May 16, 2017

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Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW, Suite CC-5610 (Annex B)
Washington, DC 20580

Re: Hearing Health and Technology – Workshop, Project No. P171200

Dear Dr. Ohlhausen,

I am writing on behalf of the International Hearing Society (IHS). First, I would like to applaud and thank the Federal Trade Commission (FTC) for its attention on hearing healthcare issues and considering solutions for increasing access and competition, and driving down cost. This evaluation is particularly timely given the many advancements in care and technology in recent years and the critical nature of hearing loss as a public health issue. Second, I would like to thank you for hosting an informative workshop, "Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care," and commend the staff on its organization and professionalism. Finally, I appreciate you allowing IHS the opportunity to provide input on the regulatory panel and share its perspective on this important topic. Today I write to provide supplementary information on the discussion topics raised during the workshop and questions posed within your meeting notice.

Founded in 1951, the International Hearing Society is a professional membership organization that represents hearing aid dispensing professionals, including dispensing audiologists and physicians, and the more than 9,000 hearing aid specialists who practice in the United States. Hearing aid specialists dispense and provide professional services to approximately half of the private hearing aid market, operate in both urban and rural areas, and often perform nursing home and home visits – delivering care to those in need, including those in remote locations. IHS promotes and maintains the highest possible standards for its members in the best interests of the hearing-impaired population they serve by conducting programs in competency accreditation, testing, education and training, and encourages continued growth and education for its members through advanced certification programs. Our members serve on the front line, supporting patients through the process of identifying and addressing their hearing loss. They also provide service to the profession and consumer population as volunteers on professional licensing boards, overseeing licensed hearing aid dispensing professionals and the application of state-based laws and policies.

Further, hearing aid specialists are recognized by the federal and state governments via the Standard Occupational Classification, Department of Labor, Department of Veterans Affairs, Office of Policy and Management, state Medicaid programs, and the FTC itself. Hearing aid specialists also work with insurance companies and other state-based programs to provide hearing aid services to those in need.

As attendees heard at the workshop, hearing health care and its delivery is going through many exciting changes. There is increased attention on the importance of hearing healthcare and its impact on other medical conditions leading to greater awareness among Americans, and we are seeing increases in hearing aid user satisfaction, both with the devices and the professionals who provide them, as well as increases in hearing aid usage overall.[1] Hearing aid manufacturers are continuing to develop research and technologies, including new options in telehealth, and we are seeing more retailers entering the marketplace like Costco and Sam's Club, leading to expanded points of access and increases in competition. In fact, just days after the workshop, news broke that CVS is intending to expand its entry into hearing health care services by opening 50 new hearing centers in its existing clinics and integrating hearing aid services into its future clinic model.[2] One unifying aspect of all of these advancements is the essential role of the hearing healthcare provider in the assessment and treatment of patients whose primary symptom is hearing impairment.

As you know, there has been significant attention placed recently on hearing health care by entities like the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Science, Engineering, and Medicine (NASEM) with all attention focused on influencing accessibility and affordability. We appreciate their attention on this critical health care issue, and particularly appreciate the NASEM evaluating a series of options that can move the needle on these goals. We know that increased public awareness, research, engagement of primary care physicians, and insurance coverage, as well as other concepts outlined in the NASEM report have and can continue to increase the number of individuals seeking care for their hearing loss. Of course, the concept that has gotten the most attention and the one for which IHS is very concerned, is the concept of creating an over the counter (OTC) classification of hearing aids – which was unsurprisingly a hot topic at your workshop.

Of utmost concern is the lack of evidence that exists that indicates that the addition of OTC hearing aids to the existing marketplace would actually influence hearing aid adoption and cost. In fact, evidence points to the opposite effect – lack of proper diagnoses and professional fittings lead to poor fittings and outcomes, leading to dissatisfaction, which people in turn talk about, leading to a lower overall perception of hearing aids.

