Report to the Federal Trade Commission (FTC): Testimony for the FTC's "Issues in Hearing Health Care Workshop"

By

Larry Engelmann, M.S., Au.D.
Doctor of Audiology

Audiology Clinic, Inc.
NW Medical Center
3330 NW 56th St., Suite 105
Oklahoma City, OK, 73112
Office: (405) 946-0364
Fax: (405) 946-3036
Email: myinnerear@cox.net

Submitted: March 30, 2017

Introduction

It is refreshing to know that hearing loss has finally become a major healthcare focus and that the problems confronted by hearing impaired people are a priority. It is long overdue and well-deserved.

I would like to thank those participants from the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering, and Medicine (NAS) for dedicating their time and efforts to providing information about hearing loss and discussing and formulating recommendations on how to accelerate technological advances with hearing aids, promote competition, and improve hearing aid accessibility and affordability for hearing impaired adults. I agree with some recommendations, but not others. Additional thanks go to the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) for providing open forums and opportunities that invite oral and written testimony with diverse input from a wide range of interested parties who have a vested interest in caring for our hearing impaired population.

These are tumultuous times, both exciting and worrisome. In the world of hearing impaired people, it is exciting because the technological advances available today are unprecedented and allow for and enable better hearing restoration than any other time in history. Further, the expectation of technology to continue advancing and at a faster pace is unquestionable. What is worrisome is the proposed radical disruption of the hearing aid manufacturing industry and the retail distribution system thereof that could result in negative unintended consequences for consumers.

On the one hand, there is a sincere concern and effort to help the hearing impaired population and advance their care and access to treatment options. On the other hand, there is a disconcerting effort and push to redesign the hearing aid distribution system to a do-it-yourself (DIY) model at the expense of minimizing and/or eliminating service providers. This model is not in the best interests of dealers, physicians, audiologists, and most importantly consumers.

I am offering you a view from the trenches, as I worked as a clinical and research audiologist from 1977-1985 at an otology clinic and the primary clinical service provider and owner of my audiology practice since 1982. I have learned many things from and about thousands of hearing impaired patients who have taken the journey from denying they have hearing loss to successfully undergoing diagnostic hearing testing, counseling, and audiologic rehabilitation, while adapting to hearing aids and reintegrating back into their family and work lives because of the professional care they received. The hearing industry can and should be able to move

forward in a way that benefits and protects consumers while at the same time makes hearing care accessible and affordable. I appreciate this opportunity to share some of these insights, offer clarifications, add new information to the discussion, and to be able to make recommendations on government involvement. As Winston Churchill said, "There is nothing wrong with change as long as it is in the right direction."

Definitions

The importance and usage of correct terminology cannot be over-emphasized. The terminology used in all future communications related to the issues and topics addressed by the FDA, FTC, and other stakeholders should be statutorily correct, representative of, and commensurate with academic/technical/vocational recognition. Otherwise, terms and phrases used incorrectly or inappropriately can lead to public confusion, deception, misleading, misunderstanding, and/or fraud. The public deserves to receive understandable, reliable, and truthful information, especially when it involves their healthcare. Consumers should be able to make healthcare decisions based on factual and accurate information. Examples are listed below:

Hearing health care professionals (HHCP): This phrase, or any derivation thereof, should **not** be used in the future by any agency or group. The NAS report reads, in part, "For the purposes of this report the term "hearing health care professionals" is used broadly to encompass those who work in hearing healthcare (including audiologists, hearing instrument specialists, and otolaryngologists). The term is used throughout the report primarily for ease – that is, one collective term, rather than listing each group repeatedly throughout the report" (NAS, 2016).

Identification and recognition of separate occupations and professions are essential for consumer understanding and transparency. Physicians, dealers, and audiologists are extremely different groups, serve very different functions, have vastly different training and education, and should be defined and acknowledged as such. Neither expediency nor convenience should be accepted as a rationale to blur the lines between them. Referring to these groups in a generic "one size fits all" manner and as a collective of HHCPs is inappropriate and will serve only to confuse and mislead consumers If the use of HHCP is not eliminated now, the phrase will inadvertently be used in future communications, legislation, policies, and consumer education. Its use is incongruent with the consumer education component of almost every recommendation presented by the NAS.

Profession: Those individuals who enter a career requiring education and training at or beyond the baccalaureate degree. As audiologists and physicians, these licensed doctors are members of a profession. In healthcare, they are considered to have "scopes of practice" (Engelmann, 2017).

Occupation: Those individuals who enter a technical/vocational career requiring education and training with less than a baccalaureate degree. They are considered to have "work-roles", i.e., job duties and responsibilities (Engelmann, 2017).

Hearing Aid vs. hearing instrument: "Hearing Aid" is the dominant descriptor in audiology's licensing statues, not "Hearing Instrument". The descriptor "Hearing Aid", used in 46 states, remains the industry's standard terminology by the following agencies and institutions: Federal Communications Commission (1988); U.S. Food and Drug Administration (FDA) (2015); Hearing Industries Association (HIA); National Center for Educational Statistics (NCES) (2016b); U.S. Department of Health and Human Services (2016); National Institute on Deafness and Other Communication Disorders (NIDCD) (2016); Department of Veterans Affairs Veterans Health Administration (VHA) (March 14, 2011); and the Federal Trade Commission (2010).

Hearing aid dealer vs. hearing instrument specialist: The statutory language predominately used in licensing laws is "Hearing Aid Dealer" and, consequently, the terminology of choice. "Hearing Instrument Specialist" is the descriptor adopted in only four state's audiology laws and six state's hearing aid dealer laws and, consequently, the terminology that should **not** be used (Engelmann, 2017).

Hearing aid dealer – hereafter referred to as "Dealer": Dealer's licensing most commonly require a minimum of a high school diploma (occasionally less); on-the-job training; or apprenticeship; and in a few states a two year technical/vocational Associate of Applied Science degree. They are considered members of an occupation, not a profession. Their work-roles are limited to hearing testing for the purpose of selecting, fitting, dispensing, repairing, and selling hearing aids and their accessories.

Audiologist: Non-physician members of the Healing Arts doctoring professions. In the context of current licensing laws, audiologists are required to earn a professional doctor of audiology degree (four years post-baccalaureate). As such, they are positioned in the healthcare hierarchy as point-of-entry primary care doctors to diagnose and treat patients who have hearing and balance disorders. Their broad scope of practice includes such things as, but not limited to: differential diagnosis of a variety of hearing disorders, tinnitus, and balance disorders; select, fit, dispense, repair, and sell hearing aids and their accessories; provide counseling and audiologic rehabilitation and vestibular rehabilitation; industrial and recreational hearing conservation; and work with cochlear implants and middle ear implantable devices.

Otorhinolaryngologist/Otologist – hereafter referred to as "Physician": Also referred to as Ear, Nose, and Throat (ENTs) physicians. They are members of the Healing Arts doctoring professions. In the context of current licensing laws, physicians are required to earn a professional doctor of medicine degree (four years post-baccalaureate). Following, they complete a five year specialty residency program for head and neck surgery to become an ENT. If desired, two additional years of an otology fellowship can be completed to sub-specialize in ear and balance medicine and surgery, e.g., cochlear implants. Their extensive medical/surgical training positions them in the healthcare hierarchy to provide tertiary, not point-of-entry, healthcare. They are not licensed to fit and sell hearing aids. However, it is common for a hearing aid dispensary to be part of their practice with either an audiologist in their employ or in partnerships with audiologists.

Medical device: According to Sec. 201 of the Food, Drug, and Cosmetic Act, the definition of a medical device stipulates that it is 1) Intended to diagnose, cure, mitigate, treat, or prevent a disease/condition, or 2) Intended to affect the structure or function of the body, and 3) Does not achieve intended use through chemical action or metabolism.

Rationale For Change

The NAS and others are pushing for radical hasty reform based on unsupported suppositions and implications lacking credible longitudinal research, e.g., a) there are not low cost hearing aids available – this is false; b) there is not sufficient competition in the hearing aid industry – this is false; c) consumers are educated and skilled enough to self-diagnose and self-treat mild-to-moderate hearing loss – this is false; d) consumers are educated and skilled enough to self-fit and program advanced hearing aid technology for themselves – this is false; e) a new category of over-the-counter hearing aids will dramatically improve the hearing aid penetration and adoption rates with consumers – again false.

Some well-intentioned people are attempting to change the face of hearing care by disrupting product distribution and putting diagnosis and treatment of hearing loss into the hands of lay people. These proponents are missing the point, because it is actually the professional/occupational component that is most crucial.

While good intentioned advocates are demanding and expecting over-the-counter hearing aids (OTC HAs), it is shortsighted to think that hearing aids are the total solution to hearing loss and communication disorders. They are overestimating an unknowledgeable, unskilled, untrained, and unregulated consumer's ability to understand and manage a complex health condition with complicated electronic medical device applications.

As I have read the PCAST and NAS information as well as other literature, I have concerns about how some of the findings, conclusions, and recommendations were arrived at. I believe that some of the premises,

assumptions, presumptions, implications, assertions, and generalizations presented are incomplete or inaccurate, misleading, unwarranted, incorrect, are flawed and lack merit. Unclear, imprecise, and/or incomplete information could lead us to incorrect or the wrong conclusions, thereby sending us down the wrong path, and cost consumers and other stakeholders unnecessarily. Steve Woolridge warns us that, "In scientific theory, if your premise is wrong then everything that follows is wrong."

Summary of the National Academy of Sciences (NAS) Report

The NAS published the report, *"Hearing Health Care for Adults: Priorities for Improving Access and Affordability"* (NAS, 2016). The report's 12 recommendations are summarized below (www.nas.edu/hearing):

1. Improve Population-Based Information on Hearing Loss and Hearing Health Care;
2. Develop and Promote Measures to Assess and Improve Quality of Hearing Health Care Services – in part: "Align and promote best practices and core competencies across the continuum of hearing health care, and implement mechanisms to ensure widespread adherence";
3. Remove the Food and Drug Administration's Regulation for Medical Evaluation or Waiver;
4. Empower Consumers and Patients in Their Use of Hearing Health Care;
5. Improve Access to Hearing Health Care for Underserved and Vulnerable Populations – in part: "… incentivize practice in underserved communities.";
6. Promote Hearing Health Care in Wellness and Medical Visits;
7. Implement a New Food and Drug Administration Device Category for Over-The-Counter Wearable Hearing Devices;
8. Improve the Compatibility and Interoperability of Hearing Technologies with Communications Systems and the Transparency of Hearing Aid Programming;
9. Improve Affordability of Hearing Health Care;
10. Evaluate and Implement Innovative Models of Hearing Health Care to Improve Access, Quality, and Affordability;
11. Improve Publicly Available Information on Hearing Health;
12. Promote Individual, Employer, Private Sector, and Community-Based Actions to Support and Manage Hearing Health and Effective Communication.

Support or Oppose the NAS Recommendations

I support recommendations 1, 2, 3, 4, 5, 6, 8, 11, and 12. I offer provisional support for recommendation 9. I will clarify my concern over "transparency" recommendations later in this report. I am also concerned about the part of the recommendation indicating that CMS evaluate options so that treatment of hearing loss is affordable for Medicare beneficiaries and with Advantage plans. My concern is over how CMS views what is "affordable". Typically, Medicare's reimbursement rates are not compatible and not competitive with appropriate and fair reimbursement that would make it attractive to become a participating provider. For example, Dr. Brayer notes, "Medicare … pays fees to primary care physicians that guarantee bankruptcy. Additionally, 70% of hospitals in the United States lose money on Medicare patients. That is why Mayo Clinic has said it will not accept Medicare payments for primary care physicians visits. Mayo gets it. Nationwide, physicians are paid 20% less from Medicare than from private payers. If you are not paid a sustainable amount, you can't make it up in volume. I just doesn't pencil out" (Brayer, 2010). It is one thing to talk about reducing healthcare costs; it is quite another to take it to extremes where consumers either are forced out of their physician's practice because the physician stopped taking Medicare or they cannot see their provider of choice because the provider does not participate in Medicare.

