April 18, 2017 Workshop Transcript

Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care

Hosted by the Federal Trade Commission

April 18, 2017

FTC Conference Center
400 Seventh Street, SW
Washington, DC 20024

[START OF WORKSHOP]

INTRODUCTORY REMARKS

- **Tara Isa Koslov, Acting Director, Office of Policy Planning, Federal Trade Commission**

TARA KOSLOV: If everyone could please take their seats, we're going to get started.

Good morning, everyone, and welcome to our "Now Hear This" workshop, where we will explore competition, innovation, and consumer protection issues in hearing health care. My name is Tara Koslov, and I'm the acting director of the FTC's Office of Policy Planning. I'm very proud of our workshop team, which was led by OPP's Dan Gilman. And as usual, as is typical for our workshops, the team comprises an interdisciplinary mix of lawyers, economists, and other professionals from throughout the agency.

On behalf of the entire workshop team, we're delighted that you're joining us today in person and also via our live webcast. We want to extend special thanks to our terrific roster of speakers for taking the time to travel here and share their expertise with us.

So I have two official jobs here today. The second will be, I'll be planted at that table doing some of the live tweeting during the day. We'll be at the handle @FTC, and we're tweeting at the hashtag #NowHearThisFTC, which others can use as well.

But before we begin our substantive program, it's my job to quickly review some administrative and safety details. Please silence any mobile phones and any electronic devices. If you must use them during the workshop, please be respectful of the speakers and your fellow audience members. Wi-Fi is available, and the access code is on a little brochure that you could pick up at the desk when you came in, at the registration table.

Please be aware that if you leave the Constitution Center building for any reason during the workshop, you will have to go back through security screening again. Please

bear this in mind and plan ahead, especially if you're participating on a panel, so we can do our best to remain on schedule.

Visitors all received a lanyard with a plastic FTC event security badge. We do reuse those for multiple events, so when you leave for the day, please do return your badge to event staff.

If an emergency occurs that requires you to leave the conference center but remain in the building, follow the instructions provided over the building PA system. If an emergency occurs that requires the evacuation of the building, which we certainly hope will not happen, but if it does, an alarm will sound, and everyone should leave the building in an orderly manner through the main 7th Street exit. After leaving the building, turn left and proceed down 7th Street and across E Street to the FTC emergency assembly area. Remain in the assembly area until instructed to return to the building.

If you notice any suspicious activity, please alert building security. Restrooms are located in the hallway just outside the conference room, and there are big signs labeling them.

As indicated in the program, lunch today is on your own. There is a cafeteria in this building at the other end of this floor. Please note that it will be closed from 11:00 to 11:30 AM and after 3:00 PM. Also, as you may have already learned, we're not allowed to bring food or beverages into this room, so please plan accordingly. You might not want to buy a big giant coffee at lunchtime thinking you can bring it in here with you for the afternoon.

Please be advised that this event may be photographed, webcast, or recorded. By participating in this event, you are agreeing that your image and anything you say or submit may be posted indefinitely at ftc.gov or on one of the Commission's publicly available social media sites.

As I mentioned, the workshop is being live webcast, with huge thanks to our amazing tech team back there who make that happen. The webcast will be recorded. A

transcript will also be generated, and these materials will be made available on the FTC website within the next few weeks.

Most of the speaker presentations are already posted on the workshop website, along with public comments received to date. Our intent is to create a lasting resource for everyone interested in these important issues. I remind everyone that the public record remains open for another month, through May 18, to enable the submission of additional public comments after the workshop.

Again, we'll be tweeting from @FTC using the hashtag #NowHearThisFTC. We encourage others to use that as well.

We will accept questions via Twitter during the workshop. We will also be accepting questions via comment cards for those who are here in the audience. Workshop staff will walk around and distribute comment cards during each session, and then they will collect the cards and bring them up to the moderators. Due to timing constraints, we will not be able to address all questions during the workshop itself, but workshop staff certainly will review all questions. So I do encourage you to submit any.

If anyone has any logistics or other questions throughout the day, please feel free to ask any of the conference staff who are wearing badges, including our great paralegal helpers who were out at the registration desks. And that is it for the housekeeping details.

Now I have the great pleasure to turn to substance and introduce our first speaker, and my longtime colleague, FTC Acting Chairman Maureen Ohlhausen. She was sworn in as an FTC commissioner in April 2012, and was designated to serve as acting FTC chairman by President Trump this past January. Among Maureen's many accomplishments, I'm proud we get to claim her as an OPP alumna. She served as OPP director once upon a time, and I know she shares my view that workshops like this one are an excellent opportunity for the FTC to promote research, scholarship, discussion, and informed policymaking on issues of importance to American consumers. So please join me in welcoming Acting Chairman Ohlhausen.

[APPLAUSE]

OPENING REMARKS

- **Maureen Ohlhausen, Acting Chairman, Federal Trade Commission**

MAUREEN OHLHAUSEN: Well, good morning, everyone. Can everyone hear me OK? Yes? OK, good.

I'm delighted to open the FTC's workshop on hearing health care. But first, I want to thank all the participants for coming to share their views and ideas on hearing loss, a problem of increasing importance to many Americans' quality of life. I can't mention by name everyone who is joining us today, but we have participants from the hearing aid and consumer tech sectors, academics, academic medicine, audiology, consumer groups, the retail sector, and others.