The supposed lowering of cost argument may also be a ruse. Consider this: Bose offers wireless headphones for $299 (which are currently not marketed to those with hearing loss specifically but undoubtedly will be if and when OTC hearing aids are approved), yet the functionality of the headphones are tied to the use of a smartphone. Same goes with the Nuheara earbuds (also $299) and countless others that are existing in the personal sound amplifier space right now or are being readied to be marketed as OTC hearing aids. To draw a cost comparison, let us consider the headphone or ear bud to serve as the hearing aid in this example, and the cell phone and service to represent the professional services – even though there is no actual similarity in the latter comparison. In 2017, the average cost of a smartphone is $567.[3] The average annual cost for cell phone service is around $963 or about $80/month.[4] Therefore, in order to make your new OTC hearing aids work, your upfront investment is $1829 in the first year and $963 in each subsequent year. That means the cost over five years for a functional device is $4,815. If the idea is to make hearing aids more affordable for people who cannot otherwise afford them, this surely is not the way. Meanwhile, people with hearing loss can obtain

[1] http://www.hearingreview.com/2015/05/introduction-marketrak-ix-new-baseline-hearing-aid-market/
[2] http://www.drugstorenews.com/article/cvs-pharmacy-opens-audio-and-optical-centers
[3] https://www.statista.com/statistics/283334/global-average-selling-price-smartphones/
[4] https://www.bls.gov/opub/btn/volume-5/pdf/expenditures-on-celluar-phone-services-have-increased-significantly-since-2007.pdf

hearing aids at all price levels that include professional services, for as little as $500 out of pocket per device or for little or no cost through insurance plans, civic organization or hearing aid manufacturing foundations. The key is getting people to seek a professional who can work with them to meet their needs – be it financial or otherwise.

Regardless, a paper published in The Hearing Review in 2011 found what many hearing aid providers know to be true – that price is not a primary factor in the adoption process, and that whether devices are subsidized does not impact hearing aid adoption rates in a major way. The authors of the paper found that the hearing aid market is an inelastic one. In other words, regardless of the economic situation, purchasers buy when they want to buy. The authors also contend that people who could benefit from the use of hearing aids are not doing so because they are not being counseled on the evidence-based potential benefits in a meaningful way.[5] This means we have to help compel potential adopters to see the value of hearing aids and understand their benefits in relatable terminology.

"MarkeTrak VIII: The Key Influencing Factors in Hearing Aid Purchase Intent," printed in The Hearing Review in March 2012, extensively explored factors that could influence an individual with hearing loss to purchase hearing aids. A key population that was evaluated was non-hearing aid adopters who were planning to purchase hearing aids within the next six months to one year. The top five influencers motivating purchase were 1) Recognition that their hearing loss was worse, 2) Spouse or relative, 3) Safety concern, 4) Audiologist, and 5) ENT.[6] IHS is equally concerned about the consumer's ability to self-diagnose which is inherent in the OTC model. A diagnosis goes beyond just assessing the degree and type of hearing loss, and should be the foundation of any consumer's ability to purchase a hearing aid – over the counter or not.

Srini Pillay, M.D[7], a Harvard trained and award winning psychiatrist, published, *The Dangers of Self Diagnosis: How Self Diagnosis Can Lead You Down The Wrong Path*. The following was taken from Dr. Pillay's article:

> *When you self-diagnose, you are essentially assuming that you know the subtleties that diagnosis constitutes. This can be very dangerous, as people who assume that they can surmise what is going on with themselves may miss the nuances of diagnosis. For example, people with mood swings often think that they have manic-depressive illness or bipolar disorder. However, mood swings are a symptom that can be a part of many different clinical scenarios: borderline personality disorder and major depression being two examples of other diagnoses. The clinician can help you discern whether you swing from normal to down or down to up, and by considering how long the mood swings last, the clinician can make the appropriate diagnosis. Here, the danger is that you may misdirect the clinician or even yourself.*
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> *One of the greatest dangers of self diagnosis in psychological syndromes, is that you may miss a medical disease that masquerades as a psychiatric syndrome. Thus, if you have panic disorder, you may miss the diagnosis of hyperthyroidism or an irregular heart beat. Even more serious is the fact that some brain tumors may present with changes in personality or psychosis or even depression. If you assume you have*

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[5] Amlani, Taylor, and Weinberg, The Hearing Review, "Increasing Hearing Aid Adoption Rates Through Value-based Advertising and Price Unbundling," December 2011.

[6] http://www.betterhearing.org/sites/default/files/hearingpedia-resources/M8_factors_impacting_hearing_aid_purchase_intent_0.pdf

[7] Srini Pillay, M.D. graduated at the top of his class in medical school in South Africa. After receiving a Medical Research Council Scholarship to study the neurochemistry of panic, he completed his residency at McLean Hospital/Harvard Medical School where he graduated as the most nationally awarded resident in his class. Following this, he directed the Outpatient Anxiety Disorders Program at McLean Hospital and also completed 17 years of nationally funded brain imaging research. He has been a physician for 25 years, maintains an active clinical practice and teaches medical students as Assistant Professor of Psychiatry (Part-time) at Harvard Medical School.