I offer provisional support for recommendation 10. It is easy to agree with providing Direct Access to audiologists for Medicare recipients who would no longer need a physician referral to an audiologist for hearing related services. However, I oppose the section that reads: "This excludes direct access to audiologic

testing for assessment of vestibular and balance disorders and dizziness, which require physician referral." The most radical hasty reform recommended by the NAS report is to turn over the diagnosis, treatment, and medical device rehabilitation of mild-to-moderate hearing loss, i.e., a chronic health condition, and make it a "Do-It-Yourself" system for unknowledgeable, unskilled, untrained, and unregulated consumers who are exempt from statutory regulation. Doctors of audiology should be allowed to practice to the full extent of their scope of practice and not be required to ask permission from another doctor to perform what they are trained and licensed to perform. NAS's recommendation to exclude audiologists from vestibular diagnosis and treatment actually serves as a barrier for consumer accessibility and affordable healthcare. The exclusion also has the appearance of restraint of trade for a licensed doctor.

I adamantly oppose 98% of recommendation 7. An explanation on this matter will be clarified and expounded upon later in this report. I do agree with the portion that stipulates, "FDA should retain a guidance document on personal sound amplification products (PSAPs) that describes PSAPs as products that are not to be offered or promoted to address hearing loss and are subject to the electronic product provisions of the Federal Food, Drug, and Cosmetic Act through its 2009 PSAP guidance document or a revision of its 2013 PSAP draft guidance document."

Semantic Gymnastics: OTC HA – Medical Device or Consumer Product

The NAS's report recommendation 7 reads, in part: "The Food and Drug Administration (FDA) should establish a new category of over-the-counter (OTC) wearable hearing devices. This device classification would be separate from "hearing aids." OTC wearable hearing devices would be defined as wearable, over-the-counter devices that can assist adults with mild to moderate hearing loss."

The recommendation to establish a new category of over-the-counter (OTC) wearable hearing devices (i.e., OTC HAs) as a separate category from hearing aids is merely "semantic gymnastics". Call them what you like: wearables, hearables, ear candy, or any other buzzword. Among other reasons that I will address below, OTC HAs would serve to confuse and mislead the public and could actually delay consumers from receiving necessary and proper healthcare. If you think that there is confusion and debate over PSAPs and hearing aids now – just wait.

PSAPs are for the general public as a retail consumer electronic amplifier product and for recreational use, not for medical purposes. Some licensees already use PSAPs to fit on hearing impaired people. Never-the-less, these OTC products currently exist. Consequently, there is no need for another OTC category.

Laws

On March 22, 2017, it was announced that a handful of Senators reintroduced the "Over-the-Counter Hearing Aid Act of 2017". The Bill proposes amending Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) to include "Regulation of Over-The-Counter Hearing Aids.". It stipulates, in part, "(B) that is intended to be used by adults over the age of 18 to compensate for perceived mild to moderate hearing impairment; (C) that, 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) that may – (ii) include tests for self-assessment of hearing loss; and (E) that 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."; "(4) Effect On State Law – No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically applicable hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids."

I will not fault the Senators for trying to do something good for a group that deserves help. However, hearing loss is a complicated chronic health condition, not a common cold. This Bill is disturbing and misleading in

ways that are similar to my expressed objections about some of the NAS report recommendations discussed throughout this document. For example, a) the Bill effectively turns a medical device into a retail commodity; b) It improperly positions unknowledgeable, unskilled, untrained, and unregulated consumers as "point-of-entry" providers in healthcare for hearing disorders instead of audiologists or physicians; c) There are no self-diagnosing tests available to consumers that have undergone adequate reliable clinical validation studies nor are there any standards established for consumer self-testing. Yet, the Bill allows for consumers to self-diagnose based on what they "perceive" as a hearing loss. If physicians, dealers, and audiologists used the sub-standard method of "perceiving" hearing loss, they would be subject to legal liability, ethical violations, malpractice, financial penalties, and loss of their licenses; d) It completely excludes and ignores State laws governing the sale, fitting, and distribution of hearing aids. Radical hasty reform bills are not in the best interest of the public safety, do not improve but degrades hearing healthcare, and are the antithesis of evidenced-based best-practices for the complicated needs of the hearing impaired population. We should take heed from the article: "Bad Policy Is as Harmful as Bad Medicine" (http://www.medscape.com/viewarticle/871989_print).

The feds should not impose their wills on nor preempt the authority of state audiology, dealer, consumer protection, and healing arts laws and should not create new laws that are inconsistent with the states. To do so would not be in the public interest and would additionally and directly undermine the work done by the doctor of audiology schools, the National Council of State Boards of Examiners for Speech-Language Pathology and Audiology, and the individual state boards of audiology and dealer's occupational licensing agency

New laws should not conflict with or violate other laws. The federal government should be cautious about interfering with and respectful of state's rights and sovereignty. There was a point in history when there were no licensing laws for dealers or audiologists. It took many years to establish those laws in all 50 states. The creation of a new OTC HA category would enable consumers to self-diagnose and self-treat mild-to-moderate hearing loss while at the same time dismissing, usurping, and excluding state's established laws regarding the sales and distribution of hearing aids.

NAS's recommendation 7 stipulates, in part, these devices would: "Be subject to regulatory requirements that would explicitly preempt current state laws and regulations for hearing aids and dispensing and preempt potential future state laws and regulations seeking to limit over-the-counter access"; "Be subject to quality system regulation (QSR) requirements, but be considered for exemption from certain QSR requirements as determined by FDA to be appropriate for this category"; and "Have the option to include accessory tests for self-assessment of mild to moderate hearing loss for purposes of selecting and fitting an OTC hearing device." These disturbing recommendations are particularly dangerous for consumers and inappropriate.

The National Institutes of Health (NIH) notes that, "Hearing is a complex sense involving both ear's ability to detect sounds and the brain's ability to interpret those sounds, including the sounds of speech." (www.nihseniorhealth.gov). If hearing loss is the 3rd highest chronic disease in the U.S. and hearing is recognized as a complex sense, what makes anyone think that the diagnosis and treatment of mild-to-moderate hearing loss should be turned over to unknowledgeable, unskilled, untrained, and unregulated consumers?

Licensure laws are established to protect the public. They define eligibility, training requirements, and what activities are and are not allowed. These and other laws guard consumers against misleading, deceiving, and unscrupulous practices.

Discussion about licensing laws is conspicuously absent from the PCAST and NAS reports and other information provided thus far. Especially consumers should understand the importance and intent of having these laws for their benefit. Below are excerpts from audiology and dealer licensing laws that should offer readers a clearer understanding of and about the serious nature of why these laws exist and for whose benefit:

1. Licensing boards promulgate rules that “are not inconsistent with the Constitution and laws of the state, and that are reasonably necessary to the conduct of its duties and proceedings”. Boards “may impose separately, or in combination, disciplinary actions on a licensee and/or suspend or revoke a license” with proof that the licensee is guilty of fraud, deceit, unprofessional conduct, gross negligence; has violated federal, state or local laws or the code of ethics; and/or “has been convicted or has pled guilty or nolo contendere to a felony or to a crime involving moral turpitude”. Those found guilty of practicing audiology unlawfully have committed a misdemeanor and subject to fines and/or confinement to jail for not longer than six months (Each day of violation is a separate offense).
2. Audiologist and dealer licensing laws have, among others, these common traits: a) they are designed state policy “to safeguard the public health, safety and welfare, and to protect the public from being misled by incompetent, unscrupulous and unqualified persons”; b) by conducting certain activities common to those defined for audiology practice, individuals are considered “holding themselves out to the public as an audiologist” – this is similar for dealers. To do so without a license is considered the unlawful practice of audiology; c) "Measurements of auditory thresholds are not included in hearing screening programs; "Hearing Screening" means a binary pure tone screening at a preset intensity level for the purpose of determining if an individual screened needs further testing prior to the selection or sale of a hearing aid. d) Exemptions from audiologist and dealer licensing laws are commonly: Federal employees, physicians, teachers of the deaf and hard of hearing, and the activities of hearing screening programs which are conducted by employees or trained volunteers who are providing these services under the auspices of public or private charitable agencies.
3. "Practice of fitting and dealing in hearing aids" means those practices used for the purpose of selection, adaptation and sale of hearing aids including direct observation of the ear together with the counseling and instruction pertaining thereto, the testing of human hearing for these purposes and the making of impressions for earmolds.”
4. “No person shall engage in the sale of or practice of fitting hearing aids or display a sign or in any other way advertise or represent himself as a person who practices the fitting and sale of hearing aids without first obtaining a license or permit in accordance with these rules from the Commissioner”.
5. “Nothing in these regulations shall prohibit a corporation, partnership, trust, association or other like organization maintaining an established business address from engaging in the business of selling or offering for sale hearing aids at retail without a license, provided it employs only properly licensed persons in the direct sale and fitting of such products. Such corporations, partnerships, trust, associations or other like organizations shall make a list of all licensed hearing aid dealers and fitters directly or indirectly employed by them available to the Department upon request.”
6. “All instruments used to measure thresholds shall be annually certified to meet American National Standard Specifications for Audiometer, S3.6-1969 or a standard which supersedes it.”
7. “Hearing testing for the purpose of fitting hearing aids shall not be conducted where ambient noise levels exceed 45 dB measured on a slow weighted dB (a) scale. If the testing environment exceeds 45 dB, the testing shall be considered a "Hearing Screening" and shall not be utilized to determine the auditory thresholds in the selection of a hearing aid …”
8. “Screening. A licensee may conduct a hearing screening at a health fair, state fair, public location or similar facility, but due to excessive background noise commonly found in these environments, measurement of auditory thresholds are not acceptable. A licensee should present to the person receiving the "Hearing Screening" a written statement at the time of the screening containing the following provisions: Results of a "Hearing Screening" are not a medical or audiological evaluation of your ear or a diagnosis of a hearing disorder. You passed/failed (circle one) the hearing screening. Failing a screening is an indication you need further testing prior to the selection of a hearing aid.”
9. Selling a hearing aid to a person who has not been given tests utilizing appropriate established procedures and instrumentation in fitting of hearing aids is prohibited.
10. Separate from state licensing laws are state’s “Healing Arts Acts”. These laws define and regulate who is allowed to “diagnose and treat”.

There is no collection of peer-reviewed, evidenced-based, longitudinal research to support and justify consumers self-diagnosing and self-treating hearing loss. On the contrary, consumers have been shown to be unreliable sources of identifying the presence or absence of hearing loss or realizing the type and degree of hearing loss. Furthermore, there are no longitudinal studies that support the unsubstantiated premises put forth about making these FDA hearing aid classification changes to a DIY OTC HA system.