We are also particularly grateful to our colleagues joining us from our sister federal agencies that lead the work on many aspects of hearing loss, and they'll be here to share their expertise, including the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Department of Veterans Affairs. I also want to recognize those from the National Academy of Sciences, Engineering, and Medicine, the Department of Health and Human Services, and the commercial sector, who've been very generous in providing input to this workshop.

And finally, I would like to thank the FTC staff for their considerable work in organizing this workshop. So as Tara mentioned, once upon a time, I was the head of the FTC's Office of Policy Planning. So I know well the work involved for a major workshop like this.

Now, I'm supposed to say that my remarks are just my own and not those of the entire Commission, but I'm going to disregard that restriction when it comes to thanking the staff for all their hard work. As most of you know, the FTC is an enforcement agency with a dual competition and consumer protection mission. And we vigorously enforce US antitrust and consumer protection laws to prevent harms to consumers and competition.

But advocacy also plays an important role in the FTC's mission. And today, we're here as part of our research and advocacy mission to bring together stakeholders to explore a critical health care issue for many Americans—hearing loss. Tens of millions of Americans suffer from hearing loss. Hearing loss ranges from mild to profound, and individuals react to hearing loss differently, but communication challenges can affect personal and work interactions, and individuals' health and quality of life.

Now, I understand that John Eichwald from the CDC will be joining us by video feed later today to present recent research on hearing loss. This CDC research suggests that up to one in four American adults has a measurable hearing loss. I believe that John will also have something to say about alternative methods of measuring the incidence and severity of hearing loss.

But I gather that all methods point to a widespread problem. Some 30 to 60 million people in the United States have hearing loss. According to a 2016 report by the National Academy of Sciences, that number is not only large, but growing, due to the prevalence of age-related hearing loss and the aging of our population. The same National Academy report suggests that the large majority of those who might benefit from some form of hearing health care do not get it. An estimated 67% to 86% of adults who might benefit from hearing aids do not use them, and by any measure, this represents tremendous unmet demand.

Now, addressing the problem of hearing loss is important and multilayered for a growing and significant number of Americans. Those who have hearing loss often do not recognize the problem, and those that want to find a solution are not able to easily understand or identify options to meet their hearing loss needs. Through this workshop, we hope to have a lively discussion on the many questions that all of us would benefit from asking and discussing among a large group, an array of stakeholders.

Among the first questions we ask—most consumers who might benefit from hearing loss help simply do not get it. Why not? For many reasons, it seems, but we should start with a simple one—treatment is expensive. To focus on the National

Academy's hearing aids example, and to borrow again from its research, prices vary considerably. But in 2013, the average retail price for a pair of hearing aids, plus support services, was estimated to be $4,700.

For most Americans, this is an out-of-pocket cost, with only the Veterans Health Administration, some state Medicaid programs, and a small number of third-party payers being notable exceptions. Thus, it's a very considerable expense for the average consumer.

Consider the impact on senior citizens. We're told that the prevalence of hearing loss rises steeply with age, from approximately 3% among adults ages 20 to 29 years of age, to an estimated 45% among the 70 to 74 age group, and more than 80% in the 85 years and older age group. Suppose both members of a senior couple are dealing with hearing loss, and they're contemplating a $9,400 out-of-pocket expenditure for hearing aids that they might need to replace every five years down the road. That would be a tall order for most seniors and their families.

So, we ask, could greater transparency on the cost of services and devices, greater consumer education on hearing loss, and a potential increase in demand, new technology, or a combination of these and other aspects, help increase competition and potentially decrease costs?

Second, hearing loss is a complex medical condition with no one-size-fits-all solution. Although there are many available treatment options, and they work well for many consumers, they work better for some consumers than for others, and not at all for some. So, we ask, what factors could spur greater innovation?

Third, information costs seem to be high, unusually high, in hearing health care. Many consumers who might afford hearing health care simply cannot determine how best to get it. There are many different possible routes to care through various professionals, including primary care physicians, ENT specialists, audiologists, hearing aid dispensers, and speech language pathologists. Some offer health services, some devices, and many offer a bundle of devices and health care or technical services.

Adding to the options, there are several different types of devices, and many consumers report having a difficult time knowing where to begin. They do not know the relative advantages of one path or another, or one provider or another. And the array of device offerings can be confounding, particularly when consumers cannot find good information about the relative advantages of products and features that come with very different price tags.

Sometimes, the basic question, what's included in a bundle of goods and services, is obscure. This raises important questions about, how might information costs be lowered? The FTC has found, across diverse industries and occupations, that competition tends to lower prices, improve quality, foster innovation, and improve consumer access. We know that we have a vibrant and dynamic tech sector, and an often innovative and sophisticated health care sector.

And this prompts some key questions. What can competitive markets do to help? Could markets do more to benefit consumers under different conditions? How can we in government best foster competitive markets to keep improving and better meet the demand for hearing health care, while balancing health and safety needs? Can we identify undue impediments to competition and innovation and consumers' access to truthful and non-misleading information about goods and services, and can we lower them?

In conclusion, health care problems can be complex, solutions imperfect, and technology costly. But the scale of unmet demand created by hearing loss stands out, not just to those of us at the FTC but to other agencies and those in commerce, in the tech sector, and health care. The FDA has cited estimates that only one fifth of the people who could benefit from a hearing aid seek intervention. Consumers deserve better options than they have now.

