

THE AUDIOLOGIST'S GUIDE TO HEARING AIDS, PSAPs, HEARABLES AND OTC DEVICES

AMERICAN ACADEMY OF AUDIOLOGY
January 2018

INTRODUCTION

The Food and Drug Administration (FDA) is developing proposed regulations for over-the-counter (OTC) hearing aid devices. According to the FDA Reauthorization Act of 2017, these devices will be available to the consumer through retail outlets and without having to engage an audiologist, either for a pre-purchase hearing evaluation, or for the selection, fitting or verification of performance of the device.

While OTC devices have not yet entered the marketplace, this guidance was developed to assist audiologists in understanding the differences between existing products and OTC devices, to be ready to answer questions about these devices, and possibly to begin to pre-position practices in anticipation of the availability of OTC devices. This guidance will be updated as the regulations for OTC devices become available.

BACKGROUND

In the summer of 2017, Congress passed a law that directed the FDA to develop regulations that make OTC hearing aids available to the public. Prior to this, a number of federal agencies, notably the Federal Trade Commission (FTC) and the President's Council of Advisors on Science and Technology (PCAST), began to review the accessibility and affordability of hearing care in the United States. Simultaneously, the National Academies of Science, Engineering and Medicine (NASEM) also convened a committee to review and report on the status of hearing care delivery in the U.S. The FDA, the FTC, the National Institutes of Health, the Veteran's Administration, the Department of Defense, and the Hearing Loss Association of America commissioned the NASEM study.

The genesis of these committees and reviews can be traced to three familiar perceptions and one emerging healthcare concept. The first is the perception that the cost of hearing care, and more specifically the cost of hearing aids, prevents some individuals from seeking treatment for hearing loss. Second, many third party payers do not cover hearing aids; including Medicare where hearing aid devices and associated services are statutorily excluded. The third perception is that the geographic distribution of hearing care providers, including audiologists, is such that there are many areas in the U.S. in which individuals cannot readily access hearing care services.

The emerging healthcare concept is that consumers are demanding greater control over their health care, including the desire to "self-direct" their hearing health care. The impetus may be, in part, to control the cost of their health care, but also to control the time and effort expended when engaged with health care providers. While many common chronic medical conditions, e.g. low back pain, are being "treated" with over-the-counter remedies, there has been no such option for the treatment of hearing loss. This emerging concept could conceivably include alternatives that allowed patients to "treat" their hearing loss without having to see an audiologist, otolaryngologist, or dispenser.

These themes led to several agencies recommending consumer access over-the-counter hearing care devices without the necessity to engage the professional. These recommendations were

based, in part, on both emerging technologies (e.g. smartphone apps, hearables, etc.) that could provide hearing benefit and the perception that an ever-increasing technologically savvy population might have the capability to fit and program hearing care devices without the assistance of an audiologist.

The OTC law passed by Congress (S934: FDA Reauthorization Act of 2017) defines an OTC device as one that:

- “(A) uses the same fundamental scientific technology as air conduction hearing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations) (or any successor regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);*
- (B) is intended to be used by adults over the age of 18 to compensate for perceived mild to moderate hearing impairment;*
- (C) through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customize it to the user’s hearing needs;*
- (D) may—*
 - (i) use wireless technology; or*
 - (ii) include tests for self-assessment of hearing loss; and*
- (E) is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.”*

This law mandates that the FDA develop and publish rules no later than 3 years after the enactment of the law. The final version of the law, signed by President Trump on August 18, 2017, specifically notes the following:

“The Secretary of Health and Human Services ... not later than 3 years after the date of enactment of this Act, shall promulgate proposed regulations to establish a category of over-the-counter hearing aids, as defined in subsection (q) of section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) as amended by subsection (a), and, not later than 180 days after the date on which the public comment period on the proposed regulations closes, shall issue such final regulations.”

The FDA has begun the process of collecting information and data, including input from professional organizations, federal agencies, and consumer groups and could publish proposed rules anytime within the next three years. Included in the proposed rules will be the time frame for the FDA to receive feedback from the public on the proposed rules. During this time, organizations, agencies, or individuals can provide comments, suggest modifications, or provide different options for the proposed rules. It is also possible that the FDA will hold a public hearing at which time the oral testimony can be provided on the proposed regulations. At the close of the comment period, the FDA will evaluate any oral or written testimony and determine whether any changes in the proposed rules are necessary. Within six months (180 days) of the close of the comment period, final rules will be published, along with a date of enactment.

TYPES OF HEARING DEVICES

This document reviews devices and technologies currently available for consumers and patients. The options presented within this document do not include surgically implantable devices (e.g. cochlear implants, middle ear implants, etc.). **As of now, OTC devices do not exist and therefore their form, function, cost, performance characteristics, or impact on audiology practices is speculative.**

Hearing Aid: FDA regulations define 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” (21 CFR 801.420). Hearing aids are regulated by the FDA as Class I or Class II medical devices and are only available from licensed providers. Hearing aids may be recommended for individuals with mild to profound hearing loss and can be customized by the provider.

Personal Sound Amplification Products (PSAP): PSAPs are over-the-counter, wearable electronic devices that are designed to accentuate listening in certain environments (not full-time use). They are generally designed to provide some modest amplification of environmental sounds but because they are not regulated by the FDA, they cannot be marketed as devices that help individuals with hearing loss. The FDA suggests that examples of situations in which PSAPs typically are used include hunting (listening for prey), bird watching, listening to lectures with a distant speaker, and listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations) (FDA Draft Guidance, 2013). PSAPs are currently available for purchase by the consumer at a variety of retail outlets, including through on-line retailers. Audiologists can sell PSAPs.

Assistive listening devices (ALD), Assistive listening systems (ALS), Alerting devices: Broadly, a category of devices that assist the person with hearing loss manage specific listening environments or situations in which conventional devices are inadequate or inappropriate. ALDs or ALSs can be used at work, home, places of employment or places of entertainment, and can be used to improve the signal-to-noise ratio, counteract the effect of distance, or minimize the effect of poor acoustics (e.g. reverberation.) These devices may be for personal use or for groups (wide area). Alerting devices typically utilize light, intense sound or vibration to connect or signal the person with hearing loss about events in their environment, and can be connected to phones, lights, doorbells, smoke alarms, etc. The FDA does not regulate ALDs, ALS, or alerting devices, although some devices, such as captioned telephones, may have to comply with FCC regulations. These devices can be purchased through retail outlets, on-line, and audiology practices. In some circumstances, these devices are available for reduced cost through government agencies.

Wireless hearing aid accessories: There are numerous accessories available today that are designed to supplement a hearing aid, enhance communication, or use alternative means of communicating. Accessories include devices that allow the listener to directly stream information from a phone or other personal listening device (e.g., tablet, computer, e-reader) as well as remote or lapel microphones that help the listener to hear over long distances (e.g., in

classrooms, conference rooms, and lecture halls). Hearing aid accessories are generally purchased through audiology practices, but are also available through retail outlets.