The federal OTC HA category would completely invalidate and exclude states from regulating and controlling the distribution of OTC HAs thereby forcibly eliminating a state's consumer protection obligation. I submit to you that it is discriminatory and irrational to require audiologists and dealers go through the rigors of licensure and adhere to continuing education requirements while simultaneously exempting unknowledgeable, unskilled, untrained, and unregulated consumers from the same or similar responsibilities. Such an OTC HA system makes a mockery of education, academic accreditation standards, equipement standards, codes of ethics, licensure, and healing arts laws.

Licensed audiologists and dealers are mandated and obligated by ethics and law to consider the Red Flag signs and symptoms of hearing loss and to direct consumers to appropriate care. They are subject to punitive and liability actions if ignored. Consumers' self-diagnosis and self-treatment models do not hold consumers to this or any standard; they require absolutely no training, and there are no established minimum competencies. Self-diagnosis and self-treatment of any type or degree of hearing loss is the antithesis of good and proper healthcare, best practices, and evidence-based practice.

If it is so unimportant for consumers to have an education and training in order to lawfully self-diagnose a mild-to-moderate hearing loss and self-treat, then why would they not logically expect to take the next step and demand that they also are allowed to self-diagnose severe-to-profound hearing loss and to self-treat with stronger hearing aids? If all that is required of consumers is to read the product labeling and an owner's manual in order to practice audiology without a license and to become an unlicensed dealer, what does that say about the occupation of dealers and the audiology profession?

Audiologists and hearing aid dealers are only the ones allowed to test hearing for purpose of fitting hearing aids. Manufacturer/consumer literature should not supersede and circumvent licensure laws. States regulate and limit the sales of hearing aids by only those licensed by the state. Even in wholesale warehouses like Sam's Club or Costco, hearing aids are sold by their employees who are licensed to sell them.

Professionals and occupations are expected to adhere to best practices and scientific rigor, etc. The FDA should not create a new OTC HA category as this DIY model will end up as another unsuccessful "social experiment" like "sight reading" or "open classrooms" and as seen in other countries like the failed OTC HA system in Japan.

By having OTC HAs and allowing consumers to self-diagnose and self-treat mild-to-moderate hearing loss completely exempts consumers from any kind of responsibility, ethics, adherence to laws, any penalties, and they would be exempt from rigorous standards and laws and would not be required to have any level of education or training.

Federal Trade Commission (FTC)

The 1944 Trade Practice Conference for the Hearing Aid Industry's opening remarks by the Honorable Robert E. Freer, read in part: "…called for the purpose of letting us all sit down together in cooperative effort toward providing against unfair or harmful practices and consequently toward the better protection of the industry and the public."; "A trade practice conference for an industry looks toward the promulgation by the Commission of rules of fair competition designed to protect both industry members and the consuming public." (Freer, 1944)

A 2007 Small Business Administration report to the U.S. president details the vital role that the 26.8 million small businesses in the U.S. play in the economic well-being of our nation. The report describes that new business entrepreneurs provide long-term benefits to the local economy, contribute to maintaining economic growth, employing workers and brining new innovations to the market place. In addition, a state's ability to generate new establishments is reported as the most critical factor leading to higher gross state product, state personal income and overall state employment (Office of Advocacy, 2007).

The FTC acknowledges that: it has a "unique dual mission to protect consumers and promote competition" (www.ftc.gov/about-ftc/what-we-do) ; "… prevent business practices that are anticompetitive or deceptive or unfair to consumers; to enhance informed consumer choice and public understanding of the competitive process; and to accomplish this without unduly burdening legitimate business activity." (www.ftc.gov/about-ftc)

The FTC indicates that, "Competition in America is about price, selection, and service. It benefits consumers by keeping prices low and the quality and choice of goods and services high." (www.ftc.gov/about-ftc/what-we-do) The OTC HA and self-diagnosis and self-treatment recommendation from the NAS and the recently proposed OTC HA Act of 2017 virtually eliminates the "service component", an area with which the FTC is invested and should have major concern.

The FTC has, on its website, a discussion about the National Society of Professional Engineers v. United States. It describes, in part, the following directive from the Court: "The assumption that competition is the best method of allocating resources in a free market recognizes that all elements of a bargain – quality, service, safety, and durability – and not just the immediate cost are favorably affected by the free opportunity to select among alternative offers**"** (Signs, 2015). It appears that the courts have recognized "service", and not just immediate cost, as an important and essential component in competition policy. The NAS and the recently proposed OTC HA legislation recommendations for OTC HAs and self-diagnosis and self-treatment by consumers for mild-to-moderate hearing loss completely ignores and excludes the "service" component by eliminating audiologists, dealers, and physicians who are the only people licensed and trained to provide a service component for hearing impaired consumers.

In "Examining Health Care Competition" a previous FTC workshop was conducted to look at achieving "… the triple aim" of health care reform: reduce costs, improve quality, and increase patient satisfaction. Our workshop will focus, in particular, on the potential implications for competition and consumer protection" (Schultheiss, 2015). a) It seems to me that a discussion about healthcare competition relates to encouraging and improving competition between and among healthcare providers for the benefit of patients, not to remove competition and providers and put what is a false illusion of healthcare into the hands of unknowledgeable, unskilled, untrained, and unregulated consumers. b) To be considered a "patient", a consumer needs to establish a provider-patient relationship. c) The "improve quality" implies it is being done by a provider for the patient. The DIY OTC HA model will **not** improve healthcare quality; rather will have the opposite effect. The HIA also reports that OTC HA systems will actually reduce patient satisfaction (HIA, 2016). d) The NAS recommendations and the recently proposed OTC HA legislation take the third largest chronic health condition in the U.S. and turn its diagnosis and treatment over to the majority of consumers with this condition who have mild-to-moderate hearing loss. Rather, than recommending and advocating for ways to advance better hearing care and ways to create and promote competition between healthcare providers, the NAS recommendations and the recently proposed OTC HA legislation effectively eliminates the providers; thereby creating a poorer healthcare environment for the hearing impaired population.

The FTC's "Bureau of Economics predicts and analyzes the economic impact of FTC activities, especially as these activities relate to competition, interstate commerce, and consumer welfare" (www.inc.com/encyclopedia/federal-trade-commission-ftc.html). As of yet, there has been no mention of an economic impact study for the dealer's occupation, the physician's and audiologist's profession, as well as audiology students and audiology schools.

Audiologists, physicians, and dealers not only work in or own small businesses; these three groups are also technically consumers who purchase medical devices from wholesale manufacturers. I have not seen any discussion about strategies on how to reduce the cost of hearing aids to the aforementioned groups. The only discussions I have read have been about strategies on how to direct one group of consumers away from these other groups of consumers and service providers. The hearing aid business has always been a low volume and higher cost business as exampled in the article reporting the average number of hearing aids sold per month per practice as 23 (Hearing Review, 2011). Noted elsewhere in this report, as much as 50-60% of hearing aid business could be directed away from these consumers/service providers with an OTC HA system, and it will cause undue burdens on the former groups. OTC HAs and self-diagnosing will not open the market to a significantly larger extent and will have a greater potential to cause harm than good to consumers. The FTC stipulates that its Mission is, in part, "To prevent business practices that are anticompetitive or deceptive or unfair to consumers." Changes for one set of consumers should not come at the expense and possible ruin of another group or groups of consumers, i.e., audiologists, dealers, and physicians.

The NAS Report, Recommendation 2 is: Develop and Promote Measures to Assess and Improve Quality of Hearing Health Care Services. It, in part, reads, "Align and promote best practices and core competencies across the continuum of hearing health care, and implement mechanisms to ensure widespread adherence;" This recommendation is counterintuitive to the proposition of self-diagnosis and self-treatment of mild-to-moderate hearing loss by unknowledgeable, unskilled, untrained, and unlicensed consumers. NAS's recommendation 7 and the OTC HA Act of 2017 proposal actually eliminate beneficial best-practices and essential proven standards from consumers. NAS's recommendations and the new proposed legislation will effectively deconstruct the occupation of dealers and the audiologist's profession; and will shift revenue from productive small businesses to a group of large wholesale manufacturers of consumer electronic products. This will not expand, but rather contract American businesses.

Small Business Administration

In discussing and proposing the disruption of the hearing aid industry and about how hearing care is provided, there is an obvious and complete lack of discussion about what it takes to establish and succeed in business and about the years of study and experience it takes to understand, work with, and care for hearing impaired people. Dismissing important and relevant information creates a void when one area is discussed without the others. Radical recommendations and decisions made like the ones proposed by the PCAST, NAS, and the recently proposed OTC HA Act legislation without looking at the complete picture, is a receipt for disaster. There is a misconception and unproven assumption that easy access to OTC HAs will result in better hearing care.

It is incongruent for one branch of the government to create policies, regulations, and laws that contradict, conflict with, or interfere with another branch's goals, vision, and directives. The Small Business Administration's (SBA) Mission is, in part, "… to aid, counsel, and protect the interests of small business concerns, to preserve free competitive enterprise and to maintain and strengthen the overall economy of our nation." and "… helps Americans start, build and grow businesses" (www.sba.gov/about/sba/what-we-do/mission).

Linda McMahon testified at her confirmation hearing to the Senate Committee on Small Business that, "Small business people are people with goals and values that can't be calculated on a profit and loss statement." and "I will do my best to advocate on their behalf" (Quittner, 2017).

The SBA's Office of Women's Business Ownership's mission is, in part, "to enable and empower women entrepreneurs through advocacy, outreach, education, and support" (www.sba.gov/offices/headquarters/wbo). The SBA "provides resources to help women entrepreneurs launch new businesses, grow their businesses and compete in the global marketplace" (www.sba.gov/starting-business/how-start-business/business-types/women-owned-business).

"Research suggests female small business owners will create 5 to 5.5 million new jobs nationwide by 2018." "They generate more than half of the 9.72 million new small business jobs expected to be created by 2018" (Leadem, 2016). "Women own 36% of all business, according to the 2012 U.S. Census – a jump of 30% over 2007" (Forbes, 2016). "In 2015, female full-time workers made only 80 cents for every dollar earned by men, a gender wage gap of 20%" (Baron, 2016).

The audiology profession is made up of 80% women and 20% men (Kirkwood, 2012). Audiologist is listed as the 16th fastest growing profession for women (Goudreau, 2010). In 2016, the mean annual income for 12 month full-time audiologists was 34% less for females than males (American Academy of Audiology, 2016).

The movement to initiate OTC HA regulations and laws could produce the profound and unintended consequences of damaging audiologist's businesses in a variety of practice sites resulting in lost revenue and consequently the possibility of increased unemployment and/or business closures. OTC HAs would create an environment of unfair competition between licensed individuals and non-licensed individuals. The FTC and SBA certainly understand what it takes to establish and maintain a business and to be available and stable in order to create longevity to provide services and care for patients year after year.

It is likely that fewer people will seek sales and services from physicians, dealers, and audiologists due to declassifying and deregulating mild-to-moderate hearing loss, turning it into a retail task. Reduced hours or job elimination usually follows a reduction of business. Resulting unemployment due to consumer self-diagnosis and self-treatment and OTC HAs will impact other businesses and have unintended consequences, e.g., landlords who rent to these small businesses could lose tenants and rent – the median range of office square footage for a solo practice = 1200 sq. ft. to 3600 sq. feet for multiple office locations (Hearing Review, 2011). Insurance companies, who insure the businesses, would lose out on office overhead premiums, etc. A move like this will not be well received by the audiology profession or with other women's groups. It will create unemployment in audiology's woman dominated profession, and the wage gap will enlarge.