depression and treat it with an over-the-counter preparation, ***you may completely miss a medical syndrome. Even if you do not want conventional treatment for depression, you may want conventional treatment for a brain tumor. (Emphasis Added)***

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Then there is the fact that we can know and see ourselves, but sometimes, we need a mirror to see ourselves more clearly. The [clinician] is that mirror. By self-diagnosing, you may be missing something that you cannot see. For example, you may be overwhelmed by anxiety and think that you have an anxiety disorder. The anxiety disorder may be covering up a major depressive disorder. Approximately 2/3 of people who present to outpatient clinics with anxiety have depression as well. In general, when two or more syndromes occur in the same person, we call this comorbidity. ***When people self-diagnose, they often miss the comorbidity that exists. (Emphasis Added)***

Another danger of self diagnosis is that you may think that there is more wrong with you than there actually is. For example, if you had insomnia, inattention and depression, you may believe that you have a sleep disorder, ADD and major depression. However, major depression can account for all of these symptoms. Thus, you may make things worse by worrying more as well.

Self-diagnosis is also a problem when you are in a state of denial about your symptoms. You may think that you have generalized body aches that started when your mood got worse, but a doctor may elect to do an EKG for chest pain that reveals possible coronary artery disease. You may have been trying to avoid the chest pain or you may have minimized this.

Lastly, there are certain syndromes that may not seem like problems to you even though they are very disruptive to your life. For example, with delusional disorder people do not think that they are delusional and because they are not overtly psychotic, they may not think to report paranoid symptoms that add up to delusional disorder. Also, many personality disorders are not spontaneously reported since they are usually problematic to other people.

Thus, self-diagnosis can have tremendous negative repercussions on the patient. For this reason, …. it is always best to discuss your impressions with a doctor before you decide on the treatment you want.[8]

Dr. Pillay's warnings could not be more on point when it comes to self-diagnosis of the cause of hearing loss. Hearing loss is a symptom of an underlying medical or functional disorder. For example, someone with the symptom of hearing loss may have the diagnosis of a cholesteatoma, bilateral age-related hearing loss, impacted cerumen, an ear infection, otosclerosis, or a variety of other conditions – some of which are discovered through testing and some of which through a visual inspection of the ear, or a combination. Consider, for example, a tear in the eardrum, which cannot be identified by a layperson and which requires medical intervention. See Attachment A for examples of pathologies of the ear requiring physician intervention. Can you identify what's wrong in the photos obtained through videotoscopy? More importantly, could you do so without the use of a videotoscope and requisite knowledge needed to identify the potential pathology? The answer is no; a self-administered pure-tone hearing test alone cannot provide a proper diagnosis, nor are lay individuals capable of reliably self-diagnosing the reason why they may be experiencing a hearing loss. Does the consumer have co-morbidities contributing to their hearing loss that will go untreated if left to self-diagnosis? Worse, do they have underlying life-threatening pathology? With all due respect, approving the marketing of self-diagnosis as an approved method for identifying and treating hearing loss, is an abdication of the responsibility to prevent false and misleading advertising.

[8] Psychology Today, May 3, 2010.

Finally, OTC hearing aids do not get at the root of the reasons why people who could benefit from hearing aids do not get hearing aids – stigma, vanity, denial, and inability to detect their loss.

Over time, the hearing aid dispensing community has worked diligently to improve patient satisfaction and acceptance of hearing aids as a solution, and most importantly build trust within their communities and with prospective and existing patients. Their efforts are reflected in the current satisfaction rates for hearing care providers (hearing aid specialists and audiologists). A recent study shows that 95% of owners and 87% of non-owners are satisfied with the health care providers they have seen in the last five years. The same study shows that satisfaction with hearing aids is high as well, with satisfaction at "91% for hearing aids obtained in the last year; 77% for hearing aids obtained 2-5 years ago; and 74% for hearing aids obtained 6 or more years ago." The overall satisfaction rate is at 81%.[9] Comparatively, cellular telephone companies' (oftentimes affiliated with consumer electronics) satisfaction rates are on average 79%, with a maximum satisfaction rate of 81% in 2016.[10] The aforementioned efforts by the hearing care provider community to build trust and a respected reputation is critical because of an overall wariness by individuals with hearing loss to obtain hearing aids due to the reasons stated above - stigma, vanity, and denial. Stigma being the number one reason that people choose not to seek out hearing aids is a difficult challenge, but IHS believes that other recommendations made by the NASEM to include increasing consumer education and awareness and engage primary care physicians can help move the needle in a positive way.