Hearables: A hearable is any ear-level device designed to supplement and enhance a listening experience, or that includes features such as monitoring vital signs (e.g. heart rate, body temperature, blood oxygen levels, etc.), activity tracking (e.g. steps, calories burned, etc.), augmented hearing (allows users to filter out or enhance specific sounds), music streaming, language translation, or improved face-to-face communication. The categories of hearables can include in-ear devices or headphones. Hearables can be purchased through retail outlets, including over the Internet, and could be sold by audiology practices.

Future devices

Over-the-counter hearing aid: Over the counter hearing aids do not currently exist, but proposed legislation describes OTC hearing aids as devices that use the same fundamental technology as a traditional hearing aids but allows the user to customize the settings to the user's hearing needs and are available without the prescription of a licensed person. The FDA would regulate OTC hearing aids and manufacturers would be subject to certain labeling requirements regarding appropriate use of the devices by consumers. Unlike PSAPs, OTC hearing aids would be allowed for use by individuals with hearing loss but unlike traditional hearing aids, would be narrowly targeted for use by adults with mild to moderate sensorineural hearing loss only. **It is not known how OTC devices will be distributed, their performance characteristics, their cost, or the impact of these devices on hearing care broadly or audiology practices specifically.**

REGULATION OF HEARING AIDS, OTC DEVICES AND PSAPS

The purpose of the FDA is to assure patient safety in the use of medical products, drugs, or medical devices. Their focus is on assuring that the benefits of any product or device outweigh the potential harm that might come from using the device (i.e. the benefit-risk ratio). Another key factor in determining if the FDA provides any regulatory oversight is the "intended use" of the product or device. The FDA regulates products designed to be used to evaluate or treat a medical condition. They do not regulate products that are not intended to be used for medical intervention. Hearing aids are intended to be used for treating a medical condition (hearing loss) while PSAPs are not intended to be used for medical conditions. Thus, the FDA regulates current hearing aids, and will regulate, in the future, OTC hearings, but not PSAPs.

Hearing aids are regulated by the FDA as Class I or Class II medical devices. In practical terms, the difference between Class I and Class II hearing aids is that Class II hearing aids are those that incorporate some sort of wireless technology (ear-to-ear transmission, Bluetooth, etc.). A Class I medical device is exempt from premarket review and clearance before marketing (21 CFR 874.3300(b)(1)), while Class II medical devices typically require a premarket review and clearance before marketing. However, wireless devices (which classify as a Class II device) are exempted from the requirement.

The following is an excerpt from the FDA regulations on Class I (21 CFR 874.3300) and Class II (21 CFR 874.3305) hearing aids:

Air-conduction hearing aid.

(a) Identification. A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400).

(b) Classification. (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9.

(2) Class II for the bone-conduction hearing aid.

Wireless air-conduction hearing aid.

(a) Identification. A wireless air-conduction hearing aid is a wearable sound-amplifying device, intended to compensate for impaired hearing that incorporates wireless technology in its programming or use.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing should validate electromagnetic compatibility (EMC) and safety of exposure to non-ionizing radiation;

(2) Design, description, and performance data should validate wireless technology functions; and

(3) Labeling should specify appropriate instructions, warnings, and information relating to EMC and wireless technology and human exposure to non-ionizing radiation.

Devices regulated by the FDA are subject to specific patient and professional labeling requirements (21 CFR 801.420.) The labeling requirements include the hearing aid device itself (e.g., model, serial number, etc.), the contents of the instructional brochure included with the devices, and specific information or instruction for the dispenser.

Existing regulations for hearing aids specify that the patient must be medically evaluated by a physician prior to the purchase of a device, although the patient may waive the medical evaluation by signing a waiver. The FDA requires that the audiologist retain documentation of the medical evaluation of waiver for 3 years following the purchase. Persons under the age of 18 must have a medical evaluation and cannot sign a waiver. The FDA announced in 2016 that the requirement for a medical evaluation or use of the waiver would no longer be enforced. However, this requirement does remain a part of the federal regulations, and as most state licensing agencies require compliance with federal regulations, the medical evaluation or waiver continues to be necessary in many states. Audiologists should check with their state licensing boards for clarification of this requirement. The FDA has stated that they intend to eliminate this rule when the OTC regulations are issued. With the elimination of the rule, the

necessity for a medical evaluation or waiver will cease. Again, the audiologist should check with state licensing boards to assure the rule is no longer in effect in their state.

Hearing aids sold through retail outlets, i.e. over-the-counter, will also be subject to FDA regulatory oversight, and thus will have to meet specific requirements regarding premarket approval, performance, and/or labeling rules. The bill passed by Congress that directs the FDA to develop regulations for OTC devices actually began the process of implementing the regulatory framework by specifying the following:

(2) REQUIREMENTS.—In promulgating the regulations under paragraph (1), the Secretary shall—

(A) include requirements that provide reasonable assurances of the safety and efficacy of over-the-counter hearing aids;

(B) include requirements that establish or adopt output limits appropriate for over-the-counter hearing aids;

(C) include requirements for appropriate labeling of the over-the-counter hearing aid, including how consumers may report adverse events, any conditions or contraindications, and any advisements to consult promptly with a licensed physician; and

(D) describe the requirements under which the sale of over-the-counter hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

Additional regulations regarding OTC device characteristics will be forthcoming from the FDA.

As noted previously, the FDA does not regulate PSAPs as they are intended for use by non-hearing impaired consumers. The FDA website describes PSAPs as:

“...intended to accentuate sounds in specific listening environments, rather than for everyday use in multiple listening situations. They are not intended to compensate for hearing impairment or to address listening situations that are typically associated with and indicative of hearing loss. Examples of situations in which PSAPs typically are used include hunting (listening for prey), bird watching, listening to lectures with a distant speaker, and listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations). Examples of listening situations that are typically associated with and indicative of hearing loss include: difficulty listening to another person nearby, difficulty understanding conversations in crowded rooms, difficulty understanding movie dialogue in a theater, difficulty listening to lectures in an otherwise quiet room, difficulty hearing the phone or doorbell ring, or difficulty listening situations in which environmental noise might interfere with speech intelligibility. Products making these or similar claims should not be considered PSAPs. In addition, products that are sold as an “over the counter” alternative or substitute for a hearing aid should not be considered PSAPs. 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 FD&C Act. As such, there is no regulatory classification, product code, or definition for these products. Furthermore, there are no requirements for registration of manufacturers or listing of these products with FDA.”