While speaking about business recently, President Trump made the following comments: "We must create a level playing field for American companies and our workers"; and "I believe strongly in free trade; but, it also has to be fair trade." In talking about improving healthcare, he called for, "… reforms that expand choice, increase access, lower costs, and at the same time provide better healthcare" (Trump, 2017). This latter goal of providing better healthcare is counter-intuitive to OTC HAs and consumers self-diagnosing and self-treating mild-to-moderate hearing loss. Evidenced-based best-practices by licensed providers should be the gold standard of care for consumers, not a free-for-all DIY model.

Audiology students are also consumers. Colleges and universities are businesses. Students purchase products from these institutions, i.e., knowledge and training. They have value and quality of life expectations from their purchases. Both students and academic institutions are in line to be harmed by some of the NAS recommendations and the recently proposed OTC HA Act legislation. Student recruitment into audiology schools and the profession could be negatively impacted by these changes; making audiology a less attractive profession to students exploring their interest in pursuing clinical doctorate education. How will potential students view entering the audiology profession when they learn that the government has minimized the importance of mild-to-moderate hearing loss and relegated and reduced its diagnosis and treatment to unlicensed consumers?

How can audiology professors be expected to justify, rationalize, and teach audiology students that while hearing loss is a chronic health condition in the U.S., that mild-to-moderate hearing loss (up to 70 dB HL) is so insignificant and hearing aids have become so simple that the diagnosis and treatment and the fitting of therapeutic rehabilitative medical devices, i.e., HA technology, can be turned over to the consumers with an owner's manual? Audiology students spend thousands of hours in clinical rotations honing their diagnostic, treatment, and rehabilitation skills; hundreds of hours of classroom and out-of-class study learning about and

understanding standards, test techniques, hearing aid technology, and clinical application with patients. Then ask students to stay in school to incur $100,000 of student debt with the probability of having fewer career options available after graduation.

Good intentions do not necessarily make for good policy. Some of the NAS recommendations talk about accomplishing goals like strengthening research training programs; align and promote best practices and core competencies; and implement a set of quality metrics and measures to evaluate hearing healthcare services, etc. The DIY OTC HA model with consumer self-diagnosing and self-treating is the antithesis to the reasons for accomplishing most of the NAS goals. So, best-practices, evidence-based practice standards, and core competencies become moot. What is the point of needing to collect data, so you can improve healthcare outcomes and efficiency, when the system created by NAS's OTC HA recommendations has no way of tracking these metrics? The system is specifically and intentionally designed to not see the very people on whom you want to collect data. Many aging people have comorbidities that need to be co-managed by licensed healthcare providers with a team approach. The DIY OTC HA model specifically allows for and encourages consumers to **NOT** seek proper healthcare.

Harvard Business School's Institute for Strategy and Competitiveness notes that, "To deliver more value, providers need to focus on quality" (http://www.isc.hbs.edu/health-care/vbhcd/Pages/integrated-practice-units.aspx). "Outcomes are the ultimate measure of quality." "In health care, measurement of value should focus on how well the care delivered meets individual patients' needs" (http://www.isc.hbs.edu/health-care/vbhcd/Pages/measuring-outcomes.aspx). In the DIY OTC HA model, there is no care delivered. Consumers only receive a product with an owner's manual. Our goal should be to lower cost while continuing to provide quality care and value to our patients. Our goal should NOT be to eliminate the care provider and alternatively create a cheap DIY system.

There has not been, but should be, an economic impact study on the effects of the considered changes on the occupation of dealers and the physician and audiology professions.

Self-diagnosis and Self-treatment

It is illogical and incongruent to rationalize that one segment of the hearing impaired population, i.e., those with mild-to-moderate hearing loss, somehow have the magical capability to self-diagnose and self-treat whereas the other segment(s) of the hearing impaired population mysteriously do not have the capability to self-diagnose and self-treat, i.e., those with severe-to-profound hearing loss.

Since self-diagnosing can be prone to error, it can lead to mis-diagnosing. This would lead to inappropriate self-treatment. The efficacy and reliability of consumers self-diagnosing and self-treating mild-to-moderate hearing loss has not been demonstrated or established. There is no valid or reliable scientific evidence, are no adequate clinical validation studies that have followed rigorous and good research practices, and are no standards established for consumer self-testing to support consumers being able to self-diagnose and self-treat hearing loss. On the contrary, studies have shown that consumers are not accurate in subjectively analyzing their hearing loss. Even if a consumer had a portable audiometer, test reliability will vary due to multiple reasons, e.g., no training on how to test; room acoustics; ambient noise, etc.

Psychometrically validated self-reported surveys and questionnaires can provide valuable information for dealers and audiologists when appropriately used by consumers and may be helpful and useful in determining an outcome assessment like for hearing aid satisfaction and use and for assessing elements of "quality of life" like interpersonal relationships. However, self-reports are **not** sufficiently precise and cannot result in valid conclusions about diagnosing the type and degree of hearing loss and should **not** be used as criteria for determining or establishing parameters for proper diagnosis, treatment, rehabilitation, and amelioration of hearing loss.

Reasons For Not Buying Hearing Aids

People don't think of hearing loss as a health hazard. In terms of health priorities, people are more inclined to pay attention to life-threatening and painful conditions first and to attend less to health issues that are invisible and do not physically hurt.

The issue of cost should not be viewed in isolation or in a vacuum; or only in terms of dollars and cents; or made out to be the predominant factor for not buying hearing aids. There are many other overriding factors and reasons why people do not seek audiologic care or purchase hearing aids. Here are several (Trychin, Samuel, Ph.D):

- Don't realize they have a problem.
- Denial – They know hearing loss exists at some level but won't admit it.
- Denial – Know they have hearing loss but do not realize it is a problem for them or for others.
- Denial – Know they have hearing loss but don't think there's anything that can be done
- Higher priorities – e.g., have dental expenses, undergoing cancer treatment, or other pressing issues
- Cost – Older people on limited, fixed incomes, people in low paying jobs, and children from economically poor families are just a few examples of people who are often priced out of the hearing aid market.
- Lack of transportation – lives alone and no longer drives; can't get a ride
- Lack of motivation to hear – e.g., has little or no social life; doesn't want to interact with others
- Family resistance – e.g., a family member may deny their loved one's hearing loss; the family member may want to spend the money on something else
- Fear of being seen as "Failing" or incompetent; sign of "old age"; don't want co-workers to think they are no longer competent.
- Unwilling to give up the "benefits" of having hearing loss, e.g., he may ask 'Would you answer the phone, go shopping for me, etc. because I can't hear people very well'.
- Afraid of doctors
- Motor coordination problems, e.g., tremors, cerebral palsy, etc. or has low vision
- Bad prior experience with hearing aids or a vendor.
- Friends or relatives had a bad experience, and they are unwilling or refuse to try.
- Over-stimulation – e.g., sounds are too loud and/or uncomfortable
- Emotional status – e.g., depression, low energy, or too anxious
- Ear pain and allergies
- Vanity
- Fear of ridicule

Other deterrents can be:

- Hearing aids aren't comfortable
- Don't meet expectations
- Too difficult to care for
- Too hard to put on
- Hearing aids are too embarrassing
- Not beneficial
- I hear what I want to hear
- My hearing is "Normal" for my age
- Thinks that "Nothing can be done to help"
- The hearing aid is too visible

- Patients are “apprehensive”, reluctant, and in denial; and there is no stronger human emotion than denial.
- Some people simply don’t want hearing aids.
- Peer pressure by friends or relatives to not get hearing aids because someone else they know didn’t like their hearing aids.
- Some don’t want to get new hearing aids because they want to get the most bang for the buck from their old hearing aids.
- Rapid change in technology does not necessarily equate to better hearing or better patient care. Rather, it could result in consumer frustration and eventual delay in acquiring help because of rationalizing always waiting for “newer and better technology”.

Dr. Elisabeth Kübler-Ross is credited for recognizing and developing an understanding of the five stages of grief and loss. They are: 1) Denial and isolation; 2) Anger; 3) Bargaining; 4) Depression; and 5) Acceptance. Patients will also go through these processes when a hearing loss is discovered. As part of the essential care needed to treat hearing impaired patients, audiologists are trained to help people progress through and adapt to these changing emotions. Left to their own volition in a DIY OTC HA model, consumers may remain in limbo captured in one or more of these stages indefinitely.

After 40 years in practice, I have not met a patient who was actually excited about getting hearing aids. They simply don’t want them. Most come in after the long-term nagging and cajoling by friends and family. When they finally take the steps to come in, they don’t know what they want or need. Generally, what they think they want does not meet their needs.

Expectations run high but knowledge about their chronic health condition runs low. There is a discord in their emotions that requires acknowledging along with proper counseling and care. It is naïve, inappropriate, and poor healthcare to think that by strapping one or two cheap OTC HAs on a hearing impaired consumer that they have received proper and necessary care.

This is a very different scenario from what is seen with other consumer electronic products. For example, some people will camp-out in front of stores for 2-3 days before a new cell phone, tablet, computer, or game system are released. They want them. They expect that the technological advancements are far greater than their “old obsolete” technology availed. They demand upgrades to occur as frequently and rapidly as possible. Their attitudes are “out with the old – in with the new”; give me the best, and give it to me now. Millions of these products are often sold on the first day of product release.

A comparison between the consumer electronics industry for the general public and providing good healthcare for hearing impaired people with hearing aids should not be made. Nor should OTC reading glasses be used as an analogy with OTC HAs. That has been refuted and dispelled as a faulty analogy (HIA, 2016; Chasin, 2017).

Cost and Affordability of Hearing Aids

“Cost” is an esoteric term and concept that has not been clearly defined or understood in discussions and presentations by PCAST and NAS. There is no question that the cost of hearing aids can be the true reason for someone not buying hearing aids due to a person’s financial limitations. For those people, I strongly believe that it is our social and moral obligation to help those who cannot help themselves. However, it is disingenuous to generalize that “cost” is largely the determining factor for consumers to not purchase hearing aids when it has not been determined who and how many actually need financial assistance; or to use “cost” as the major yardstick for radically changing or creating new federal laws and regulations that completely dismiss state’s rights and responsibilities for consumers.

Some of the implications revolving around the cost issue are demonizing hearing aid manufacturers, dealers, physicians, and audiologists; leaving consumers believing that they are being ripped-off. This only serves to damage the necessary trust that must be established and fostered between consumers and service providers. "Cost" concerns cannot be viewed in isolation only in terms of dollars. There are far greater costs consumers could suffer in a DIY model, e.g., psychological, social-interaction, isolation, etc.

Consumers already have access to low-cost hearing aids. How much lower is low enough to satisfy some consumer's idea of low-cost. What quality of technology will be available at that low price point? Will these efforts just perpetuate the self-fulfilling prophecy of, "I want cheap hearing aids; now that they are cheap, I don't like how they sound and how they work which substantiates my original opinion that hearing aids aren't any good."? Will the demand for "cheap" result in reduced quality, fewer technological options, and a move away from advancing high-end technology innovation? Low cost no-frills hearing aid technology seems like a race to the bottom.

What does "cost too much" actually mean? There is a difference between "I can't afford the price" vs. "I don't want to pay that price". For those who say they cannot afford the price of hearing aids, does that mean they can't even afford the already existing low-cost hearing aids of, e.g., $500 each? If that is the case, they are likely eligible for state funded assistance. These, and other issues, have not been fully explored and understood. There is no detailed analysis or longitudinal studies to clearly understand what the consumer really means. It is irresponsible to push an OTC HA agenda forward on the grounds of unsubstantiated generalizations.