While the eyeglass analogy tends to be used in comparison to hearing aids - truly an apples and oranges comparison in terms of the complexity in identification, physiological and medical implications, and treatment of hearing loss - the regulation and delivery of eyeglasses and contacts can serve as a useful model for drawing the line between expanded competition and the overall lowering of cost, and patient safety. The current model allows for individuals to purchase eyeglasses and contacts from online and other retailers if they have a prescription from a licensed ophthalmologist or optometrist within the previous six months. This model ensures that the eyeglasses or contacts are appropriate for the patient/consumer, yet still allows for them to investigate the delivery model that will best meet their needs and shop around. If hearing aids were to be sold direct to the consumer, building in a requirement that the consumer obtain an order from a licensed professional within the previous six months that affirms the individual has had an audiometric evaluation and visual inspection of the ear, has mild to moderate hearing loss, and could benefit from the use of a hearing aid, coupled with FDA regulations governing the safety of the devices, would minimize patient safety and efficacy concerns. This model would create an informed consumer who could then explore all the options available to him/her, which would be a better alternative than the complete elimination of the hearing care provider in the process. Further, the vast majority of hearing aid providers offer free hearing screenings, so this requirement is not likely to not add a cost barrier.

In your meeting notice, you posed five questions for which we offer the following responses.

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

[9] http://www.hearingreview.com/2015/05/introduction-marketrak-ix-new-baseline-hearing-aid-market/
[10] http://www.theacsi.org/index.php?option=com_content&view=article&id=147&catid=&Itemid=212&i=Cellular+Telephones

There is plentiful information available online, in print, and otherwise through multiple online sources related to hearing loss and associated treatments, including the Centers for Disease Control, Food and Drug Administration, National Institute on Deafness and other Communication Disorders, AARP, Better Hearing Institute, Consumer Reports, manufacturers and provider networks, and consumer and professional organizations. IHS has the Hearing Aid Hotline, which connects callers with information about hearing loss and contact information for local providers, and produces a brochure called "Have You Heard?" that takes patients through basic hearing anatomy, types of hearing loss, the benefits and varieties of hearing aids, and includes answers to commonly asked questions. Consumers can also find a list of providers and reviews on site like Yelp, Healthgrades, Google Reviews, Care Dash, and Angie's List.

That being said, we are agreeable to the recommendation released by the NASEM that calls for conformity and the use of common terms in conveying information to consumers about hearing loss and hearing loss treatment, as well as an emphasis on addressing health literacy levels. We believe such action will lead to a greater understanding and acceptance of the hearing healthcare system and services available, as well as the benefits and use of hearing aids and other assistive listening devices.

As this question relates to the potential for a future OTC hearing aid market, however, IHS has significant concerns about its likely impact on the: perception of non-OTC (traditional) hearing aids, influence on future hearing aid acceptance and purchases, and the significant amount of confusion that will come from having two differently-delivered and -supported products with the same name. Evidence from the Asian markets reveals that consumers are widely dissatisfied with over the counter hearing aids (50% dissatisfaction rate in Japan according to Japan Trak 2015). According to the American Express Global Customer Service Barometer 2014 survey, "When it comes to poor customer service experiences, nearly all (95%) consumers talk about them, with 60% reporting that they talk about these experiences all of the time. On average, consumers tell 8 people about their good experiences, and over twice as many people (21) about their bad experiences." These statistics do not bode well for the concept of an OTC hearing aid market since we know that satisfaction and hearing aid use is tied to the involvement of the licensed provider and use of best practices.[11] In a study conducted by Amplifon in 2016, 34% of participants were dissatisfied with their over-the-counter hearing aid experience, while just 6% were dissatisfied when they obtained a hearing aid through a licensing hearing aid provider. (These outcomes are relatively consistent with the findings of Better Hearing Institute's MarkeTrak 9 survey, which showed an 81% satisfaction rate with professionally-fit hearing aids compared to Amplifon's rate of 83%).[12] That would be 26.6% more people talking about poor "hearing aid" outcomes than present day if the over-the-counter model is replicated nationally.