Although PSAPs are not hearing aids, and therefore not subject to oversight under existing hearing aid regulations, PSAPs can be considered a consumer electronic, and, as such are subject to applicable provisions of the Radiation Control for Health and Safety Act of 1968, under which FDA regulates electronic products that emit sonic vibrations, such as sound amplification equipment. (21 CFR 1000.15.) Manufacturers of PSAPs must report defects and adverse events (21 CFR Part 1003) and must comply with the requirements to repurchase, repair, or replace electronic products (CFR Part 1004.)

The Academy developed and submitted several statements to Congress and the FDA to assist in their deliberations regarding OTC devices. The first statement (Appendix A) addressed four areas: (1) accessibility to hearing care; (2) assessment and identification of hearing loss; (3) management of hearing loss; (4) affordability of hearing care technology and services; and (5) education for the consumer. Subsequent to the signing of the FDA Reauthorization Act, the Academy also submitted additional recommendations to the FDA for consideration during the rule-making process (Appendix B.) These recommendations were targeted on specific technological or labeling requirements for OTC devices.

POTENTIAL IMPACT AND OPPORTUNITIES OF OTC DEVICES

OTC hearing aids do not currently exist in the U.S., and therefore there is only speculation as to the uptake and/or benefit of these devices by consumers, or the subsequent impact on audiologic practices. The recently passed law targets that segment of the population who has mild-to-moderate hearing loss. OTC devices are not supposed to be available to patients with severe hearing loss or greater.

Numerous scenarios have been proposed regarding the impact of an OTC devices on audiologic practice, ranging from the potential to increase the number of individuals seeking hearing care due to positive trials with OTC devices, to the potential to close practices due to a large uptake by consumers and the subsequent negative economic impact on practices. However, until OTC devices become available, the true impact will not be known.

Mitigating the impact of OTC devices on audiologic practice should be driven, in part, by the ability to differentiate the device from the critical services provided by the audiologist, both during the evaluation and during the development of a treatment plan. The procedures conducted during the evaluation, and the instruction and counseling beyond the device, are key elements to successful outcomes of patients using amplification devices and it may be reasonable to expect that these factors could be used to create an important distinction in the mind of the consumer, and therefore justify the need to engage an audiologist.

The argument has been made that consumers may not be able to differentiate sensory hearing loss from those forms that are medically or surgically treatable, and therefore there is an increased likelihood of significant pathology being missed as part of the OTC process. Per the NASEM report, which included otolaryngologists and audiologists on the writing panel, the incidence of significant medical pathology is fairly low in the target population for OTC devices, and many of those pathologies have unique symptoms (e.g. unilateral tinnitus in the absence of hearing loss, pain, drainage, etc.) and therefore these patients may commonly self-select into the health care system. Based on these factors, the impact of OTC on missing treatable otologic pathology was not considered to be significant by the NASEM report. In spite of this perspective, the Academy believes that it is in the best interest of any patient considering amplification to have a comprehensive hearing evaluation by an audiologist prior to making decisions regarding hearing devices. In this way, significant otologic pathology can be detected, and amplification devices, if necessary, can be integrated into a comprehensive treatment plan. Audiologists are advised to promote the concept of the necessity of consumers having a comprehensive audiologic evaluation prior to purchasing any amplification system or PSAPs.

Within the Congressional mandate for OTC devices is that devices be available for persons with mild-to-moderate hearing loss, which is inconsistent with research that demonstrates that patients cannot self-identify even the presence of a hearing loss or are able to differentiate their degree of hearing loss (e.g. mild, moderate, severe, etc.). The recent study by Humes et al. (2017) confirms this perspective. This dichotomy raises the question as to how a consumer can be able to differentiate their degree of hearing loss without first obtaining an audiogram.

The ability to differentiate between types and degrees of hearing loss, understanding the variety of communication needs of each person with hearing loss, and the contribution of individual characteristics of each patient has been found to be crucial to assuring the best treatment outcomes for each patient. As consumers cannot differentiate type, degree, configuration or etiology of hearing loss, it follows that best outcomes will not be achieved based on perception of hearing loss alone. The necessity to provide guidance to patients regarding the appropriate technology would indicate the need to obtain a comprehensive audiological evaluation prior to making decisions regarding specific technologies is in the best interest of the patient. Therefore, the Academy recommends that patients considering the use of a technology to overcome communication or functional limitations would be best served if they obtained a comprehensive audiologic assessment prior to acquiring any technology. In this manner, the consumer can be informed as to their needs and their possible solutions. Conversely, consumer perception regarding hearing difficulty may not translate to pure tone loss, and therefore audiologists should be prepared to communicate effective solutions, including offering treatments, the individual could use to mitigate their communication difficulties, in spite of normal pure tone thresholds.

There is no prohibition against an audiologist selling a PSAP, ALD or hearables, in addition to the traditional hearing aid, and therefore audiologists are free to choose which of the categories of devices to make available within their practices. An audiologist can select the technology that meets an individual's long-term needs, addresses their primary communication concerns, and/or enhances quality of life, particularly when provided within the context of a comprehensive communication treatment plan. Identifying device(s) that fit a patient's

lifestyle, are easily utilized, and meet financial constraints are also important considerations. Audiologists may consider incorporating into their counseling whether the device is intended to be used to address hearing loss (hearing aids, OTC hearing aids) or not (PSAPs) and therefore is an off-label use of the device

Concerns about OTC devices are often narrowly focused on the potential for a direct and negative impact on a practice. Recent investment reports (Bernstein, 2107) suggest that the impact of OTC devices on hearing aid sales will be minimal, and that any losses realized by industry or practices will be more than offset by growth in the aging population. In fact, these investors suggest a greater than 5% annual growth in the hearing aid market over the next few years, in spite of the advent of OTCs.

SELECTION OF CURRENT DEVICES FOR PATIENTS

The following is provided as general descriptive information and should not be interpreted as constituting definitive guidance on use or dispensing of different products. OTC devices are not included in this section as there is no information currently available about their utilization.

HEARING AID

DESCRIPTION: A Class I or Class II (wireless and tinnitus) wearable sound-amplifying device that is intended to compensate for impaired hearing and is therefore regulated by the FDA as a medical device. Manufacturers and providers must comply with specific regulations related to the design, dispensing, and use of these devices.

TARGET POPULATION: All ages with any degree of hearing loss, most commonly sensory type losses, and in some cases, conductive or mixed hearing loss

UTILIZATION: Usually an appropriate consideration for any degree of hearing loss

WHERE PURCHASED: Audiologist

DISPENSING GUIDANCE: Following a comprehensive audiological evaluation, a device is ordered, fit, and programmed specifically to the individual's needs by the audiologist as part of a comprehensive treatment plan. Instruction on use and care of the device is provided. Additional instructional or rehabilitative services may be provided to increase compliance, or improve outcomes or benefit from the device. Although the FDA previously required medical clearance from a physician prior to the fitting of a hearing device, in December 2016, the FDA indicated it no longer intends to enforce this requirement. Depending on your state, you may no longer be required to obtain medical clearance before the hearing device fitting. It is expected that the FDA will remove the medical evaluation requirement when the regulations for OTC devices are finalized.