Senior citizens make up about 20% of the U.S. population and they hold 70-80% of consumer's spendable income. In our discussion about affordability, we would be remiss to ignore the inclusion of and discussion about the intergenerational shift in wealth that has already started to occur. The "Greatest Generation" was born in the 1920s and 1930s. Baby Boomers were born from 1946 – 1964. Gen Xers and Millennials were born in the late 1960s and later. Badkar reports that, "We are currently witnessing the 'Great Transfer' of wealth from the Greatest Generation to the baby boomers, according to Bank of America's Sarbjit Nahal and Beijia Ma." "But Nahal and Ma point out that a second and even larger wealth transfer from the Boomers to their heirs is starting now and will continue over the next 30-40 years. The great transfer will see a handover of about $12 trillion from those born in the 1920s and 30s to the boomers. But the boomers are expected to transfer some $30 trillion in assets to their heirs over the next 30-40 years in just the U.S." (Badkar, 2014).

Many senior citizens ask for discounts expressing that they live on a "fixed income". I have heard this many times in my practice when patients are deciding whether or not they can afford the cost of new hearing aids. It is important to understand that annual income is different from net worth. Walter Williams, an economist, stated that, "Income measures fail to capture important components of economic well-being, such as wealth and the ownership of durables, e.g., houses and cars. For example, official measures would consider a retired couple who owned their car and mortgage-free $700,000 home and lived on $20,000 savings to be poor. Clearly, their income does not reflect their material well-being." (Williams, 2011).

Dr. Gailmard expresses that, "It is up to the patient to let us know if there is a financial issue, and if they do, we have alternative options that we can go to. But let's presume the patient wants the best. It is not our job to save the patient money. Remove money from the equation unless the patient brings it up. We all know, but need to be reminded, that to prejudge a patient is rude and somewhat discriminatory. And you will often be wrong in your assumption about a person's wealth or spending habits." (Gailmard, 2017)

Everyone prioritizes what is important in their lives and what they are interested in and willing to pay for something. We can be told that the reason a consumer did not buy hearing aids is because of cost, but there could actually be overlying and overriding reasons with which a consumer does not want to reveal – perhaps something more personal or embarrassing. Cost could be a diversion or deflection. Most people buy what they want to buy. Just because someone says that a product is too costly doesn't mean that they cannot afford

it. People buy 2-3 cars, 2-3 TV sets, 2-3 cell phones, large homes, etc. They afford what they want to afford. Is the government trying to get the automotive industry to reduce the price of $20000, $30000, $40000, and $50000 cars so they are more affordable? Even though people complain that they cost too much and they can't afford them – they still buy these high-priced products.

Low-cost DIY OTC HAs is a journey to mediocrity at best and a cliff-dive to the bottom at worst for consumers. Some refer to audiologists, dealers, and physicians as middle-men; however, they provide essential and necessary care per their license. A DIY OTC HA model would still have "middle-men". These would be the retail stores that provide NO care.

I have seen many "price shoppers" come in not wanting to spend much money and save on buying hearing aids. Often times, 1-3 years later, they return for quality and appropriate care. They ended up actually spending more money trying to save money than they would have if they received the proper care in the first place. OTC HAs will compromise quality healthcare and the safety of patient care and will likely lead to an increase of "In-the-dresser-drawer" hearing aids (ITDD HAs); thereby reversing a positive trend. Hearing aids "in the drawer" decreased from 12% in 2008 to 3% in 2014 (Abrams and Kihm, 2015). The proposed changes may make some people feel good about "helping others" but it could very well lead to further frustration, dissatisfaction with hearing aids, and could delay proper care and treatment.

Cost should be considered not only from a financial perspective but also in terms of emotional, psychological, psycho-social, communication, etc. Unsuspecting consumers will pay a far higher "price" for a "low-cost" DIY OTC HA system than what they are being misled into believing. This costly system will ultimately be less affordable. These proposed changes do nothing to promote a higher standard of care; rather, they create an environment that fosters and promotes a lower standard of care.

How To Pay For Hearing Aids

I accept that cost can be a deterrent to purchasing hearing aids for some consumers, and I agree that it is a noble cause and reasonable to identify ways to make hearing aids more accessible and more affordable for consumers. However, I do not accept that it is as big of a deterrent as the PCAST and NAS information led me to believe as a big enough reason to justify creating and establishing a new radical hasty disruptive OTC HA system. For example, Strom notes that the average hearing aid technology levels dispensed in the survey were reported as: 37% were premium level, 44% were mid-level, and 19% were economy-level (Strom, 2014).

There is not a pending crisis for consumers because of hearing aid costs. What has been left out of the discussions are ways that are currently available for consumers to pay for or subsidize the purchase of hearing aids. There is no urgency to deal with the cost issue because much of the exposed and expressed concerns are addressed for the majority of consumers.

The list below is comprehensive but likely does not cover a complete and exhaustive list of resources that consumers already have available to purchase hearing aids:

1. There are already, and have been for a long time, low-cost hearing aids available for consumers.
2. Sales tax exemption: hearing aids are medical devices. Some states, consequently, exempt them from sales tax; saving consumers hundreds of dollars.
3. Hearing aids and related products, services, and mileage to and from appointments can be considered out-of-pocket medical expenses and itemized on income tax returns, thus allowing consumers to recoup some of the cost of hearing aids in the form of income tax savings.
4. State Medicaid services have programs to purchase hearing aids for those meeting defined financial need requirements.
5. State Vocational Rehabilitation services pay for and provide eligible low-income hearing impaired consumers looking to improve their job search opportunities with hearing aids.

6. Pro bono and philanthropic care to patients provided by physicians, dealers, and audiologists.
7. Hear Now Foundation provides hearing aids for those who have a defined financial need.
8. Indian Health Service provides hearing aids to those who are eligible.
9. "Ease the pain of high out-of-pocket costs by putting money into a health savings account (HSA)". "That's' pre-tax money - up to $3400 annually for individuals and $6750 for families – that you can use for qualified medical expenses, including your deductible. And if you don't use your HSA funds, they roll over and can grow tax-free, year after year." (Posato, 2017)
10. Insurance companies providing hearing benefits, e.g., $1000 per hearing aid allowance every five years, should also allow patients to be balanced billed if they choose better technology that costs more.
11. Care Credit and Wells Fargo Credit offer: 12 month interest free loans and varying interest rates based on a longer duration loan.
12. Credit Unions will finance hearing aids.
13. Credit Cards
14. In-house financing through the physician, dealer, or audiologist.
15. Consumers who are also business owners can write-off hearing aids as business expenses; considered as communication aides. This can become a "job benefit" for employees offered by an employer..
16. Mandatory withdrawals from retirement accounts increase disposable income for hearing aid purchases. (Castelli, 2017)
17. State Workers Compensation program pays for hearing aids and related services for state employees and retirees who have been identified as having work related hearing loss.
18. The U.S. Department of Labor pays for hearing aids and related services for federal employees and retirees who have been identified as having work related hearing loss.
19. The U.S. Veterans Administration pays for hearing aids and related services for military personnel and retirees who have been identified as having service connected hearing loss.
20. Many retired patients today, i.e., the demographic with the highest incidence of hearing loss, are from the era where they prefer to live debt-free and will pay for hearing aids in full when fit.
21. "Some nonprofit organizations provide financial assistance for hearing aids, while others may help provide used or refurbished aids. Contact the National Institute on Deafness and Other Communication Disorders (NICDC) Information Clearinghouse with questions about organizations that offer financial assistance for hearing aids." (www.nihseniorhealth.gov)
22. FTC Advice: "People who can't afford a hearing aid should contact the National Institute on Deafness and Other Communication Disorders' Information Clearinghouse to find out about organizations that offer financial assistance. (Federal Trade Commission, 2010).
23. Check local churches, synagogues, etc. for case-by-case financial assistance for hearing aids.
24. Charity crowdfunding: Grandstaff explains, "Charity crowdfunding sites such as GoFundMe and Generosity.com allow users to solicit donations for charity or personal causes." (Grandstaff, 2017).

Accessibility

There is no doubt that there are some instances where elderly, frail, or disabled individuals may find it difficult to travel to an appointment. However, I believe the claims we are being told about how consumers have a hard time finding providers for hearing care are largely exaggerated and unsubstantiated by any sources other than individual consumer claims or opinion polls. Consumers who travel more than a couple of miles in densely populated large metropolitan areas might report that trip as "inconvenient". However, in sparsely populated rural areas, it may be commonplace to travel 20-50 miles for necessary healthcare. Below is a partial list of common easily accessible locations for physicians, dealers, and/or audiologists:

1. Hospital audiology/ENT departments
2. ENT Practices
3. Easter Seals Agencies
4. Public/Private Schools
5. University/Teaching Hospital audiology departments

6. Indian Health Service
7. VA Hospital
8. Audiologists Private Practices
9. Manufacturer owned retail stores
10. Retail warehouse stores, e.g. Sam's Club, Costco, etc.
11. Audiology practices and/or retail, stand-alone hearing aid stores with satellite offices in rural areas.
12. ENTs are largely in medical practices and/or hospital settings. Dealers are most commonly found in retail stores in shopping malls or stand alone businesses. Audiologists are often found in community Speech and Hearing Clinics, medical centers, and private practices.
13. Mobile units provide service around the state.
14. Tele-audiology

Vital Statistics

A 2013 survey was administered by the Hearing Review to its dealer and audiologist database. Some of the survey's findings showed that: the average (mean) number of hearing aids dispensed per month per practice site was 23 (Strom, 2014). The source of gross revenues in 2009 for all practices in the survey – HA sales = 74.9%; Diagnostics = 15.3%; Batteries/Accessories = 4.6%; other products/services = 4.4% (Hearing Review, 2011).

There may be differences in hearing loss prevalence comparing a population from China vs. an American population. However, we are likely to see similar trends. A 2011 study in China reported 110 hearing loss patients that ranged in age from 50-96 years old with a mean age of 74.4 years. The audiometric testing revealed 29.5% normal; 59.5% slight-to-moderately severe hearing loss; and 11% severe and profound loss. (Fei, et al, 2011)

The highest incidence/prevalence of hearing loss in America is in the same age range as reported in the China study. If America's prevalence rates are similar to those reported in the China study, that would mean OTC HA Act legislation or the one recommended by the NAS report could virtually eliminate 50-60% of hearing impaired patients from seeking help from a physician, dealer, or audiologist and turning to self-diagnosis and self-treatment**.** An OTC HA Act and NAS's recommendations allow for hearing loss up to 60-70 dB to be self-diagnosed and self-treated by unskilled, untrained, and unlicensed consumers. There is reason to believe that these actions will economically injure, harm, and/or devastate the dealer's occupation and audiology profession. During a period of increased incidence/prevalence of hearing loss as a result of the Baby Boomers retiring, nothing should be done to decrease the number of service providers. At a time when we understand that there is increasing demand for audiologist services, the proposed radical and hasty reform changes could reduce career appeal, decrease audiology school recruitment opportunities, and create a forced labor shortage in the audiology profession.

Strom notes that the average price for hearing aids including all styles and all levels of technology was $2363, while the average range depending on the style and technology level was $1580 – $2993 per hearing aid. The average lowest priced hearing aid offered was $1025. About 2/3s of the practices offered lowest prices at less than $800 with some offering its lowest priced hearing aid for less than $500 (Strom, 2014).