Thus, we are pleased to convene this workshop to bring together such a broad array of panelists to share information on innovations in technology and methods of health care delivery, about new consumer tools and regulatory initiatives, and what's

being accomplished now, and about how reform might better enable competitive markets, old and new industries, technologies, platforms, services, and professionals to meet the critical, burgeoning, and unmet demand for hearing health care. So thank you for joining us today, and we all look forward to the upcoming discussions.

[APPLAUSE]

PRESENTATION: ADULT HEARING LOSS: RECENT DATA FROM THE CDC

- **John Eichwald, Office of Science, National Center for Environmental Health, Centers for Disease Control & Prevention**

DANIEL GILMAN: Hi, I'm Dan Gilman. I'm from the Office of Policy Planning here at the FTC, and I have no card, but wanted to just dash up here to introduce our first speaker. In keeping with past practice, we're going to skip people's very distinguished bios in the introductions and give just their names and affiliations. But we do have biographies available as handouts and on our website.

So I'm very pleased to announce that John Eichwald from the Office of Science, National Center for Environmental Health, at the Centers for Disease Control and Prevention will be joining us live from Atlanta, and our Southeast Regional office in Atlanta, where he's going to talk about adult hearing loss, recent data from the CDC. Thank you.

JOHN EICHWALD: Thank you, Dan. Hope my audio signal is coming through clear, and also that you can view my slides.

Good morning to you all. First of all, I want to thank the Federal Trade Commission for asking me to present today. As introduced, my name is John Eichwald. I'm an audiologist currently working for the National Center for Environmental Health within the Centers for Disease Control and Prevention here in Atlanta, Georgia. I'm going to be speaking this morning about how CDC collects and reports information about hearing loss and how it's taking steps to communicate the need for protecting hearing in the community. Next slide, please.

In June of 2016, the National Academies of Sciences, Engineering, and Medicine published the report "Hearing Health Care for Adults—Priorities for Improving Access and Affordability." The study was sponsored by the seven organizations listed on the slide. The report's recommendations for health were developed by an exceptional 17-member committee with broad expertise in hearing health care services. In total, the committee developed 12 goals and corresponding recommended actions.

Although this report focused on hearing health care for adults, it provides steps to support and manage hearing health and foster environments that maximize hearing and communication for all ages. Next slide, please.

Four of the 12 committee recommendations included the CDC as one of the related public health partners. These recommended actions included strengthening efforts to collect, analyze, and disseminate population-based information on hearing loss and hearing health care, promoting hearing health in regular medical and wellness visits for those with concerns about their hearing, evaluating and implementing innovative models of hearing health care to improve access, quality, and affordability, and improving public available information and promoting public awareness about hearing and hearing health care. CDC'S federal partners identified in these efforts included several other federal agencies and multiple institutions, organizations, associations, and state public health agencies. Next slide.

Before I talk about the work at CDC, I want to provide you with some background about hearing loss in general. It may be obvious to many, but hearing is vital to most communication, and can have a direct impact on an individual's health, daily function, and overall quality of life. Hearing is a complex physiologic process and pathological changes can occur in one or more regions of the entire auditory system, from the visible outer ear to the highest levels of cortical brain function. The diagnosis of hearing loss can easily be misunderstood, and its impact on an individual person is highly variable.

The severity of hearing loss varies in degree from mild to profound. It can occur in one or both ears. It can be identified at birth or may occur suddenly or gradually over a person's lifetime. Hereditary is the most common cause for hearing loss diagnosed in the newborn period. Other causal factors include conditions and complications in prenatal period and during delivery. Acquired hearing losses later in life are due to many factors, including infectious diseases, harmful medications, injuries, noise exposure, and aging.

In adults, most hearing loss progresses slowly, is permanent, and does not improve. The effects of hearing loss on communications and its consequential impact on social interactions and functional abilities has serious public health implications for persons of all ages. Next slide.

Hearing loss is both a significant societal issue and a public health concern. It has huge economic impact, which has been captured using different modeling approaches, and with varying assumptions.

According to one estimate, for seniors over 65 in the United States, total cost during the first year for audiometric screening, audiological evaluation, binaural hearing aids, and fitting is projected to increase fivefold between 2002 and 2030, from $8.2 billion to over $51 billion. In another analysis, an estimated $123 billion of economic benefit would be attained if 20% of hearing loss from noise exposure were prevented. The predicted impact of lost wages range from $58 to $152 billion, and was recorded to be a conservative estimate because it did not take into account additional costs, especially vacation, health care, and reduced quality of life. Next slide, please.

As background for the rest of my presentation, this graphic represents an audiogram of the varying degrees of hearing sensitivity. Across the top, frequencies or pitch are represented from left to right, and sound intensity or loudness measured in decibels of hearing loss ranges from very faint sounds at the top to very loud sounds at the bottom. As is illustrated, hearing is generally considered to be normal in adults when thresholds for all frequencies are better than about 20 to 25 decibels. In children,

normal hearing is generally considered where all thresholds are better than 15 decibels. Next slide.

When hearing test results are reported, it's extremely important to understand how it was defined. Sometimes hearing loss is reported as an average of three frequencies, sometimes four. Sometimes only frequencies in the speech range are recorded, for example, 501 and 2,000 hertz. And other times, when only high frequencies are reported, for example, three, four, or six kilohertz.