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

Historically, hearing aids were distributed and sold through hearing aid dispensers and the Department of Veterans Affairs until the enactment of the Hearing Aid Rule in 1977, which sought to address the fraud and abuse that inevitably came with an unregulated marketplace. The combination of the FDA

[11] "MarkeTrak VIII: The Impact of the Hearing Healthcare Professional on Hearing Aid User Success: Correlations between dispensing protocols and successful patient outcomes." Hearing Review, April 2010.
[12] http://www.hearingreview.com/2015/05/introduction-marketrak-ix-new-baseline-hearing-aid-market/

Rule and its authorizing the states to license those who dispense hearing aids, did wonders for the perception of the profession, which - combined with advancements in technology - has led to the high satisfaction rates for hearing aids and licensed professionals that we observe today. And despite the (justified) need to have a licensed professional fit and dispense hearing aids, we are seeing a dramatic increase in points of access from even ten years ago. Today, you can purchase hearing aids through private clinics, warehouse clubs like Costco and Sam's Club, and even perhaps your local grocery store or pharmacy.[13,14] These new points of access, price points, and competition, coupled with changing attitudes and demographics, have led to a continuous increase in overall hearing aid sales from year to year - a trend we expect will continue.[15]

Further, the addition of devices like personal sound amplifiers, caption telephones, and specialized alarms over the years has contributed to hearing aid professionals (hearing aid specialists and audiologists) enhancing the variety of services available at their clinics – providing consumers with access to the full scope of products to address all their communication needs. It likely won't be long before hearing aid clinics are offering hearables for sale for normal-hearing consumers.

Of course, hearing aids are also being sold online through a conservative application of the FDA requirements for sale. This development has created some confusion about the cost of hearing aids, leading some consumers to believe that obtaining hearing aids through a licensed provider is comparable in cost to an online hearing aid.

At the crux of any future policy-making, however, IHS continues to assert that professional intervention is necessary to obtain satisfactory outcomes and grow hearing aid adoption rates. A recent study showed a significant difference between hearing aids that were fitted using a best-practices model delivered by an audiologist versus one in which the consumer makes decisions about the device, which would replicate, in part, the self-treatment and self-management concepts of an OTC model. The outcome of the study showed that while 81% of those who went through the best-practices model indicated they would keep the hearing aids, only 55% of the self-treat/-manage participants indicated they planned to keep them."[16] This is a significant difference and consistent with our estimates that about 26% more people would be talking about unsatisfactory outcomes using "hearing aids." More importantly, that same 26% will go untreated as a result of their frustration. Another study conducted in 2014 found that the "meticulous optimization" of hearing aid fittings performed provided no discernable difference in outcomes in the use of basic and premium hearing aid technology by older adults with mild-to-moderate hearing loss – the key being the meticulous fitting.[17] However, with the OTC model, patients lose the very tool that optimizes success – the individual who performs the meticulous fitting - the provider.

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

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[13] http://www.assurehearingaids.com/index.html
[14] https://www.cvs.com/content/hearingcenter
[15] http://www.hearingreview.com/2015/07/hearing-aid-sales-increase-8-8-first-half-2015/
[16] http://aja.pubs.asha.org/article.aspx?articleid=2608398
[17] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4224118/

There are many exciting things happening in the space of technology advancements both related to the devices and identification of hearing loss. For example, Oticon's Opn just captured top honors via the Edison Awards and was described as one "The Four Technologies That Are Turning Our World Into the Future."[18] We are also seeing the distribution of FDA-approved hearing aids that use lasers to amplify sound through EarLens.[19] The National Hearing Test is available and being widely-marketed to likely hearing aid candidates, raising awareness of hearing loss as an important condition and ushering people into clinics for evaluation and treatment. We would direct the FTC to presentations offered at the FDA Workshop in April 2016 for a more expansive review of the advancements in technology, which are helping to drive improved outcomes.[20,21]

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

Hearing aids offer tremendous value in their interoperability capabilities. The technological advancements we have experienced in the function and sound quality of today's hearing aids means that for some, very little is needed by way of additional assistive technology. Others can gain great benefit from wireless features that allow for hearing aids to connect via Bluetooth for participating in phone calls, listening to television, adjusting the volume, and even stream music directly into the ear. Their smartphone compatibility also allows for hearing aids to be programmed remotely, opening up tremendous opportunity for the continued advancement of telehealth service delivery in the hearing healthcare marketplace.

IHS believes that federal and state standards governing hearing aids and their delivery draw a reasonable line between encouraging innovation, protecting patient safety, and adhering to their founding goals, which was to address fraud and abuse in the hearing aid market. Again, consider technologies like the Oticon Opn and EarLens, which were previously mentioned, both of which involve a licensed hearing healthcare professional. In other words, existing regulatory standards do not hinder innovation – they balance innovation with public safety.