The life of a hearing aid is thought by some to be 3-5 years while others note 6-8 years. Table 1 shows the amortized cost of hearing aids per day over the life of different hearing aids having different values per Strom's results above. The results are reported as 3 years = 1095 days; 5 years = 1825 days; 6 years = 2190 days; and 8 years = 2920 days.

Table 1: Amortized cost of hearing aids per day over various lifetimes. Average price = $2363; Average range = $1580 - $2993.

Life of hearing aid (years)	Cost per day ($2363)	Cost per day (range = $1580 - $2993)
3	$2.16	$1.44 - $2.73
5	$1.29	$0.87 - $1.64
6	$1.08	$0.72 - $1.37
8	$0.81	$0.54 - $1.03

Table 1 shows that the amortized cost per day per hearing aid and for a variety of hearing aids over different lifespans is no more than $2.73 and as little as $0.54. You would pay more than that if you went out and bought a cup of coffee, a hamburger, or a milk shake at a fast-food restaurant.

The lowest priced hearing aid reported by Strom was less than $500, but we don't know how much below. For discussion purposes, I will use $500. It is not unreasonable to consider that low-cost hearing aids will not last as long as mid to high-end hearing aids. Presuming a 3 year lifespan for this level of technology, its amortized cost for the three years is $0.45 per day. In comparing this cost with the costs in Table 1, a hearing aid costing $2363 with a lifespan of 6 years is amortized at $1.08. However, the $500 would need to be replaced twice over the same six year period. That doubles the cost of the $500 hearing aid to $0.90 per day; which is not much different than the cost of the better hearing aids.

The proponents of the DIY OTC HA model would have you to believe that "low-cost" hearing aids are a panacea allowing for the glass-ceiling to be broken to reach vastly higher numbers of hearing impaired consumers with mild-to-moderate hearing loss. On the surface that seems like an effective mantra to get new legislation passed costing the taxpayer who knows how much in the long run. However, comparing merely dollars and cents, you see from the above discussion that "low-cost" hearing aids are **not** as cost-effective as you are being led to believe.

Further, "Hearing loss is the third most prevalent chronic health condition facing older adults." (Collins, 1997) Adoption rates of hearing aids in the U.S. are reported to be 30.2% overall; and, the adoption rate is highest for 65 year olds and older at about 40% (Abrams and Kihm, 2015). Norway, the UK, and Switzerland provide hearing aids to their citizens for free. Even so, they report a usage rate of 43%, 41%, and 39%, respectively (Audiology World News, 2017; Hougaard et al, 2013). Based on this information, the multiple reasons for not purchasing hearing aids, and the U.S. history of hearing aid usage; even if an OTC HA system were put into effect with low-cost hearing aids, we should not expect a large increase in hearing aid purchases and use because cost does not appear to be an overriding factor to obtaining hearing aids.

The Hearing Industry Association (HIA) reports that during an FDA Workshop testimony, "the Japanese and South Korean experiences demonstrate the failure of the PSAP/OTC do-it-yourself model"; and "In Japan, … the deregulation of hearing aids has led to lower consumer satisfaction and lower adoption rates" (HIA, 2016). I wholeheartedly agree with HIA's comment, "… if an OTC hearing aid category is created, patients are free to mis-diagnose, mis-treat, and mis-manage their care on their own."

Also, low-cost hearing aids would be less likely to last as long as high-end technology which adds to the overall cost of hearing aids over time. For example, expanded programming capabilities, options like changing to stronger receivers easily, and extended warranty options will add to the longevity and value of high-end hearing aids. When these benefits are amortized and factored into the cost per lifetime of the hearing aids, the difference between the costs of low-end vs. high-end hearing aids will be even less than purported.

Over my 40 year career, I have learned that you cannot limit the "cost" of hearing aids to simply dollars and cents. For example, mid to high-end hearing aids come equipped with better programming flexibility. As a person's hearing loss progresses, it remains easier to continue using the same hearing aid by reprogramming it; allowing the person to hear and communicate more efficiently and effectively over the extended life of the hearing aid compared to having to buy cheap hearing aids more frequently. This provides consumers not only better healthcare but also provides them better cost-effectiveness, and a better value and better quality for their purchasing dollars. We should keep in mind the wisdom of Will Rogers, "Quality is a lot like buying oats. If you want fresh, clean, first quality oats, you have to pay a fair price. But, if you can be satisfied with oats that have been through the horse, those come quite a bit cheaper."

Competition

One implication put forth in the PCAST and NAS reports is that there is not enough competition in the hearing aid industry. What is inherently misleading in that implication is that the current hearing aid delivery system neither blocks nor interferes with competition; nor does it stifle innovation like some would have you believe. An example of innovation occurred early in 1985 when an engineer purchased the patent rights of a sound processing system developed at AT&T/Bell Labs. He found investors and created the ReSound hearing aid manufacturing company. That technology revolutionized the hearing aid industry and had a major influence and impact on all other hearing aid manufacturing companies. Today, that company is GN ReSound. The Widex Company brought digital signal processing to the hearing aid industry in 1995. These and other hearing aid manufacturers have led the way in creating and developing amazing advanced hearing aid and accessory technology.

Over the last 10-15 years, the trend has been hearing aid wholesale manufacturing consolidation with the "Big-6" accounting for an estimated 93% of hearing aids sold. They are Sonova, Starkey, William Demant Holding, Great Nordic, Siemens, and Widex. Added competition in the wholesale hearing aid manufacturing sector is welcomed. It would be great to have a "Big 10" or "Big 20". However, it should be kept in the realm of higher standards of regulated hearing aid manufacturing of medical devices and not lower manufacturing standards as OTC HAs.

To clarify another misperception, there are already hearing aid manufacturers who focus on low-cost hearing aids. There is absolutely nothing preventing companies like Bose, QualComm, Apple, Samsung, etc., from joining the current hearing aid manufacturing industry, competing and offering new and innovative technology even if it is exclusively with low cost hearing aids. But, this competition and innovation needs to be done on the same playing field and under the same regulations as all other hearing aid manufacturers.

However, Karl Strom notes, "Importantly, QualComm, Samsung, and other huge electronics and telecommunications firms are lobbying for the FDA to get completely out of hearing device regulation. This would constitute a "nuclear option" for the Agency – waiving quality controls (QSRs) and destroying professional hearing care as we know it. Given the Committee's own findings about hearing loss and its impact on health, I would hope this is an unlikely option" (Strom, 2017).

If these consumer electronic companies are merely waiting in the wings with new technology so they are unencumbered from current hearing aid manufacturing standards, this would suggest that their motivation to compete and innovate is disingenuous and misleading. Instead of caring for the hearing impaired segment of our population, they may just want to dump new technology into the audio industry. This has created

problems with other consumer electronic products. Lieff et al warn that, "… from PCs, notebooks, and tablets to smartphones, smart TVs, game consoles, and other electronic gadgets, manufacturers too often ship products that lack necessary software, are incomplete or simply defective because of pressure to get them on store shelves." They note class action lawsuits for faulty consumer electronic products against companies like Toshiba, Dell, and Apple. (Lieff et al, 2017).

The DIY OTC HA system eliminates state laws governing licensing and regulations regarding the sale and distribution of hearing aids as a safety net for consumers. Any product or service complaints for OTC HAs will not be directed to licensing boards. Seebacher warns that, "Many contracts for goods and services now contain binding mandatory arbitration provisions. Consumers are required to waive their right to sue, to participate in a class action lawsuit or to appeal." Further, "According to the Washington, D.C.-based National Association of Attorneys General: Consumers are often unaware they have agreed to binding arbitration, thus depriving them of their right to make informed decisions. Binding mandatory arbitration provisions are tucked in paragraphs of fine print or provided as a separate form among many forms. Companies rarely mention or highlight the provision. If they do, it is often presented on a 'take it or leave it' basis. Binding mandatory arbitration also limits consumer options for resolving a dispute. Before a problem arises, consumers are locked into binding arbitration for future disputes or problems" (Seebacher, 2013).

Hearing aid manufacturers have existed for over 100 years and have been dedicated to improving the lives of hearing impaired people. They have spent multi-millions of dollars in research and development for advancing hearing aid and accessory technology and providing training and education for dealers, physicians, and audiologists. Consumer electronic product companies have no experience with the hearing impaired population. They should not be cut loose on an unsuspecting population with a chronic disability to exploit consumers with new under-regulated electronic OTC HA products. Further, there is nothing wrong with promoting and creating competition between dealers, physicians, and audiologists; even with manufacturers who have retail stores

Another example of irresponsible consumer electronic product manufacturing is with children's headphones. A consumer product recommendation website, the Wirecutter, found that half of 30 headsets they tested did not keep the volume down to safe levels reported in the product literature (Wirecutter, 2016). Also, literature has shown that lack of effective safety regulations in the consumer electronics industry and their obvious disregard for consumer safety and self-monitoring and self-regulating is resulting in noise induced hearing loss (NIHL) being identified as early as elementary school due to noise trauma from devices such as iPods, iPads, smart phones, various earbuds, etc. News reports have abounded lately with stories such as XBOX battery chargers catching fire; Samsung Galaxy Note 7 smartphone battery catching fire; and hover boards catching fire. If consumer electronic companies want to enter the hearing aid manufacturing industry, let them do so as a medical device company and compete with all hearing aid manufacturers on the same playing field. If they want to produce only low cost hearing aids, so be it – but, not OTC HAs.

"Extra attention was focused on the question when the PCAST wrote last October in a much-debated report that concentration and overregulation of the hearing aid industry have meant that these devices (i.e., hearing aids) have not followed the same path as so many consumer electronics devices, with technology opening up markets to innovation and causing a drastic drop in prices, thus making the devices more widely accessible" (Audiology Worldnews, 2016). The "logical" conclusion is wrong. Consumer electronics have an entirely different purpose of being made for everyone's use while medical devices are designed for a unique niche market targeted for a specific health treatment.

Transparency

The NAS Report, Recommendation 9 addresses transparency by stating: "Hearing health care professionals should improve transparency in their fee structure by clearly itemizing the prices of technologies and related

professional services to enable consumers to make more informed decisions." Transparency can also be discussed in terms of "bundled" vs. "unbundled" pricing. Transparency is synonymous with unbundling.

Bundling prices is neither illegal nor an unfair or deceptive trade practice. Bundling prices for hearing aids has been the time-honored rule rather than the exception since the advent of hearing aids. Unbundling remains a topic of debate in the audiology profession and is the model used only by a minority of audiology practices. The majority of dealers and audiologists continue to bundle prices as a commonly accepted business practice. For example, a 2013 Hearing Review survey revealed that bundled prices made up 83% of the respondents (Strom, 2014). Dealers cannot unbundle pricing because billing for test services would connote diagnostic audiology testing, and that violates dealer and audiologist licensing laws. It is also illegal for dealers to bill Medicare. Forced unbundling would unnecessarily and inappropriately preclude physicians, dealers, and audiologists from conducting business in a lawful manner of their choosing.

Proponents of unbundling, or pay-as-you-go, seemingly have a short-term vision of care. Bundling, on the other hand, is more of a longer-term fuller cycle of care realizing that caring for hearing impaired patients is a process extended over time and not merely a series of single events. Included in this cycle of care is testing, diagnosing, counseling, fitting and dispensing a medical device, audiologic rehabilitation, and additional follow-up care.