THIRD PARTY COVERAGE: Varies by payer. No coverage from Medicare for device or associated services.

NOTES AND CONSIDERATIONS:

- Typically includes, or has the option to include, a device warranty, follow-up services, and access to a provider for other supplemental care
- Regulated by the FDA
- Likely to offer more advanced features and flexibility in programming than OTC devices

- When comparing costs, it is important to differentiate between the device only and the device plus associated services (bundled). The American Academy of Audiology encourages its members to distinctly describe device and professional fees to support patients' greater understanding of costs associated with their treatment plan.

PERSONAL SOUND AMPLIFICATION PRODUCT (PSAP)

DESCRIPTION: Wearable electronic device that minimally increases amplification in certain listening environments to accentuate hearing

TARGET POPULATION: Adults with normal hearing; cannot be marketed as a treatment for hearing loss. There is no prohibition for children, as these devices are not intended to treat hearing loss.

UTILIZATION: Patients in need of minimal amplification, particularly in specific and infrequent listening situations (e.g. hunting, restaurants, etc.)

WHERE PURCHASED: Audiologists, online, retailers

DISPENSING GUIDANCE: PSAPs can be purchased over the counter or through an audiology practice. A prescription from a licensed provider is not necessary. Audiologists should be prepared to discuss the appropriateness of this technology for their patient's needs and provide guidance before purchase. Audiologists can sell PSAPs as alternative products to hearing aids.

THIRD PARTY COVERAGE: None currently and not expected

NOTES AND CONSIDERATIONS:

- Low cost and easily accessible
- Not regulated by the FDA
- Self-fitting with minimal features; volume control common; some high-end devices have smart-phone apps that allow programming of frequency response
- Have the potential to over amplify certain sounds which can be damaging to hearing
- Have the potential to act like an earplug and thus diminish hearing ability
- Could cause cerumen impaction
- Warranties based on manufacturer

ASSISTIVE LISTENING DEVICE (ALD)

DESCRIPTION: A category of devices that assist the person with hearing loss manage specific listening environments or situations in which conventional devices are inadequate or inappropriate.

TARGET POPULATION: Any age; with or without hearing loss. There is no prohibition for children, as these devices are not intended to treat hearing loss.

UTILIZATION: Used in specific listening situations or within specific environments to assist the person with hearing loss

WHERE PURCHASED: Audiologists, Online, retailers

DISPENSING GUIDANCE: ALDs can be purchased over the counter or through an audiology practice. A prescription from a licensed provider is not necessary. Audiologists should be prepared to discuss the appropriateness of this technology for their patient's needs and provide guidance before purchase. Audiologists can sell ALDs as an alternative product to hearing aids.

THIRD PARTY COVERAGE: None currently and not expected although some agencies will provide some ALDs at low or no cost

NOTES AND CONSIDERATIONS:

- Low cost and easily accessible
- Not regulated by the FDA
- Warranties based on manufacturer

HEARABLES

DESCRIPTION: Any of a number of devices worn at ear level that provide the wearer with functionality within the auditory domain, including audiocuration, music or communication streaming, language translation, improved understanding in background noise, etc. May include minimal amplification to accentuate hearing in certain listening environments.

TARGET POPULATION: Adults with normal hearing; cannot be marketed as a treatment for hearing loss. There is no prohibition for children, as these devices are not intended to treat hearing loss.

UTILIZATION: If a patient needs minimal amplification, particularly in specific and infrequent listening situations (e.g. hunting, restaurants, etc.), or desires connectivity with devices such as smartphones or TVs

WHERE PURCHASED: Online, retailers, audiologists

DISPENSING GUIDANCE: Hearables can be purchased over the counter or through an audiology practice. A prescription from a licensed provider is not necessary. Audiologists should be prepared to discuss the appropriateness of this technology for their patient's needs and provide guidance before purchase. Audiologists can sell hearables as alternative products to hearing aids.

THIRD PARTY COVERAGE: None currently and not expected

NOTES AND CONSIDERATIONS:

- Low cost and easily accessible
- Not regulated by the FDA
- Self-fitting with minimal features; volume control common; some high end devices have smart-phone apps that allow programming of frequency response
- Could cause cerumen impaction
- Warranties based on manufacturer

WIRELESS CONNECTIVITY AND ACCESSORIES

WHO: All ages

WHAT: Includes remote microphones, personal neck loop systems, FM systems, Bluetooth® phone systems, TV streaming systems, and others.

WHERE: Audiologist; some online retailers

WHEN: If hearing aids work well in most situations, but additional help is needed in challenging listening situations like over distance or in noise, or for easy use of other technologies like phones and personal electronic devices

HOW: Accessories that are specifically designed to be used with one brand of hearing device must be ordered through the hearing care provider. Generic or globally compatible systems, such as personal neck loops working through telecoil, are available from the hearing provider as well as online providers.

CONSIDER:

- Wireless connectivity and accessories enhance the benefit of hearing devices by making it easier to use personal electronics and communicate in challenging environments
- May be additional cost above hearing device; not usually covered by insurance

BUNDLING VERSUS UNBUNDLING WITHIN AUDIOLOGY PRACTICES

Within the audiology delivery system, the costs of the treatment services, particularly if those services include amplification devices, may be “bundled” together as a single price. In addition to the scope of the treatment services, the bundled price also will include costs for warranties, replacement guarantees, batteries for the devices, cleaning kits, ear molds (if necessary), and some predetermined length of time during which office visits are provided at no charge. Thus, bundled pricing includes both the device and the services associated with the treatment plan.

This process is similar to the manner in which surgical procedures are conducted, charged and reimbursed. In addition to the surgical procedure itself, the surgeon’s charge also includes some pre-determined, post-operative time period during which the office visits and physician encounters are provided as part of the necessary follow-up to the surgery. Patients may return as often as necessary during this time to receive care as the office visit charges are bundled with the surgical charge. While all patients generally return once or twice, there may be those that have smooth recoveries that do not need additional care, and those that have difficult recoveries that may need additional care from the surgeon. Similarly, when individuals receive hearing aids, they are generally provided with follow-up care for some pre-determined length of time, and the number of encounters with the audiology providers will vary depending on the needs of the patient.

The exception to bundled charges for audiology services is that the initial diagnostic services are generally not included in a bundled pricing structure. Third party payers, including Medicare, generally reimburse diagnostic services provided by audiologists. It is important to recognize that Medicare requires a physician referral to be reimburseable and any hearing test provided for the purpose of programming hearing aids is statutorily excluded. As participating providers with Medicare, audiologists must charge Medicare beneficiaries the same fee as any other patient, and therefore do not offer free hearing tests.