The regulation of hearing aids and the individuals who dispense them date back to the 1970s, during which Congress, the FTC, and FDA were seeking to deal with widespread fraud and abuse within the hearing aid marketplace, including the incidence of the public being sold hearing aids when they were either not appropriate or not necessary or in lieu of medical intervention.[22] The "Hearing Aid Rule" was adopted in 1977 as the result of the FDA's Interdepartmental Task Force on Hearing Aids' evaluation of the hearing aid market. In developing the FDA Rule, in addition to delineating definitions, conditions for sale, and labeling requirements, including medical evaluation requirements, the FDA specifically encouraged the states to adopt licensing requirements for those dispensing hearing aids. "The Commissioner recognizes that the professional and patient labeling regulations and restrictions on the sale of hearing aids are only a partial solution…State and local licensing laws, as administered by State

[18] https://futurism.com/the-four-technologies-that-are-turning-our-world-into-the-future/
[19] http://www.hearingreview.com/2015/09/fda-allows-marketing-new-laser-based-hearing-aid/
[20] https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM497365.pdf
[21] https://www.ftc.gov/system/files/documents/public_events/1022593/edwards_1.pdf
[22] FDA letter to Etymotic Research, 2004

and local agencies, are the appropriate legal mechanisms for establishing minimum competency standards…Such licensing statutes thereby protect the public against unfit and inept practitioners…"[23]

In 1986, the State of Colorado determined that the regulation of audiologists and hearing aid specialists was no longer needed because of a lack of complaints by consumers and subsequently eliminated professional licensure and all standards that went along with licensure. This action essentially created an OTC hearing aid marketplace in the state. Within months unscrupulous, untrained, unlicensed, and incapable would-be sales people flocked to the state. These were people who could not get licensed previously or had their licenses revoked either in Colorado or in other states, or who were merely trying to make a quick dollar. They would open storefronts or operate out of their vehicles, but when a client needed services, they would often disappear. Many would hold seminars for the public promising phenomenal results, taking money from those in need, and not deliver on their promises. People with hearing loss, including the elderly, were hurt in these transactions both financially and psychologically, and the recovery, once licensure was reinstated, took several years. In its 1999 Sunset Review, the Colorado Department of Regulatory Agencies Office of Policy and Research stated, "This sunset review found that there is significant actual public harm by the unregulated practice of hearing aid sales," and as a result the department recommended continued regulation of hearing aid dealers.[24,25] This is in spite of the fact that during the deregulation period - from 1986 through 1995 - the regulation of hearing aid sales had been governed by the state's Consumer Protection Act. Even with state oversight, licensure of those dispensing hearing aids was still deemed necessary.

The concept of reestablishing this model across the country, and with our most vulnerable population as the target, is of significant concern. Federal and state regulations governing who can dispense hearing aids and requirements associated with the sale are a necessary safeguard and must be maintained in order to prevent the widespread abuse and mistrust that would inevitably arise out of the establishment of an OTC hearing aid classification. Not to mention the lack of state-based consumer protections that would no longer be afforded the patient who purchases an over the counter hearing aid. The mistakes corrected after Colorado's failed experiment should not be repeated on a nationwide scale.

The combination of the Hearing Aid Rule and state licensing establish a minimally invasive process that insures that competent professionals evaluate an individual's condition, make medical referrals as warranted, and identify when a hearing aid may be the appropriate solution. They also provide a mechanism to deal with unscrupulous or fraudulent practices. Fortunately, at the time, the FDA took great caution in developing the rule to provide the proper amount of regulation and to keep the cost of regulation as low as possible - a consideration that is still relevant today. "FDA has judiciously exercised its rulemaking authority to provide for minimal Federal intervention consistent with essential protection of the public health in the delivery of hearing aid health care services. This approach recognizes the limitations of FDA statutory authority in dealing with such factors as the cost of a hearing aid and the inadequacy or absence of State licensing laws."[26]

As recently as 2004, the FDA reinforced its belief in the importance of the role of the physician and licensed hearing healthcare professional. "FDA continues to believe that the safe and effective use of

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[23] *Fed. Reg., Vol 42, No 31, 2/15/1997*
[24] http://hermes.cde.state.co.us/drupal/islandora/object/co%3A4646
[25] Also known as hearing aid specialists, hearing instrument specialists, hearing aid dispensers, and hearing aid fitters.
[26] FDA Hearing Aid Rule Preamble, 1977

hearing aids depends on the collateral measure of a physical examination to ensure that a hearing aid, rather than medical or surgical treatment, is the appropriate solution to a particular person's hearing impairment."[27] The audiological and Red Flag evaluations are critical screening tools that are and should remain an essential hearing healthcare requirement in any patient encounter.

