a rule under the Administrative Procedures Act requiring that audiologists and hearing aid dispensers who perform standard diagnostic hearing tests and hearing aid fittings provide the customer with a copy of their audiogram and the programmable audio profile for a hearing aid at no additional cost and in a standardized form that can be used by other dispensers and vendors. The rule should also mandate that availability of a hearing test and fitting must not be conditioned on any agreement to purchase goods or additional services from the provider of the test. In addition to giving consumers more options when purchasing traditional hearing aids, this data portability requirement could also potentially help consumers identify or customize the PSAP or OTC hearing aid devices that work best for them. As innovation in the PSAP market continues, manufacturers may find ways to incorporate audiogram and hearing aid profile data into their devices. This proposed rule, which was recommended by the 2015 PCAST letter,[50] would be analogous in many ways to the FTC's "Eyeglass Rule," which prevented bundling by ophthalmologists and opticians by requiring them to give consumers a portable copy of their prescriptions.[51]

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50 PCAST, *supra* note 14, at 6.

51 16 C.F.R. § 456.2.

III. CONCLUSION

CTA applauds the FTC's efforts to bring light to this important issue by examining the ways in which enhanced competition and innovation might increase the availability and adoption of hearing assistive technology. We are hopeful that the FTC's work will help spur the changes that are needed in this industry, and we look forward to assisting with this work in any way possible.

Respectfully submitted,

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