Harvard Business School's Institute for Strategy and Competitiveness explains who benefits from bundled payments (http://www.isc.hbs.edu/health-care/vbhcd/Pages/bundled-prices.aspx):

- **Patients** receive proven and effective care for their medical conditions.
- **Providers** earn a positive margin for efficiently treating patients and producing good outcomes; over time, they attract more patients in their area of expertise, enabling their total margins to increase.
- **Suppliers** of drugs, devices, and diagnostic tests that improve outcomes and/or lower total costs will find their products incorporated into the treatments used by effective and efficient providers.
- **Payers** (private insurers, corporations, governments, or self-pay individuals) will reduce their spending for treating medical conditions and providing primary and preventive care for population segments.

Price transparency is also of interest to the FTC. It has stated: a) "Is more information about prices always a good thing for consumers and competition? Too much transparency can harm competition in any market, including in health care markets"; b) "But transparency is not universally good. When it goes too far, it can actually harm competition and consumers. Some types of information are not particularly useful to consumers, but are of great interest to competitors. We are especially concerned when information disclosures allow competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price, or increases the likelihood that they can coordinate on higher prices"; c) "Too much transparency can harm competition in any industry, including health care"; d) "We believe it is possible to give consumers the specific kinds of information they need to make better health care choices, while avoiding broad disclosures of bids, prices, cost, and other sensitive information that may chill competition among health care providers"; e) Certain types of transparency "might harm competition by enabling competing providers to coordinate or collude on price, while being unlikely to help consumers become better health care shoppers"; f) "We share the goal of empowering health care consumers – but we think it is important to remember that consumers benefit from vigorous health care competition, too." (Koslov, 2015)

Forced unbundling should not be mandated as that removes competitive business strategy choices from the free-enterprise system. It seems to me that it would be unlawful to force a business to discontinue conducting business in a lawful manner. It would, however, be appropriate and legal to recommend offering unbundling of prices as a volunteer pricing structure option.

Third party payers may require unbundling of products and services as a contractual reimbursement provision for those interested in becoming participating providers. It will then be the decision of the provider as to

whether or not they want to accept the conditions of the contract before signing. That is the free choice that drives America's free enterprise system. The desire or expectation to create transparency should not collide or interfere with what is legal.

Hearing Screening Devices (HSD)

There is no debate about the psycho-social, cognitive, and physiologic benefits of hearing aids for hearing impaired consumers. Unfortunately, the DIY OTC HA model actually removes "health" out of "public health" and "health care".

Instead of creating a new category of OTC HAs and promoting self-diagnosis and self-treatment by consumers for hearing loss, the public's interests would be better served by creating a new category of OTC Hearing Screening Devices (HSD) and a consumer educational campaign about hearing loss and about how consumers can "self-identify" the presence or absence of hearing loss and can "self-direct" themselves to appropriate licensed individuals. There are more people who would acknowledge and accept a hearing screening model to determine whether or not to pursue proper care than to go to the expense of buying a cheap product first to determine need. This would be more-cost effective than to purchase OTC HAs and would not downgrade hearing healthcare for consumers. It would increase access to hearing loss identification at low costs and direct consumers to appropriately licensed individuals for necessary and proper care. Validation studies must be submitted to the FDA for these HSDs, and standards should be adhered to for these devices.

We already have precedence for a hearing screening model: 1) Public schools – Rather than fitting all children with hearing aids or sending them for medical care to determine need, a hearing screening program is instituted to identify those children who are at risk for educationally disabling hearing loss. Even these types of screening programs acknowledge the importance and necessity of using calibrated test equipment and not merely an "I think you have a problem" or "survey" approach; 2) Universal Newborn Hearing Screening – it is part of the Early Hearing Detection and Intervention program.

Hearing screening uses a pass/fail criterion. Computer, tablet, and smartphone technology as well as tele-audiology could become a viable cost-effective opportunity to expand access to identify those with hearing loss; the purpose of which is NOT differential diagnosis. For example, The Guardian, "App Designed to Detect Hearing Loss Developed in South Africa" (Feb. 2017, www.audiology-worldnews.com/awareness/1976-app-designed-to-detect-hearing-loss-developed-in-south=africa). Those without access to these technologies could avail themselves to OTC HSDs that would be required to conform to American National Standards Institute (ANSI), International Standards Organization (ISO), and FDA standards. Analogous products exist today for consumers to be able to measure or estimate sound intensity levels to help consumers avoid noise hazardous environments.

Abrams and Kihm report that 23% of the survey respondents had a hearing screen during a physical examination for adults. About 1/3 noted that their PCP "discussed or screened their hearing as part of the appointment" (Abrams and Kihm, 2015). It is realistic and an important goal to dramatically increase these numbers.

Hearing screening reduces barriers to access and will help direct consumers to licensed providers so they can receive appropriate hearing care outcomes for a better quality of life. Cost-effective HSDs will help consumers avoid wasting their financial resources on OTC HAs and assist them in directing their time and efforts to the proper care provider.

There are better ways to expand access and availability of care to hearing impaired people through consumer education efforts and provision of better screening tools. Hearing screening is a non-threatening cost-effective way for consumers to determine if hearing loss exists or not. It offers a helpful way for consumers to move through the initial stages of hearing loss, i.e., denial and projection, where they tell others, "I don't have a

hearing problem. If you spoke clearly, I would know what you are saying." Subsequently, they can be directed to seek proper healthcare.

Negative Consequences of Over-The-Counter Hearing Aids

There are numerous negative unintended consequences from enacting ill-conceived reform legislation in the hearing and hearing aid industries that could come with inherent dangers and serious problems for consumers and our society. These proposed sweeping changes fail to ensure that consumers are protected and that an environment is not created that will actually make matters worse, not better.

If the drivers of this proposed radical, hasty, disruptive change with OTC HAs and the inappropriate recommendation of consumers self-diagnosing and self-treating hearing loss are allowed to move forward with conditioning and socializing our society into the illusion of accepting cheap amplification products/devices as the viable solution to and model of hearing restoration and auditory rehabilitation without professional care, then consumers will eventually acquiesce and migrate to the inferior products and services as the standard of care. This could very well remove the incentive for hearing aid manufacturers to advance high-end technology, because there will become a race to the bottom.

The FDA and FTC would position consumers to be exempt from any licensing laws or regulations. Friends and family could fit friends and family with hearing aids. There would be nothing in place to prevent this activity. Further, an opportunity for unscrupulous, unlicensed, and unskilled individuals could go around charging other consumers to have them diagnose and treat them with OTC HAs. Individuals could effectively create a fraudulent business of hearing aid dispensing that is unregulated, and consumers would have no recourse if they were injured, improperly fit, or taken advantage of financially. This could actually revert hearing aid distribution back decades to the era of why the 1977 FDA regulations were implemented in the first place. It would be worse for consumers, because the FDA regulations governed licensed individuals. The scenario above would involve unlicensed consumers. It would be naïve to think that there would not be individuals or groups that would not prey on senior citizens in this manner or as predatory telemarketers; and the FDA, FTC, and legislators would be responsible for this consumer injury and fraud.

Essentially, a consumer(s) could establish a business relationship with the consumer electronic companies that manufacturer OTC HAs and open an OTC HA store(s) and sell OTC HAs to anyone who has a mild-to-moderate hearing loss based on a consumer questionnaire or a perceived subjective opinion and without the need to obtain a dealer or audiologist license. There would be nothing stopping unlicensed individuals from canvassing unsuspecting consumer's neighborhoods like door-to-door salesmen or meeting people in unsavory motel rooms to sell others OTC HAs. Some unscrupulous individuals could collect the hearing impaired person's money ahead of time, disappear – never to return; and there would be no recourse afforded to the consumer. These tactics were used by unscrupulous dealers up until about the 1980s. The OTC HA model could usher in the return of these objectionable practices.

For the majority of hearing aid users, it has been shown that binaural hearing aids provide better hearing and user satisfaction. Monaural fittings decrease effective communication, consumer satisfaction, and understanding speech in a background noise. Consumers with bilateral hearing loss could be inclined to purchase only one (monaural) OTC HA instead of two so they can "try it out" before committing to doubling their cost. The chances are high that the consumer would not be provided sufficient amplification to satisfy their "buying needs" and would return the one hearing aid and consequently delay their properly needed care.

Ineffective and inappropriate self-diagnosis and self-treatment will not correct the consumer safety issue of patients buying OTC HAs when their hearing loss actually needed audiological and/or medical intervention. Rather, it will exacerbate this problem.

The DIY OTC HA model is an affront to national standards, academic and program accreditation standards, as well as licensing and consumer protection law standards and healing arts acts.

If a DIY OTC HA model with consumer self-diagnosis and self-treatment for mild-to-moderate hearing loss is implemented, a good attorney for the insurance industry and for state and federal agencies could easily argue that all hearing aids and related audiology and medical services are excluded from being covered expenses except for those individuals who have severe-to-profound hearing loss.

Recommendations

1. Lobby Congress to abandon the OTC HA Act of 2017 and the FDA to discontinue its efforts to create a new OTC HA category because there are already low-cost hearing aids for consumers, and there are ample venues for consumers to seek and locate physicians, dealers, and audiologists who are licensed to properly care for hearing impaired consumers. The OTC HA system is flawed in ways that would result in more harm than good to consumers.
2. Abandon the NAS and OTC HA Act of 2017 initiatives allowing untrained, unskilled, and unlicensed consumers from self-diagnosing and self-treating any degree or type of hearing loss. These initiatives do nothing other than lower and/or eliminate standards of care and degrade the quality of healthcare for hearing impaired consumers.
3. Invite consumer electronic companies to join the hearing aid industry to enhance more cost-effective competition and advance more rapid technological innovation; with the proviso that the manufacturing of hearing aids remains under the currently required FDA safety regulations and standards and/or amend and modernize Good Manufacturing Procedures that apply to all hearing aid manufacturers.
4. Government regulations and compliance mandates should be reviewed to find ways to reduce their costs to the hearing aid industry and have shared-savings handed down to retail suppliers and consumers. As part of this, manufacturers should be empowered and encouraged to release hearing aids and accessories to the consumer faster. Doing so allows manufacturers to recuperate R & D investments sooner which should aid in reducing manufacturing costs that could be handed down to the consumer in reduced retail costs. Manufacturers should consider making "software upgrades" available periodically with the manufacturer's proprietary software for a nominal downloading and reprogramming fee for the patient after the warranty expires. The intent of this would be to prolong the hearing aid's life so that the amortized cost of hearing aids is a more cost-effective value to the consumer.
5. Initiate the creation of regulated and standardized OTC Hearing Screening Devices (OTC HSDs) along with creating "apps" for various consumer electronic devices; and advance a national consumer education campaign about hearing loss, its diagnosis, and treatment. Along with this, enhance the availability of hearing screening programs by physicians and trained non-physician healthcare providers. This system enhances, not degrades, healthcare; empowers consumers to learn how to self-direct themselves to appropriate care; and educates consumers about the essential importance of the service components involved in proper hearing healthcare. This latter component is supported and acknowledged by the FTC and the courts.
6. Modernize Medicare for audiologists and consumers by establishing Direct Access to audiologists for Medicare recipients. Medicare is the only federally based healthcare system remaining that does not allow Direct Access for individuals to audiologist services that will be reimbursed without physician referral. Direct access to audiologists has shown comparable or better health outcomes, lower costs, and higher patient satisfaction. This goal would remove barriers for better consumer access, promote competition, and reduce healthcare costs.
7. Encourage states that continue to charge sales tax on hearing aid purchases to exempt these medical devices from sales tax as is done with other medical devices. This would save consumers hundreds of dollars.
8. Establish loan forgiveness programs for audiology students who work in low income rural areas to encourage outreach programs for under severed consumers. Reducing student debt for new and young

audiologists encourages them to consider practice ownership, thereby creating more competition, philanthropy, etc. Also, increase funding for auditory research and product development for devices used to treat hearing loss.