Some insurance companies require bundling of the device and services. Bundled pricing generally includes the following advantages to the consumer:

- Inclusion of post-fitting services
- Cleaning and in-office repairs at no charge
- Long term loss and damage warranties
- Batteries and accessories (e.g. wax guards) provided at no charge
- Semi-annual checks of hearing aids and reprogramming of hearing aids at no charge.

Conversely, unbundling requires that the charge for amplification devices be separated from the associated services. In this scenario, the devices and accessories (e.g. care kit, batteries, ear molds, etc.) are priced independent of the diagnostic services, the delivery fee for the hearing

aids, long-term warranties and the long-term post-fitting follow-up services. The unbundled model (also called “pay-as-you-go” model) has the following advantages:

- Allows the consumer to readily differentiate the cost of the device, accessories and services.
- Provides the consumer with the opportunity to be selective in choosing the level of services.
- Reduces the price differential between low, mid-range and high-level technologies as the cost of the services are fixed, regardless of the technologies.
- Allows consumers to purchase devices through other platforms and then receive only the service components from the audiologist

The Academy believes that pricing for amplification devices, accessories and associated services should be transparent to the patient, and has published guidance, educational materials, and a number of resources to support unbundling, most recently in our statement on Affordability and Accessibility of Hearing Care. In spite of the benefits of unbundling, challenges exist. For example, there is a lack of consistency among payers leading to some services being reimbursed by insurance and some not. Some patients may be able to access their benefits more fully when services are bundled. The complexity of reimbursement does not allow for the development of a simple solution to the issue of unbundling. As the OTC approach develops, unbundling should provide the opportunity for patients to more directly compare the cost of devices across different acquisition outlets. It should also highlight the services associated with optimizing outcomes with amplification devices. In this regard, one of the critical elements for success in the OTC era will be to highlight the critical role services play in achieving benefit with amplification.

CONSUMER FAQs:

As consumers are introduced to new technologies and may begin to investigate options for more “self-directed” care, audiologists should be prepared to consider and answer the following questions.

Why is an audiologic evaluation important prior to acquisition of any amplification device?

Consumers may be able to “self-identify” the presence of a communication problem or a functional limitation or participation restriction. However, there is no evidence that individuals can consistently correctly identify the degree, type or cause of hearing loss, or to discriminate those hearing losses that require audiologic or medical intervention. Ideally, individuals who believe they have a communication problem or functional limitation are best served by having a comprehensive audiological evaluation prior to accessing any treatment option. This evaluation serves to identify the options for treatment as well as assures that underlying treatable medical conditions are identified.

Furthermore, it is important to recognize that the management of hearing encompasses far more than the simple fitting of a device. An audiologic evaluation allows for a thorough understanding of the capabilities and limitations of an individual to communicate in a variety of environments. A hearing needs assessment conveys to the audiologist which features and functions are essential for achieving the stated communication goals. Realistic expectations for specific situations can be outlined, and communication strategies or assistive devices that can supplement a hearing device can be identified. The focus of an audiologist is not simply on dispensing a hearing device. Rather, the audiologic evaluation is centered on improving the quality of life of a patient. With the introduction and increasing availability of over-the-counter devices to the general public, it is important to recognize that incorporation of audiologic evaluation and discussion of appropriate management options remains best practice.

Can the audiologist program a device acquired through a retail outlet?

Many PSAPs that are currently available on the market have some frequency response programming along with volume controls and directionality. These devices are commonly programmable through smartphone apps. Audiologists can make a determination as to whether they want to program a direct-to-consumer device, as well as set any fees associated with the service delivery.

Can an audiologist sell a PSAP or, in the future, an OTC device?

Yes, audiologists can sell PSAPs in their practices currently. Dermatologists sell skin-care products that are also available at retail outlets. Similarly, dental hygiene products can be purchased within dental practices and retail sites. However, audiologists should be aware of several important factors should they decide to sell PSAPs in their practices. First, as these devices may not necessarily be considered “medical” devices, there may

be a sales tax implication within certain states. Audiologists should check with their legal counsel or state licensing boards to assure they are compliant with tax laws for these products. Second, as OTC hearing aids will be available without a prescription or without the necessity for professional engagement, the legal responsibilities for OTC versus traditional hearing aids may be different when the devices are sold side-by-side in an audiology practice. When OTC devices become available, licensing boards should be able to offer guidance in this regard.

The third factor is the necessity to develop practice guidelines regarding the sale of products that may carry different outcomes or uses than traditional hearing aids. Warranties, dispensing fees, expected life span, return policies, refundable fees, and follow-up services might be different with PSAPs devices than traditional hearing aids. The audiologist and staff will have to be able to communicate the differences and patients will have to be made to understand the differences between the devices when acquired through an audiologic practice. Finally, the ethical parameters associated with devices that are available through retail outlets are not the same as those associated with traditional hearing aids. As previously noted, dermatologists can sell skin care products through their practices, and so long as those same products are available through retail outlets, the dermatologist can negotiate different arrangements with suppliers than would otherwise be in place for products not available through retail.

What is the difference between acquiring a device through a retail outlet versus acquiring the device through an audiologist?

The most obvious difference is in the expertise of the audiologist in conducting a thorough evaluation, assuring the correct device is selected, setting realistic expectations, guiding a patient in utilization, and increasing compliance in using the device through comprehensive instruction. The role of the audiologist in assessing, diagnosing and treating hearing loss cannot be understated, and should be a point of emphasis regardless of the type of technology available. In addition, the audiologist can provide any additional treatment options, including audiologic rehabilitation.

How do I decide whether to recommend devices other than a hearing aid?

Treatment for hearing loss may include developing alternative communication strategies, counseling of both patient and their significant others, acquisition of assistive listening devices, provision of amplification devices, or some combination of the above. Two individuals with identical hearing losses may have completely different communication needs, and therefore decisions regarding treatment plans are based on individual patient characteristics, including lifestyle variations, employment status, or socialization requirements. The manner in which treatment is delivered will vary based on the access of the patient to hearing care services, physical characteristics such as dexterity and cognitive function, and the family support status of the patient. Thus, the complexity of the characteristics of the patient, beyond the hearing loss, will dictate the scope of a treatment plan. Decisions regarding the device to recommend to a patient will be based on all of the above factors, including socioeconomic status.

The audiologist will have to determine which device to use based on the specific complaint of a patient, in combination with the results of an audiological evaluation. There has been no specific guidance developed on utilization of PSAPs within audiologic practices, and, as OTC devices do not currently exist, there is also no guidance on dispensing these devices.