There is no gold standard for reporting the degree of loss. As I stated, normal hearing in adults is generally considered different than that for children. An individual's hearing threshold may be similar at all frequencies, that is, in terms of a flat configuration. It may differ across frequencies, such as a high frequency sloping hearing loss, or sometimes hearing damage only occurs at a certain frequency, and is described as notched or even a cookie-bite configuration.

It's also important to understand whether hearing results are being reported for the better ear, the worse ear, or both ears combined. Next slide.

CDC'S National Center for Health Statistics has two very important sources of data concerning hearing loss. The first of these is the National Health Interview Survey. NHIS is a household interview of about 87,500 individuals conducted for CDC continuously throughout the year by interviewers from the US Census Bureau. This is supported through the National Institutes on Deafness and other Communication Disorders, to NIH. Several questions about hearing loss have been instrumental in providing national population-based data.

One of these questions asks, is your hearing excellent, good? Do you have hearing trouble, moderate trouble, a lot of trouble, or are you deaf? Other questions ask about hearing and understanding in different listening environments, assistive technologies, including hearing aid use and cochlear implants, causal factors, and referrals for hearing care. The question about an individual's trouble with hearing is asked every year of one randomly-selected adult in each interviewed family. Next slide.

In 2014, information on hearing loss was collected on over 36,000 adults ages 18 and over through NHIS. In that year, 15.8% of adults surveyed reported that they had trouble hearing without a hearing aid. Next slide.

A weighted analysis of this sample produces an estimate that over 40 million adults in the United States have trouble with their hearing. This was reported more by males than females. It was the third most commonly reported condition, and was almost as much as the prevalence reported for diabetes and cancer combined.

CDC also collects data concerning hearing loss through the National Health And Nutrition Examination Survey. NHANES includes data from households in interviews and physical examinations conducted in mobile examination centers across the country of about 5,000 people each year. The 2011-2012 NHANES cycle included audiometric testing and hearing-aid-related questions for a nationally representative sample of adults between 20 and 69 years of age. Again, support for this national data was provided through the National Institutes on Deafness and Other Communication Disorders. Next slide.

A recent analysis of the NHANES data collected in 2011 and '12 revealed one out of seven adults had a hearing loss in their speech frequencies. The weighted analysis of this data produces an estimate that nearly 28 million adults in the US have this type of hearing loss in one or both of their ears. High-frequency hearing loss was found in nearly one of three adults, which suggests over 61 million adults have this type of hearing loss. For both types, hearing loss was diagnosed more often in both ears than hearing loss in one ear. Next slide.

In partial response to the National Academy of Sciences report, CDC'S National Center for Environmental Health started research and participated in activities to raise awareness that excessive exposure to loud sounds outside of the working environment can cause permanent hearing damage. We analyzed NHANES data from the 2011-12 cohort. This morbidity and mortality weekly report was published as part of a larger health promotion launched at CDC's February "Vital Signs" report, which also included a

broad-reaching media release, a graphic fact sheet, new website content, a town hall webinar, and multiple social media tools, most of which were provided both in English and Spanish. Next slide.

For our report, we analyzed audiometric data using an algorithm to identify high-frequency audiometric notches that were suggestive of hearing damage caused by noise exposure. We defined the presence of this audiometric notch when any threshold at three, four, or six kilohertz exceeded the average threshold at 500 and 1,000 hertz by 15 or more decibels, and the threshold at 8,000 hertz was at least five dB lower—better than the maximum threshold at three, four, or six kilohertz.

This algorithm is more liberal than that used by many other researchers, but was deliberately chosen to identify potential early damage to hearing even before hearing threshold exceeded normal limits, or that participants might be aware that damage had occurred. This algorithm is the same as is used for reporting purposes in "Healthy People 2020" to signify probable noise-induced hearing loss, but our analysis, we included damage that was found in one or both ears.

The graphic on this slide represents an audiometric configuration that would meet our report criteria, but a person with this damage would most likely be classified as having hearing within normal limits. Next slide.

A total of 3,583 adult participants had complete audiometric data for our analysis. The weighted prevalence of an audiometric notch was 24.4%, which, when extrapolated to the total population, represents nearly 40 million adults in the United States. Audiometric notches were identified nearly three times more often in one ear than [INAUDIBLE] hearing damage in both ears. Next slide.

Audiometric notches in one or both ears were consistently found more often in men than in women. Participants who reported exposure to loud noise at work were twice more likely to have hearing damage than those not exposed.

However, nearly one in five participants who reported no exposure to loud or very loud noise at work had an audiometric notch in one or both ears. These included

participants who reported exposure to loud noise outside of a job, for example, noise from power tools, recreational vehicles, or listening to music for 10 or more hours a week. This means 21 million adults in the United States likely have hearing damage from loud sounds, sound sources at work or in their communities. Next slide.

The presence of an audiometric notch increases with age, ranging from 19.2% among participants in their 20s, to 29% in their 40s. The decrease in the prevalence of notches beginning for those in their 50s is believed to be due to the increasing effect of aging later in life that may mask the audiometric measured damage already caused by noise exposure. You can see that notch has almost been completely masked by participants in their 60s, but this group still met our study definition and is included in our analysis.