9. PSAPs should remain classified as a consumer electronic product and not designated for treatment of hearing loss.
10. Support Hearing Aid Tax Credit legislation
11. Create incentives for third party payers to offer hearing care components to their coverage while providing incentives for audiologists to join managed care programs such as: a) making the application process to join less complicated, b) contracts should be negotiable and not "take it or leave it", c) better reimbursement schedules, and d) fast turn around times for receiving money owed for services rendered.

12. Many wholesale hearing aid manufacturers also own retail distribution stores and compete with hospitals, dealer businesses, physician practices, and audiology practices that don't have the buying power of the manufacturer's retail outlets. The Veteran Administration's audiology division receives some of the lowest wholesale hearing aid pricing in the industry. If the government wants to lower consumer cost and foster competition, especially without endangering dealer's, physician's, and audiologist's businesses and their livelihoods, consider figuring out a way for smaller businesses and practices to fairly get the same wholesale hearing aid pricing as the VA gets.

Summary and Conclusions

The President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering, and Medicine (NAS) have brought forth recommendations on how to, among others, improve hearing aid accessibility and affordability for hearing impaired adults. Most of the recommendations are sound and reasonable. The Food and Drug Administration (FDA) has already acted on the recommendation to eliminate the Medical Clearance requirement for adults wanting to purchase hearing aids that was established in 1977. Recently, several Senators re-introduced the Over-the-Counter Hearing Aid Act of 2017.

There are major problems identified and discussed in this report to the Federal Trade Commission (FTC) regarding some of the above efforts. Additional information and clarification is provided in this report to justify and support the recommendations and request to abandon efforts surrounding the implementation of an OTC HA system and to not allow self-diagnosing and self-treatment of any type and degree of hearing loss by unskilled, untrained, and unregulated consumers. This report also offers additional ways of improving hearing healthcare for consumers.

Respectfully submitted,

Larry Engelmann, Au.D.

Dr. Engelmann's Background

- Academy of Doctors of Audiology, Fellow and Past President
- American Academy of Audiology, Fellow member
- Oklahoma State Health Department's Hearing Aid Dealers and Fitters Advisory Council, Former member; revised the licensing law several times
- Academy of Dispensing Audiologists: Chaired the Model Licensing Law Committee and liaised with the AFA and the AAA to collaboratively develop an Audiology Model Licensing Statute
- American Academy of Audiology: Task Force on Audiology Assistants
- American Academy of Audiology: Task Force on Audiology Education

- Oklahoma Board of Examiners for Speech-Language Pathology and Audiology -- Audiology Ad Hoc Committee to revise and update Oklahoma licensing laws for SLPs and audiologists.
- Authored and co-authored several articles related to licensure for dealers and audiologists.

References

1. Abrams, H.B., Ph.D. and Kihm, J., M.S., "An Introduction to MarkeTrak IX: A New Baseline for the Hearing Aid Market", Hearing Review, 22(6): 16, 2015.
2. American Academy of Audiology 2016 Compensation and Benefits Report, December 28, 2016.
3. Audiology Worldnews, "Changing context for hearing aids and sound amplifiers in the U.S.", May 03, 2016, www.audiology-worldnews.com
4. Audiology World News: "The Difference between Hearing Aids and Good Hearing", 02-01-17, www.audiology-worldnews.com/market2/1978-the-difference-between-hearing-aids-and-good-hearing.
5. Badkar, Mamta, "We're On The Verge of the Greatest Transfer of Wealth In the History of The World", Business Insider, June 12, 2014.
6. Baron, D., "Have American Women Abandoned the Battle for Equal Pay?", 11-17-16, www.entrepreneur.com/article/285205.
7. Brayer, Toni, M.D., "Why the Mayo Clinic Is Refusing to See Medicare Patients", www.kevinmd.com/blog/2010/01mayo-clinic-refusing-medicare-patients, January 25, 2010.
8. Castelli, Craig, "Macro Factors Impacting Audiology Practice Acquisitions", January 2017, www.caberhill.com.
9. Chasin, Marshall, Au.D., "Facts vs. Values: Faulty Analogies in the Rationale for OTC Devices", Hearing Review, March 15, 2017, www.hearingreview.com.
10. Collins, J.G., "Prevalence of selected chronic conditions: United States 1990-1992.", Vital and Health Statistics, 10(194), Hyattsville, MD; National Center for Health Statistics, 1997.
11. Department of Veterans Affairs Veterans Health Administration (VHA) (March 14, 2011), "VHA Handbook 1170.02 Transmittal Sheet, VHA Audiology and Speech-Language Pathology Services".
12. Engelmann, Larry, Au.D., "Branding the Lie or Branding the Truth: Growing Concerns about the International Hearing Society (IHS)", Submitted for publication, 2017.
13. Engelmann, Larry, Au.D., "Dual Licensure: Audiologist's Exemption from Hearing Aid Dealer Licensure", Audiology Today, Jan/Feb 2016, Vol. 28, No. 1, pps. 80-82.
14. Federal Communications Commission (1988), "Federal Communications Commission Hearing Aid Compatibility Act of 1988", www.fcc.gov.
15. Federal Trade Commission (2010), "FTC Offers Sound Advice for People Considering Buying a Hearing Aid", October 15, 2010, www.ftc.gov.
16. Fei, Ji; Lei, Lei; Su-ping, Zhao; De-fang, Liu; Qi-you, Zhou; and Shi-ming, Yang, "An Investigation into Hearing Loss among Patients of 50 Years or Older", Journal of Otology, 2011, Vol. 6, No. 1, pps. 44-49.
17. Forbes: "Why the Force Will Be With Women Entrepreneurs In 2016", 01-06-16, www.forbes.com/sites/geristengel/2016/01/06/why-the-force-will-be-with-women-entrepreneurs-in-2016/#562d2aa4ce2.
18. Freer, Robert, E., "Chairman of the Federal Trade Commission Opening the Trade Practice Conference for the Hearing Aid Industry", June 15, 1944.
19. Gailmard, Neil, B., OD, MBA, FAAO, "Pick One Thing: Frame Selection, Part Two", Optometric Management, Tip of the Week #773, 02-01-17.
20. Goudreau, Jenna, "The 20 Fastest-Growing Jobs For Women", 07-19-10, www.forbes.com/2010/07.
21. Grandstaff, Mark, "It can be a great resource for emergencies, but don't count on it."; USA Today, Section 6B Money, March 09, 2017.
22. Hearing Industries Association (HIA), i.e., the representative trade association for hearing aid manufacturers, www.hearing.org.

23. Hearing Review: “A Survey of Key Metrics for Benchmarking a Hearing Practice, Part 1”, June 3, 2011, www.hearingreview.com.
24. HIA, Hearing Industry Association “Comments on the FDA’s public workshop on “Streamlining Good Manufacturing Practices (GMP) for Hearing Aids”, Docket No. FDA-2015-N-4602, June 30, 2016.
25. Hougaard, Soren; Ruf, Stefan; and Egger, Christian, “EuroTrak + JapanTrak 2012: Societal and Personal Benefits of Hearing Rehabilitation with Hearing Aids”, www.hearingreview.com/2013/03/eurotrak-japantrak-2012-societal-and-personal-benefits-of-hearing-rehabilitation-with-hearing-aids/.
26. Kirkwood, David, “Sex and Audiology”, 04-18-12, www.hearinghealthmatters.org.
27. Koslov, Tara and Jex, Elizabeth, “Price transparency or TMI?”, July 2, 2015, www.ftc.gov/news-evens/blogs/competition-matters/2015/07/price-transparency-or-tmi.
28. Leadem, Rose, “Female Entrepreneurship Is on the Rise”, 11-27-16, www.entrepreneur.com/article/285656.
29. Lieff, Cabraser, Heimann, and Bernstein, Attorneys at Law, “Computer Defects & Faulty Electronic Devices – Under Pressure to Bring Computers and Other Consumer Electronic Products to Market, Manufacturers Sell Defective Products” 2017, www.lieffcabraser.com/defect/computer-electronics.
30. NAS 2016, “Recommendations: Hearing Health Care for Adults: Priorities for Improving Access and Affordability”, http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2016/Hearing/Hearing-Recs.pdf).
31. National Center for Educational Statistics (NCES) (2016b), "Classification of Instructional Programs (CIP), CIP Code 51.0918**,** www.nces.ed.gov.
32. National Institute on Deafness and Other Communication Disorders (NIDCD) (2016), https://www.nidcd.nih.gov/health/hearing-aids#hearingaid_03.
33. Office of Advocacy of the U.S. Small Business Administration, *The Small Business Economy for Data Year 2006: A Report to the President*. United States Government Printing Office; December 2007, http://www.sba.gov/advo/research/sb_econ2007.pdf.0).
34. Posato, Donna, “How to Survive a High-Deductible Health Plan”, Consumer Reports Jan 2017.
35. Quittner, Jeremy, “6 Things Linda McMahon Plans to Do for Entrepreneurs and Small Businesses”, 01-24-17, www.fortune.com/2017/01/24/linda-mcmahon-plan-entrepreneurs.
36. Schultheiss, Patricia, and Papagiannopoulos, Tina, “Examining health care competition: time for the next check-up”, February 2, 2015, www.ftc.gov/news-events/blogs/competition-matters/2015/02/examining-health-care-competition-time-next-check.
37. Seebacher, Noreen, “Broken, Bound, Gagged: Customers Silenced About Defective Products”, November 25, 2013, www.cmswire.com.
38. Signs, Kelly, “FTC Milestone: A New Age Dawns for the FTC’s Competition Work”, February 20, 2015, www.ftc.gov/news-events/blogs/competition-matters/2015/02/ftc-milestone-new-age-dawns-ftcs-competition-work.
39. Strom, Karl, “HR 2013 Hearing Aid Dispenser Survey: Dispensing in the Age of Internet and Big Box Retailers”, Hearing Review, April 2014, www.hearingreview.com/2014/04/hr-2013-hearing-aid-dispenser-survey-dispensing-age-internet-big-boxpretailers-comparison-present-past-key-business-indicators-dispensing-offices.
40. Strom, Karl, “NAS Presents Great Opportunity”, The Hearing Review, January 2017.
41. Trump, Donald, Presidential Address to Congress, 02-28-17.
42. Trychin, Samuel, Ph.D., “Why Don’t People Who Need Them Get Hearing Aids?”; www.users.clas.ujl.edu.
43. U.S. Department of Health and Human Services (2016), "Food and Drug Administration, Center for Devices and Radiological Health, Office of Device Evaluation, Division of Ophthalmic and Ear, Nose, and Throat Devices, Ear, Nose, and Throat Devices Branch", www.fda.hhs.gov.
44. U.S. Food and Drug Administration (FDA) (2015), "Code of Federal Regulations Title 21, Subpart H, Section 801.420 – Hearing aid devices; professional and patient labeling.", www.fda.gov.

45. Williams, Walter, E., “Poverty in America?”, November 16, 2011, www.econfaculty.gmu.edu/wew/articles/11/PovertyInAmerica.
46. Wirecutter, “Headphones and the Risk of Hearing Loss”, December 2016, www.audiology-worldnews.com/market2/1985-headphones-and-the-risk-of-hearing-loss.