When amplification is included as part of the overall treatment plan, the amplification services have historically included comprehensive follow-up services to assure the patient is appropriately fit as well as achieving the required benefit. This includes adjustment of the devices over time as the brain acclimatizes to the changed auditory input. In this regard the treatment plan may also include counseling regarding expectations of benefit, development and implementation of an instructional plan for increasing communicative competence, coordination of care with other providers in the cases of existing comorbidities, and measurement of progress and outcomes associated with the devices. In addition, decisions regarding alternative options for overcoming functional limitations (e.g. FM systems, direct audio input, streaming capabilities, cochlear implants, etc.) are also included in the post fitting services for amplification.

What are the contraindications for PSAPs or other non-traditional hearing aids?

There are four primary concerns with completely unsupervised use of a PSAP: (1) providing more amplification than is necessary and potentially causing greater hearing loss; (2) providing less amplification than is necessary and suffering consequences of undertreated hearing loss; (3) providing gain without regard to the type of hearing loss and the associated processing abilities of the patient can actually make them hear worse rather than better, even if the amount of gain is appropriate; or (4) failing to identify an underlying medical condition to the hearing loss. This oversight may be as simple as failing to recognize the ear canal contains impacted earwax or as serious as failing to recognize the hearing loss is the result of a tumor.

The American Academy of Audiology recognizes that best practices would suggest these devices would best serve individuals with no more than mild hearing loss for whom the benefits of amplification with the device outweigh the risks that are inherent to self-diagnosis and self-directed treatment. In other words, when consumers select a hearing device, without the evaluation of an audiologist, there is a risk that further harm may be done by selecting an inappropriate device or using it ineffectively. Consumers should be aware of these risks and use PSAP devices cautiously. The American Academy of Audiology recommends that consumers complete a comprehensive hearing evaluation before selecting an OTC device, and that they choose to use these technologies only upon the advice of an audiologist.

APPENDIX 1

Statement of the American Academy of Audiology with respect to accessibility and affordability of hearing care for adult consumers January 26, 2017

The American Academy of Audiology supports consumer autonomy with respect to control over their health care decisions, including access to safe and affordable hearing care. In this context, hearing care describes a broad range of services, including the assessment of hearing function, determination of the type and extent of the hearing loss or loss of function, diagnosis of the cause of the hearing loss or loss of function, determination of the options available for treatment or management of the loss, and the provision of those services or technologies to mitigate the hearing loss or minimize the communicative impairment.

The increasing need for hearing services among the aging population, including management of hearing loss with hearing devices, coupled with advancements in technology that may offer consumers more opportunity to self-direct their care, have recently garnered the attention of federal regulatory agencies and advisory boards. It is well documented that hearing aid adoption by individuals with hearing loss is low. Studies have suggested that barriers to adoption include mild hearing loss or no perception of activity limitations or participation restrictions, younger age, perceived stigma, lack of encouragement to seek intervention from primary care provider or significant others, and perception of more obstacles than benefit to amplification (Jenstad & Moon, 2011; Meyer & Hickson, 2012). The Academy recognizes that accessibility, appropriate assessment and management, and affordability of treatment options may be critical components to encouraging appropriate adoption of hearing technologies. As such, the Academy seeks to offer guidance that will optimize the quality of care for patients with hearing loss in light of recent proposals that suggest changes in the established hearing care delivery model.

Recommendation #1: Accessibility

Several factors may make access to appropriate hearing care challenging for consumers. These include several classes of hearing devices, various providers of services, geographic distribution of providers and heterogeneity among industry manufacturers and devices. The American Academy of Audiology recommends improving access to hearing healthcare for consumers through the development of the following:

- a.) A common language and terminology to be used across hearing healthcare venues and providers that the consumer can easily understand. This language should apply to professional practices, providers, and hearing devices, regardless of point of service or sale.*
- b.) A clear differentiation of the cost of services from the cost of products when purchasing hearing devices. Continued bundling of the cost of products with the cost of services does not provide the transparency that allows consumers to make informed decisions nor does it encourage consumers to appreciate the role the audiologist plays in assuring optimal outcomes when treatment is indicated. Bundling products and services is therefore not in*

- the best interest of the consumer nor the members of the Academy, nor the audiology community at large.*
- c.) Regulatory or statutory requirements that allow direct and cost-effective access to audiologic services, including elimination of the requirement for Medicare beneficiaries to obtain a physician’s order for audiologic evaluation and the elimination of the FDA requirement for medical clearance or waiver prior to fitting a hearing device (as opposed to non-enforcement of the current regulation).*
 - d.) Increasing access to audiology services through the support for telehealth initiatives that allow consumers in underserved markets to receive hearing care services.*

Recommendation #2: Identification and Assessment

The Academy endorses the rights of individuals to self-direct their hearing care provided that care is safe and effective. The Academy supports the concept that consumers may be able to “self-identify” the presence of a communication problem or a functional limitation or participation restriction. However, no studies suggest that consumers can differentiate degree, type or etiology of hearing loss, or to discriminate those hearing losses that require audiologic or medical intervention. The concept of self-diagnosis implies the capability to determine the etiology, the type, and the degree of the loss, which is not possible without a comprehensive audiologic evaluation. Therefore, the Academy does not support the concept of “self-diagnosis” with respect to self-directed hearing care, and instead recommends that the term “self-identification” be used to identify the consumer’s ability to determine the need for hearing care.

Ideally, individuals who believe they have a communication problem or functional limitation hearing loss are best served by having a comprehensive audiological evaluation prior to their accessing any treatment option. There are a growing number of tools (e.g. smartphone apps, on-line tests, home hearing tests) available for patients to assess their hearing without the need for a professional evaluation. In their present form, however, these tools only provide general classifications of loss or function, but cannot provide comprehensive data on degree, configuration, type or etiology of loss, nor quantify communication ability. As such, the Academy recommends that any devices or applications that claim to evaluate hearing or auditory function, and are made available to the consumer for self-evaluation, clearly describe their use as a screening tool rather than a diagnostic hearing test, and that labeling of devices indicates that these devices are used solely to screen communicative function rather than hearing loss per se.

Furthermore, the Academy endorses the need for increased awareness of hearing loss and its comorbidities as part of annual primary care examinations, and encourages increased referral for a comprehensive evaluation with the understanding that there is no “normal” age-related hearing loss, and any degree of hearing loss should be appropriately evaluated.