As you know, the FDA announced in December 2016 that it would no longer be enforcing the medical clearance and waiver requirements for adults to obtain hearing aids. This came as the result of a recommendation from the NASEM report, "Hearing Health Care for Adults," released in June 2016. And while the committee members reasoned why they believe the medical clearance requirement is unnecessary, the reality is that the initial identification and assessment of one's hearing loss typically occurs when a patient initially sees a hearing aid specialist or audiologist. The physician evaluation, which typically comes after the initial assessment, will either confirm the findings of the hearing aid specialist's or audiologist's evaluation, or lead to an intervention for a possible medical condition. The value is in the initial visit to a hearing healthcare provider, during which a patient's condition is assessed and a determination of treatment or referral is made. Should an over the counter hearing aid classification and model advance, it is our hope that the FTC and other stakeholders will strongly encourage the continued intervention of a licensed provider in the consumer's initial evaluation of his/her hearing loss at the very least.

Further, we believe it is imperative that the FDA determine the appropriate standards for OTC hearing aids, should they become a reality, and that their consideration of the safety and efficacy of the devices should evaluate not just that of the devices but their implication on perception, overall adoption rates, and public health outcomes. If it were up to the Consumer Technology Association and its members, they would extol the "virtues" of self-diagnosis (and none of the risks), self-regulate (because no one else will) and promote their devices as OTC hearing aids. This is evident in the fact that CTA developed its own standards for personal sound amplifiers, which has become its suggested standards for OTC hearing aids. This is an industry that has knowingly violated the law by selling their products as personal sound amplifiers so they did not have to comply with existing federal regulations. Just as the existing hearing aid dispenser and manufacturer market – and consumers – benefit from oversight from a neutral party – state and federal governments – OTC hearing aids and the companies that manufacture and distribute them should be overseen by the FDA and FTC and comply with existing standards like the 510(k) report, which provides evidence of the safety and efficacy of the devices.

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

Existing federal standards establish an appropriate line between ensuring patient safety and allowing innovators to enter the hearing health care marketplace. As previously mentioned, the FDA took great care when developing the Hearing Aid Rule to minimize federal intervention and regulations but still protect patient safety and minimize their impact on cost.[28] As it relates to the 510(k) process and good manufacturing practices, IHS does not believe that any hearing aid manufacturer should be held to a different standard in the production and review process regardless of whether they are established parties or new entrants who choose to now legally promote their devices to people with hearing loss.

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[27] FDA letter to Etymotic Research, 2004

[28] FDA Hearing Aid Rule Preamble, 1977

Hearing loss is a medical condition, and by necessity requires the involvement of a licensed provider who can perform a comprehensive hearing evaluation, make referrals to medical professionals as needed, and determine the patient's course of action in addressing their hearing loss. Therefore, the role of licensure is critically important as it establishes a baseline competency for those practicing in the field and a series of consumer protections, the latter including mechanisms for disciplining unscrupulous and unethical providers.

In addition to seeing increasing educational levels and competencies in our pool of hearing aid specialists, there are several state-level changes that would improve competition, outcomes, and access to care. The integration of telehealth into licensing acts would offer providers the guidance and cover needed to be able to offer their patients remote services when appropriate. Advancements in technology and the existing compatibility of many hearing aids with smartphones make the use of telehealth an ideal solution for making care more accessible and convenient for patients. We also support greater consistency in state licensing requirements, which would also provide hearing aid specialists a greater ability to use reciprocity when moving or applying for licensure in a second (or third) state.

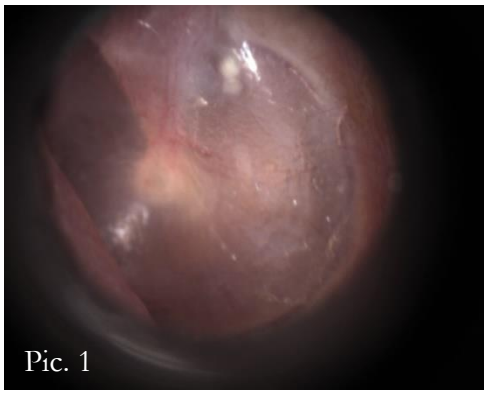
Again, thank you for the opportunity to comment on these critical issues, and thank you for the important work you do. With questions or for further discussion, please contact IHS Government Affairs Director Alissa Parady at aparady@ihsinfo.org or 734-522-7200.