Regardless of their work or recreation noise exposure, nearly one in four participants identified with this damage reported that they felt their hearing was excellent or good. This suggests that many people with these audiometric configurations are either unaware or ignoring existing damage to their hearing from noise exposure. Next slide, please.

Almost all hearing loss from noise exposure is preventable. However, the NHANES survey found that 70% of persons exposed to loud noise in the past 12 months had never or seldom worn hearing protection. Noise reduction and avoidance can prevent hearing loss or slow its progression.

Steps individuals can take for personal protection are relatively easy. Move away from the sound source, loud sounds such as loudspeakers or cannons at college stadiums. Use quieter products and tools. Take breaks from exposures. Avoid high volumes on personal listening devices. Reduce listening time to loud levels of music, and use hearing protection devices.

Hearing protectors need to fit well to reduce noise exposures effectively. Discussions between patients and personal health care providers about hearing loss symptoms, tests, and ways to protect hearing might help with the early diagnosis of

hearing loss, and provide opportunities to prevent harmful noise exposure. Avoiding prolonged exposure to loud environments and using personal health protection devices can prevent noise-induced hearing loss. And last slide, please.

Hearing loss is both a societal and public health concern. Engagement and actions are needed across multiple government agencies and a wide spectrum of stakeholders, including individuals, families and communities, professionals, nonprofit organizations, industry, and the entire hearing health community. Thank you for your time today.

PANEL 1: INNOVATIONS IN HEARING TECHNOLOGY

Panelists:

- **Stavros Basseas, Chief Executive Officer and Co-Founder, Sound World Solutions**
- **Brent Edwards, Chief Technology Officer, Earlens Corporation**
- **Jani A. Johnson, Assistant Professor, Hearing Aid Research Lab Director, University of Memphis**
- **Jan Metzdorff, President, Sonova Wholesale US**
- **Dianne J. Van Tasell, Senior Scientist, Bose Corporation**

Moderators:

- **Karen A. Goldman, Office of Policy Planning, Federal Trade Commission**
- **Daniel H. Wood, Bureau of Economics, Federal Trade Commission**

KAREN GOLDMAN: Good morning. We're going to start now with the panel on innovations in hearing technology. I'm Karen Goldman from the Office of Policy Planning, and this is my co-moderator Dan Wood from the FTC's Division of Consumer Protection in the Bureau of Economics.

This panel will provide an introduction to the products that will be discussed throughout the workshop—hearing aids, hearables, and personal sound amplification products, often referred to as PSAPs. Our expert panelists will discuss not only technology and innovation regarding these products, but also consider the implications for competition. In introducing the panelists, we're not going to give you the detailed biographical information that you can find in your bios document.

To my left, our first panelist will be Jan Metzdorff, who is president of Sonova Wholesale USA. He'll provide an overview of hearing aid technology and how it addresses hearing loss.

Our next panelist will be Dianne Van Tasell, who holds a PhD in audiology and is a senior scientist at Bose Corporation. She'll discuss hearables and compare them to PSAPs and hearing aids.

DANIEL WOOD: Our third panelist is Stavros Basseas, PhD. He is the CEO and co-founder of Sound World Solutions. Stavros will discuss one approach to making hearing aids affordable and accessible.

To his left, our fourth panelist is Brent Edwards, PhD. He is the chief technology officer at Earlens Corporation. He will discuss innovations in the hearing aid industry.

And our last panelist is Jani Johnson, who is a doctor of audiology and PhD in communication sciences and disorders. She is an assistant professor at the University of Memphis, and she will discuss the impact of hearing aid technology on outcomes for hearing loss.

KAREN GOLDMAN: So we'll begin with Jan Metzdorff's presentation, and panelists can move to the podium if they like.

JAN METZDORFF: OK. I'll do that. So good morning, good morning. My name is Jan Metzdorff. I'm president for Sonova's wholesale business here in America. We are a Swiss hearing health care company, one of the largest in the industry. We have about 11,000 people working in the organization around the world, and this year we're actually celebrating our 70th anniversary.

So I was asked to give an overview of technology within our industry. So I'll do that very briefly, in six minutes. But before going there, I just wanted to touch very briefly on, what is it actually we're trying to solve, because there's been a lot of discussion when we talk OTC, a lot of comparisons between reading glasses and hearing aids. Why can't you get a hearing aid OTC, just like you do with reading glasses?

But there's a very, very big difference, and that is, unlike reading glasses, when you put a hearing aid on, it does not restore the hearing to normal. We are dealing with an individual in a complex medical situation that I've been trying to illustrate up here in this diagram, where the cochlea is now represented with piano keys. And on the left, you have the healthy ear, and on the right, you have a typical hearing loss. So a cochlea, or a piano key is missing, or inner hair cell is missing in the cochlea.

And our experience over many, many years here is to optimize a hearing situation for a patient with a damaged cochlea or with a hearing loss, we need a hearing health care practitioner involved. It's very important that we program and manipulate sound through our hearing aids the best way possible to get to an optimal result for these individual hearing losses.

We can manufacture the best hearing aids in the world, but if they're not programmed to the appropriate hearing loss and to the individual situation of the patient, they may not end up providing a lot of benefit. So when we dive into technology, we are dealing with highly sophisticated medical devices here.