Recommendation #3: Management of Hearing Loss

The symptom of hearing loss is loss of communicative function, and therefore individuals may seek to self-manage their communication deficits, but this should not be construed as treatment for hearing loss or a medical condition. Self-treatment cannot occur in the absence of an accurate diagnosis. The Academy believes individuals who have self-identified with a hearing loss or

communicative impairment are best served when diagnosis leads to the development of a comprehensive treatment plan that may include instruction, counseling, rehabilitative services and/or amplification products. It is critical to recognize that any selected device is only one aspect of the successful management of hearing loss and cannot be considered in isolation as the only necessary treatment. Furthermore, the Academy remains concerned that consumers may not understand the ramifications of under-fit or untreated hearing losses, which may include, but are not limited to, negative impact on cognitive function and diminished success with appropriate but late-fit hearing devices. The Academy recommends a hearing care delivery model that optimizes safe and effective management of hearing loss, and is firm in its position that such a model includes the following:

- a. determination of appropriate management option based on a comprehensive evaluation and individual hearing needs assessment performed by an audiologist;*
- b. consideration of a spectrum of hearing management options that may be appropriate including, but not limited to, hearing aids, assistive listening devices, implantable technologies, communication strategies, and auditory-based therapy;*
- c. recommendation for medical assessment and intervention when appropriate; and*
- d. counseling and recommendations that is cognizant of individual factors that may limit access to appropriate hearing healthcare, including but not limited to geographic constraints and financial limitations.*

Recommendation #4: Affordability

The Academy appreciates that consumers are concerned about the cost of hearing care, particularly as many insurance plans, including Medicare, provide inadequate payment for diagnostic services, and limited coverage for non-surgical treatments for hearing loss, including hearing aids. Moreover, unlike dental care or optometric care, there are few supplemental insurance plans available that cover the cost of hearing care. Improved reimbursement for hearing care services would serve to reduce the burden of consumers to access affordable hearing care. Additionally, requirements such as the need for a physician referral for audiology services by Medicare can add further costs to hearing care by compelling prerequisite physician visits to acquire that referral. The Academy recommends removal of statutory and regulatory requirements that place additional financial burdens on individuals who seek hearing care, particularly for those with mild hearing losses or communicative impairments. Removal of regulations such as that requiring physician referral will result in reducing the cost of hearing care to the consumer.

The Academy also supports access of individuals with hearing loss or communicative impairment to low-cost alternatives for treatment, including low-cost amplification technologies. As such, the Academy recommends that audiologic practices include a broad range of amplification treatment options for patients, and that members endeavor to provide both services and products that meet the communicative and financial needs of patients. In this same regard, the Academy supports the development of a purchasing model for devices that benefits both the practice and the consumer.

The Academy recognizes that for some consumers, there may be a discrepancy between their perceived communication limitation and the relative value of hearing devices. As a result it is possible that over-the-counter (OTC) hearing aids may represent an introductory path to hearing

healthcare that seems more palatable for those consumers with mild hearing loss or mild communicative impairment. While the Academy appreciates that there may be potential benefits of over-the-counter (OTC) hearing aids, their safety and efficacy have not been established. The number of individuals who gain benefit from OTC devices, the magnitude of that benefit, and the patient perspective about the benefits can only be established once the devices become available to the public. Similarly, the risk associated with OTC devices in the U.S. has not been determined. The likelihood of risk, the severity of harm, the number of patients who fail to receive necessary medical treatment, the use of devices by populations other than that intended, and the patient tolerance of risk will be determined if and when the devices are available, and the short-term and long-term outcomes become evident. Until such time that the safety and efficacy of OTC devices has been established, the American Academy of Audiology believes the consumer of hearing care products must continue to be protected from accessing products that put them at risk for greater hearing or economic loss, or fails to provide benefit for their communication impairment. However, the Academy also recognizes that hearing devices are currently under-utilized by appropriate candidates and recognizes that identifying the root cause of this situation as well as appropriate countermeasures should be a high priority focus of professional organizations and government agencies.

Recommendation 5: Education

The Academy recognizes that regulatory or statutory changes to the hearing care delivery system or products require a comprehensive and collaborative education process for the consumer, primary care physicians, the audiology community, other hearing care providers, and government and non-government agencies. The Academy recommends a collaborative approach with key stakeholders to develop the message, materials and delivery system to support this educational endeavor.

Summary:

The Academy recognizes that existing service delivery models for hearing care may need to be reconsidered in order to optimize hearing healthcare for a greater number of consumers impacted by hearing loss. Improving accessibility, encouraging appropriate assessment and management of hearing loss, and recognizing the impact of affordability on amplification usage are all priorities for the Academy. To this end, the Academy presents this position statement on the accessibility and affordability of hearing care for adult consumers.

APPENDIX 2

Products American Academy of Audiology Regulatory Recommendations for Over-the-Counter Hearing Aid Devices and Personal Sound Amplification Products

The American Academy of Audiology (the “Academy”) is the world's largest professional organization of, by, and for audiologists, representing over 12,000 members. The Academy promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research. In anticipation of formal rulemaking related to the development of a category of over-the-counter (OTC) hearing aids and the finalization of draft guidance related to personal sound amplification products (PSAPs), the Academy respectfully submits the following recommendations for consideration by the U.S. Food and Drug Administration (FDA). These recommendations are being offered to ensure that the audiologist’s expertise in managing a patient’s hearing health outcomes are taken into consideration as FDA looks to create a new category of OTC hearing aids. The Academy looks forward to working with the FDA as regulations are finalized through the rulemaking process.

- ***Recommendation 1: Labeling for OTC devices should include language that advises the user that better outcomes are achieved when a comprehensive audiological examination is conducted prior to the acquisition of an OTC device.***

The Academy endorses the rights of individuals to self-direct their hearing care provided that care is safe and effective. The Academy supports the concept that consumers may be able to "self-identify" the presence of a communication problem or a functional limitation or participation restriction. However, no studies suggest that consumers can differentiate degree, type or etiology of hearing loss, or to discriminate those hearing losses that require audiological or medical intervention. Therefore, the Academy does not support the concept of "self-diagnosis" with respect to self-directed hearing care, and instead recommends that the term "self-identification" be used to identify the consumer's ability to determine the need for hearing care. Ideally, individuals who believe they have a communication problem or functional limitation hearing loss are best served by having a comprehensive audiological evaluation prior to their accessing any treatment option. The Academy advocates for inclusion of labeling language that advises the consumer that better outcomes are achieved when a comprehensive audiological examination is conducted prior to the acquisition of an OTC device.