Sincerely,

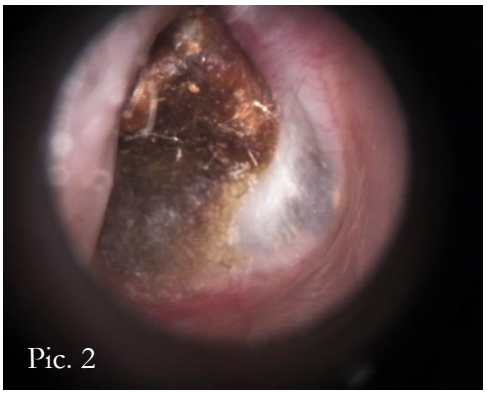
Richard Giles, ACA, BC-HIS
President
International Hearing Society

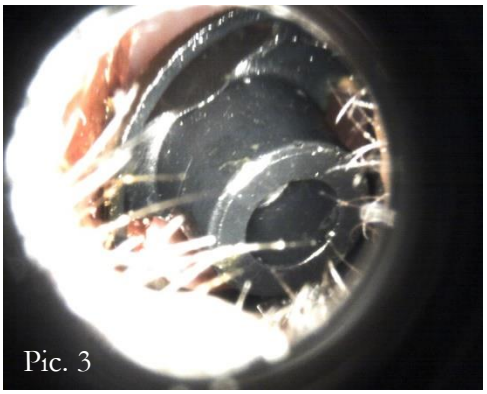
Attachment

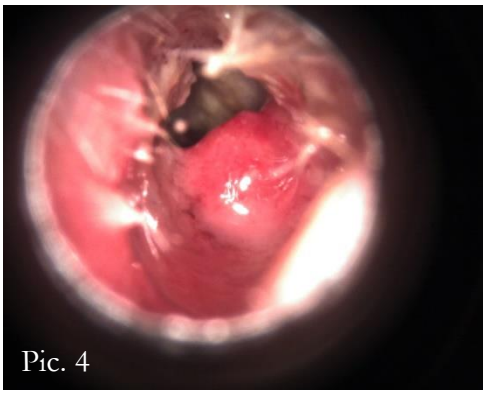
Attachment A

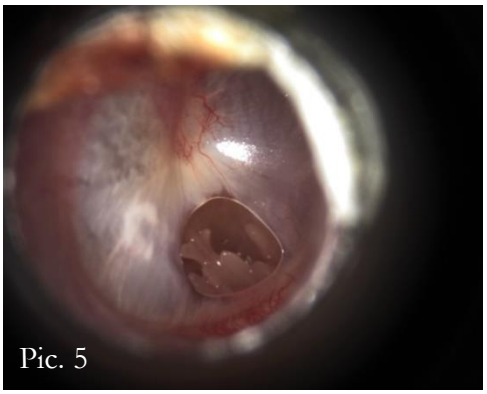

Pic. 1

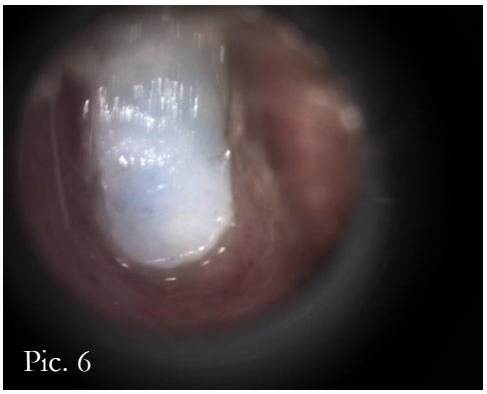
Picture 1: Normal ear
Picture 2: Impacted cerumen (earwax)
Picture 3: Device dome in ear canal
Picture 4: External ear cholesteatoma
Picture 5: Perforated ear drum
Picture 6: Soap embedded on tympanic membrane
Picture 7: Foreign object impacted deep in ear canal

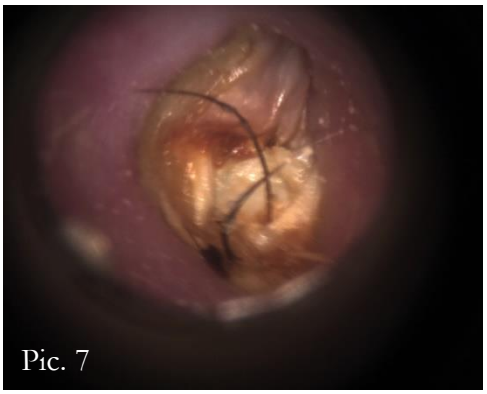

Pic. 2


Pic. 3


Pic. 4


Pic. 5


Pic. 6


Pic. 7