Many of you will recognize the audiogram on the left. So one of the things we do when we try and find a solution to the hearing loss and to the damaged cochlea is we divide, for instance, the audiogram or the frequency spectrum into a number of channels. That allows us to get higher resolution. And there will be amplification. There will be compression. There will be frequency compression or even transposition taking place to try and navigate around this damaged cochlea and optimize hearing the best way possible.

So there's a lot of parallel processing going on here. The channels, they range from a few to 20 or more in the more sophisticated hearing aids. And again, giving us that resolution and that opportunity to optimize the hearing aid for the individual loss.

We also know a hearing aid that's optimized for a particular sound environment will not necessarily be optimized for another environment. So we work with a number of automatic programs in the hearing devices today that are optimized for a speech-in-noise situation, for music, maybe the sound environment in a car, and so on. And today, most hearing aids in our industry, they're able to detect the environment that the patient is in and find that program automatically and shift between programs to constantly optimize the situation.

So there's a lot of processing taking place. It's a complex thing. There are a lot of other things—noise cleaning, noise suppression, and signal enhancement and so on going on in the hearing aid.

So when we look at different levels of technology being available, from premium down to basic, one of the ways we differentiate is to the left—it's hard to read up here, probably. But in the premium segment, and I've taken an example from my own company here, we deal with 20 channels. So we divide up the frequency spectrum here in 20 channels, and manipulate the sound in each of those individually. And it all runs in parallel. We have, in our operating system, as you can see on the top, we have seven automatic programs where the hearing aid is able to detect what environment we're in and pick up the appropriate program accordingly.

And there are a number of other features in the middle here that are taking place—wind block, there is sound recovery, there's noise block and what have you. So a lot of computation going on in parallel. I should just remind you that in hearing aids, this needs to happen super-fast. All this computation that takes place here happens super-fast, right? We cannot have a delay of even a half second, right, between sound coming in and going into the ear.

So we're dealing with very, very fast processing. We're dealing with very small devices, very small components, and also devices that can draw only a very limited current, because we're dealing with small batteries as well.

So in the basic level, of course, less channels, in this case, actually no automatic programs, and so on. And in between, you have a variation. So a range of price points, and a range of technology levels that we make available.

Hardware evolution, there's been a lot of that over the last 10 years in our industry, mostly around comfort, design, and ensuring that we build small as possible hearing aids. The big beige bananas on the left, as people like to refer to, yeah, that's where we were maybe 10, 15, 20 years ago. There's been a lot of evolution into RIC products with modern designs, with open fits, no occlusion, and so on.

We make constant developments in in-the-canal devices, getting smaller through smaller components and new materials all the time. We have solutions like Lyric, that is extended-wear product that sits deep in the ear canal and is only replaced every six to eight weeks. And there has been developments also in water-resistant products and also more recently in rechargeable products, for instance.

Hearing aids are going wireless. This allows them not only to talk to each other, either by data transmission or by sound transmission, so in our premium category—again, an example from my own company here—which allows us to use four microphones, actually, and create, again, a higher sound resolution and better way to deal with this incoming sound signal.

Also externally, hearing aids going wireless. There are a number of applications here—remote controls, sort of different radio equipment that can be attached to the hearing aid, direct streaming today to all sorts of devices, to the phone, to the iPhone, to the satnav in your car, to the television and so on. And I would say all manufacturers today have a wide library of apps, either as remote controls, as hearing screeners, also as an opportunity to log a particular sound environment by the patient, and via the cloud, stream that experience back to the audiologist in the office.

And more recently, we have also seen teleaudiology coming up, where you can do adjustments at a distance by the audiologist.

I was asked about activities in research in our industry. It may be difficult to read here. Of course, we do a lot of things outside just hearing aids. We do signal processing, DSP development, product design, and so on, but also looking at basic aspects of hearing and cognitive science. For instance, what is the influence of hearing loss on development of dementia and so on?

A company like Sonova, we spend 7% to 8% of our revenue on R&D, and research and development. So we are way over $100 million a year in research.

Quick conclusion here—there's been a lot of evolution and development in hearing aid technology over the years. Does it work? We definitely believe so. We

believe the investment in R&D is paying off for us, but also for the patients. We see every time we launch a new product platform, and we do that every two to three years, we see a significant uptake in the technology and the acceptance. And I think today, some market studies will show patient acceptance is as high as ever for the recent technology.

We are very adamant that the best—I'll have to click a few times here—the best outcome is achieved when there is a hearing care professional involved in this. Again, the hearing [INAUDIBLE] the solution. The hearing care professional is a very important piece as well.

So along the same lines, if we proceed with an OTC category, we have to do that with a lot of caution, and take into consideration the possible impact to the patient. Thank you. That was six minutes, more or less.

[APPLAUSE]

DAN WOOD: Next, Dianne Van Tasell will make her presentation.

DIANNE VAN TASELL: That is not a picture of me. Don't I wish. OK.

I'm Dianne Van Tasell, with a cold. I'm a senior scientist at Bose Corporation, and I want to thank you, FTC, for inviting me to be here today. Sorry. I'm going to need to get my water.

Must be all these trees that are blooming here in Washington, DC. So my job today is to try and clarify some terms for you, those terms being hearables, PSAPs, and hearing aids.