- ***Recommendation 2: Labeling should address utilization of OTC devices, including both hearing aids and/or PSAPs, by individuals under the age of 18. Specific language should be included noting that use of OTC devices by individuals less than 18 years of age should only occur under the direction of a licensed audiologist.***

The Academy firmly believes that OTC devices should be labeled as intended for use by adults over the age of 18. Every effort should be made to ensure these devices are not acquired or used by individuals under the age of 18 years except when dispensed or prescribed by a licensed audiologist. In addition to regulatory language and labeling

requirements that reinforce this principle codified in Section 709 (a)(q)(1)(A)(ii) of the FDA Reauthorization Act, the Academy requests that labeling requirements for OTC hearing devices include the following statement: “Use of OTC devices by individuals less than 18 years of age should only occur under the direction of a licensed audiologist.” Infants and children identified with hearing loss are generally managed by audiologists from the point of identification forward, which may include the use of amplification devices as a part of the treatment process. Throughout the course of this treatment process, there may be infants and children who have short-term or temporary hearing losses for whom traditional hearing aids may not be necessary. In such cases, the audiologist may determine that an OTC type device or PSAP may be the most suitable treatment option for children due to the nature of the loss and other factors. For example, children who have a mild conductive hearing loss who, for medical reasons, must wait for surgical correction and therefore might benefit from a lower cost alternative to a traditional hearing aid. Similarly, OTC or PSAP devices may be beneficial for specific situational needs for children, such as if a child has minimal hearing loss, or an auditory processing disorder without hearing loss. In these situations, a simple amplifier could provide the needed acoustic boost when the child is in the educational environment. Within this context, there may be instances where an OTC device, or a PSAP, may be a suitable alternative for children.

The Academy does not advocate that the intended age limit be changed to allow open access to OTC devices by parents. Due to the role of the audiologist as the primary care giver for children with hearing loss, we suggest the labeling requirements include the qualifier of allowing children to access the device only under the direction of their audiologist.

- ***Recommendation 3: Labeling of OTC devices should advise consumers to seek an evaluation by an audiologist if they are not receiving satisfactory results with an OTC device.***

Many view the emergence of OTC devices as a catalyst for improving accessibility and affordability of hearing care. They believe the availability of OTC devices expands the market to include individuals with perceived mild to moderate hearing loss who may not have previously sought treatment for hearing loss through more traditional channels. Utilization of OTC devices may prove to be another entry point into the hearing health care system and lead to consumers seeking hearing health care from an audiologist as hearing needs increase or change over time. Conversely, there are concerns that a consumer may purchase an OTC device which does not meet their hearing or communication needs, especially as OTC devices are not intended for use by all individuals with hearing loss. The potentially detrimental effects of undertreated hearing loss are well-documented and could negatively impact long-term hearing ability just as much as over-amplification. Furthermore, if a consumer does not receive satisfactory results from the OTC device, they may be discouraged from seeking further treatment. The Academy encourages the FDA to include labeling information directing consumers to seek an evaluation by an audiologist if they do not receive the results they hope for when purchasing an OTC device.

- ***Recommendation 4: Labeling of OTC devices should specify that the output may exceed levels that could cause either additional hearing loss or initial hearing loss in those with normal hearing. Standards for the acoustical characteristics of these devices should be set to limit these risks.***

The category of OTC devices has been established to include targeting listeners with up to moderate hearing loss. Consequently, appropriate gain and output levels (as defined by current prescriptive gain methods), will provide output levels that exceed NIOSH and OSHA recommendations in higher gain and output devices, with consistent exposure to moderately high (or greater) sound levels throughout the day. Therefore, utilizing labeling to acknowledge such a risk is important. In addition, gain and output levels should be limited to the lowest possible levels that remain appropriate for these degrees of hearing loss as specified by currently accepted and validated prescriptive gain methods. Since many devices will include amplitude compression, gain limits should be considered as a function of input level.

Though the FDA Reauthorization Act passed by Congress on August 3 directs the FDA to create a category of OTC hearing aids for adults with perceived mild to moderate hearing loss, the Academy maintains its position that OTC devices be labeled as intended for use by adults with mild hearing loss and with mild communicative impairments. As stated, the Academy believes the FDA should take steps to caution consumers about the effects of potential over-amplification, but also recognizes the need for setting acoustical characteristic standards for these devices in order to limit such risk. Conversely, for those consumers experiencing moderate hearing loss with moderate communicative impairments may find that the devices provide less than optimal amplification. The Academy believes that professional intervention, either through device adjustment or through prescriptive recommendations for devices with specific gain configurations, may be necessary for OTC devices to provide appropriate amplification for those with moderate hearing loss.

- ***Recommendation 5: Labeling of OTC devices should advise consumers to seek an evaluation by an audiologist when they notice any change in their hearing, including temporary changes, as sustained long-term exposure to moderate to high output levels may have a negative effect on hearing.***

Depending on the agreed upon gain and output limitations, OTC devices have the potential to lead to hearing loss in some individuals due to long term exposure to sound levels exceeding OSHA and NIOSH recommendations. Listeners with normal hearing may be particularly at risk. As noted previously, there is no data supporting the concept that individuals can differentiate degree, type or etiology of hearing loss. Indeed, some data have suggested listeners with normal hearing may mistakenly self-identify as having poor hearing thresholds and therefore may purchase and use an OTC device. The Academy recommends that consumers be advised to seek immediate attention from an audiologist should they notice any change in their hearing or communicative function resulting from the use of an OTC product.

- ***Recommendation 6: The Academy recommends that the FDA regulations related to the sale and purchase of OTC devices specify that OTC devices are medical devices and not consumer electronics.***

The Academy recommends that the FDA create regulations related to the sale and purchase of OTC devices to ensure consumers understand that these are to be used to improve communicative impairment and, as such, are medical devices and not consumer electronic products. Certain types of hearing loss may require audiologic or medical intervention. Red flag warning signs should be included with all labeling for products intended to manage hearing loss or communication deficits, and that indications for referral for an audiologic or otologic evaluation should be clearly noted. Retailers and distributors should be required to implement measures to provide consumers with access to clear, easy to understand safety information for OTC devices. One such measure could include having the consumer sign an acknowledgment that they have read and understood the safety and labeling information related to the OTC device prior to purchase. The Academy also encourages the FDA to develop regulations establishing a formalized trial period to allow consumers, who have purchased an OTC device, to have the option to return that device.

- ***Recommendation 7: The FDA should take steps to mitigate consumer confusion regarding the difference between PSAPs and OTC hearing aid devices.***

Hearing aids, including OTC hearing aids, and PSAPs are not interchangeable from the standpoint of intended use, but may overlap greatly in terms of the amplification and processing strategies applied. Given the two distinct intended uses of each classification of product, and the related level of regulatory oversight, marketing for these devices should appropriately and clearly convey to consumers the intended use of the product. The Academy is concerned about the ability of the consumer to differentiate between OTC hearing aids and PSAPs. We applaud efforts to protect consumers who use OTC devices with appropriate labeling and device gain and output limitation. These same protections are, however, currently not applied to PSAP devices. Therefore, as supported by published data, users of current PSAP devices may actually be exposed to higher sound levels than users of appropriately regulated OTC devices. The Academy urges the FDA to define and regulate these devices in such a way as to minimize consumer confusion and maximize consumer satisfaction and protection. We encourage the use of appropriate labeling to allow the consumer to differentiate between OTC hearing aids and PSAPs and would also advocate that gain and output limitations be applied to both OTC hearing aids and PSAPs to ensure proper safeguards exist for consumers purchasing such devices.