I have several objectives. One is to clarify the terminology, and I want to use my time to debunk what I think are some common assumptions. And those assumptions have to do with the notion that if it's not a hearing aid, it has to be a basic device somehow. It can't do the fancy things hearing aids can do. It can't incorporate the same features, can't actually do the same things that hearing aids—the kind of signal

processing that hearing aids do, because it's not for a person who has a hearing loss. I hope I can convince you of that by the time we're done.

So what is defined? What is known? Well, the definitions that you're going to be hearing about a little bit more this afternoon come from FDA. A hearing aid is something that is intended to compensate for impaired hearing. A PSAP, a personal sound amplifying product, is not intended to compensate for impaired hearing.

The confusion comes because the two may be identical devices, here in the US markets. Some of them are medical devices that are manufactured by medical device companies, are sometimes sold as either PSAP or hearing aids, and the difference is whether the labeling and marketing specifies that the device is for people with hearing loss or for people with normal hearing.

That's confusing. I'm not going to talk about that much more, because that's a situation many of us are aware of. What I am going to do is turn our attention to this new category called hearables. So there are—I discovered there are about as many definitions of hearables as there are people who think about this. So we're going to use Nick Hunn's definition—that's as good as any—is that a hearable is anything that fits in or on an ear and contains a wireless link.

Now, interestingly, you can see in this little graphic on the left, which is from an interesting website called hearable.world, that that means that there are a lot of things that are in the universe of hearables, and that includes wireless hearing aids and wireless PSAPs. And when I got to looking at this, I thought, well, OK, let's stop thinking about individual devices, because devices are now beginning to do a lot of different things. Let's think about what things in the hearable world actually do.

So if you think about the functional domains, you can think that these devices are already streaming audio. They are connecting us with our personal digital assistants, with Siri or whoever lives in this thing on the palm of your hand. They can do fitness tracking, biometric sensing. And the two areas that we're a little bit more familiar with, it can do sound augmentation, that is, making sound more comfortable, and it can do

hearing aid functions. You don't have to be a hearing aid to do a hearing aid function, which is amplification.

So I want to zero in a little bit more on those two issues. Hearing aids and PSAPs can do the same kind of functions. In what ways are those the same? Or in what ways are those different?

Well, we can go through the table, but the most important thing to remember is it's the same auditory system whether it's damaged or not. Therefore, the desirable functions of a PSAP, something that's made for normal-hearing listeners, or a hearing aid are essentially the same, both in terms of the hearing aid functions. We want to make soft sounds louder without making loud sounds louder. We want to customize the frequency response. We want to use wireless programming.

And sound augmentation would make sound more comfortable, make sound more understandable—conversations more understandable in noise. And then, of course, we want to do audio streaming. The things in red signify that the consumer electronics industry brings a little bit more to the party in some instances. We can use technology that we've developed for noise canceling. We can generally achieve wider bandwidth, at least in the streamed audio signal, just because we can use more power.

So how are wireless hearing aids and wireless PSAPs different? Well, they're different in several different domains having to do with customizations, sales, channels, price, and regulation. In general, obviously, hearing aids are regulated, and so they can only be sold by licensed professionals.

This little thing down on the corner, I included because I wanted to mention something Jan touched on. Hearing aids have done a remarkable job of getting very small and very low-power and achieving long battery life. Current wireless PSAPs are larger and have shorter battery life. On the other hand, the trade-off there, at least so far, is streaming audio quality. For smaller devices that have to work in a low-power environment, that's what has to be sacrificed.

But in the immortal words of Avenue Q, only for now. The new Bluetooth standard and some other innovations currently taking place are going to mean that that's all going to change.

So in summary, two things. The distinction between PSAPs and hearing aids is regulatory, not technological. And I want to emphasize this, that wireless PSAPs and wireless hearing aids are subsets of hearables, and that the rapid innovation in the CE area is already taking place. There are already devices that have hearing aid functions incorporated into them that are consumer products, can be sold at consumer prices. But the regulatory barriers you're going to hear about a little later on today are preventing CE companies from entering the market with products that are clearly messaged for people with hearing loss. Thank you.

[APPLAUSE]

DANIEL WOOD: Dianne, thank you very much for that presentation.

KAREN GOLDMAN: Now, Stavros Basseas will begin his presentation.

STAVROS BASSEAS: Thank you. I have to press the slide. We are a social mission company that tries to address the problem of lack of amplification for a large portion of the Earth's population. It's estimated to be almost 1 billion people, including the people who need occasional use of amplification.

We develop products having the whole global market in mind, because this is where the largest need is. In the US market and European market, and the developed countries in general, the penetration is low, 30%. But in the developing countries, it's nonexistent.

The quality of hearing aid technology, especially in the last 20, 30 years, has improved tremendously. And it's serving those who can afford it well. But the existing so-called medicalized channel of distribution is accessible in the developed countries, but it's not affordable most of the time. And definitely, it's not scalable for the developing countries.

I would say here that in the developed countries, the penetration—it's a function of the hearing loss, and that's how we should estimate it for—evaluate it. If we take the example of United States versus let's say the Scandinavian countries, people who have debilitating hearing loss, which is estimated to be approximately 3% to 4% of the population, which is close to 300 million people globally, if you segment the market based on debilitating loss—and mild loss and moderate loss, people with debilitating loss, they cannot function without a hearing aid.

In the Scandinavian countries, the penetration for those populations is over 90%. The reason I mention this is that for hearing aids in the developed countries is a function of people wear hearing aids. There's stigma involved, and also there's price involved. If we look at the hearing loss which is debilitating in the Scandinavian countries, where the hearing aid is provided through medical care, the penetration is 90%. But for mild hearing losses, the penetration is much less, because stigma becomes an issue.

In United States, the penetration for debilitating hearing loss is less than 50%, so stigma is not the main issue here. It's price and access and affordability.

And of course, in developing countries, this is much greater, because here we have a channel which is accessible, even though it's not affordable. But in developing countries, the channel is nonexistent. And so the model that we have here, the so-called medicalized model which bundles the price with the services in—the cost of the device with the services is in one price.

In developing countries, this model is not possible because the infrastructure required is huge. We tried to do some work in India, for instance, where still, the regulatory body requires that every hearing aid is dispensed by an audiologist, yet the fact is that there are very few audiology schools in India, and they produce very few audiologists per year. So it's like we are asking to put the communication telephone in India and trying to put in a couple lines instead of going directly to the cellular phone.

The infrastructure, both in terms of buildings, materials, equipment, and in terms of requiring highly-trained professionals, is not there in those countries.

So the opportunity that the technology presents to us now allows us to actually get away. I'm not advocating that the existing model is not serving its purpose. I'm saying that the existing model that we have in the developed countries is not scalable. During my 25 years in the hearing aid industry, I would go to many countries and give free hearing aids to many people. We were doing the same way we were dispensing hearing aids in those countries. And the infrastructure requirement was huge, and there is no upkeep. People could not even find batteries to actually be able to support their hearing aids.

So we need to address that problem. And the technology, fortunately, gives us that opportunity. And we have to think not in terms of the technology of the device itself, but the overall system. And the smartphones, the Bluetooth, the wireless infrastructure, the penetration of this technology globally allows people to be able to do things by themselves. Or, if they're technology-challenged, they can always find somebody who has access to technology, or a person who is not highly trained, that can actually help many people.

So the single solution model not only it's not scalable, it's obsolete. And if we want to impose it on everybody, the available technology makes it indefensible.

So I will not cover this slide. Dianne covered it very well. I mean, we have products—we have released products that they are both—we call that the identical product. We call it hearing aid and a personal amplifier. It's the identical product.

The same way you fit the product, the same way you use the smartphone to optimize it. But in one case, it's called a hearing aid, and you have to go through the regulatory requirements, and dispensing, and practically, it makes it more expensive. And then a personal amplifier that does the same thing.

And we have all kinds of signal processing in there, and more. So we have here the fitting of a hearing aid. It involves physical fitting, because many times, it's not a simple part to put a device into your ear and adjust it properly and select the proper ear tips, tulips, that really are suitable for your needs. And it's not always easy for some

person to do it without the help of access to some technology—YouTube or a video. That makes things much easier.

And then you have the electroacoustic adjustments, which is the adjustments of the parameters of the device. You can do self-screening. You can estimate your hearing loss. And then the device itself automatically adjusts.

OK. So I'll take just a couple of second. We did a self-fitting—our device was used in [the National Acoustic Laboratories], a very respected lab in Australia that took our device and asked people to self-fit, and then compared the results with the outcome of professionally-fitted hearing aids, and that there was no difference between them. Not everybody was able to self-fit, so we have to have a way of screening out the people who cannot do self-fitting.

Very quickly and I'm done, the technology, we pay a big penalty by selecting an off-the-shelf technology. Bluetooth chipsets that has tremendous amount of computing power and allow us to do many more things, and it gives us access to the smartphone, and also allows the person to do the self-fitting, or some person with a minimum training to help. Thank you.

KAREN GOLDMAN: Thank you so much.

[APPLAUSE]

Thank you, Stavros, for your very interesting perspectives.

DANIEL WOOD: Our next presenter is Brent Edwards.

BRENT EDWARDS: Good morning, everyone. I'd like to thank the FTC, Dan, and Karen for inviting me to speak today. So I'd like to talk briefly about innovation in the hearing aid industry.

So let's start sort of by talking about innovation, what it is, and where it comes from. The definition I like is generating value from creativity. And we find opportunities for innovation by identifying unmet needs by the customers of whatever is being developed.

So the unmet needs of people with hearing loss are quite significant and quite complex. And so I've listed some of them here. We tend to focus on the very first one, audibility, but hearing loss is a lot more complicated than just an inability to hear sounds. And the development of innovation and solutions for these people are very complicated as well, and try to match all of these unmet needs for people with hearing loss.

Now, I think the development of solutions for people with hearing loss is not just the innovation and the development and research of technology. It's also, hand-in-hand with the development of new technology comes research and investigation into new diagnostic and new outcome measures, in part because we need to understand the unique individual aspects of hearing loss, as we heard about earlier today, in order to develop the technology to meet those issues, but also develop new methods of measuring benefit from the technology in order to, again, understand the individual needs and benefits that are being provided that assess those different unmet needs.

So I think this is sort of articulated in this data here by Larry Humes, showing the ability to understand speech in the y-axis as a function of hearing loss level in the x-axis. And you see that speech understanding gets worse as hearing loss increases. However, when you amplify sound, so you overcome that audibility issue, you still see a wide variety of difficulty with understanding speech. That's no longer correlated with the gold-standard diagnostic for hearing loss.

So this tells us that the audiogram, and measures of audibility, are not sufficient to identify the unmet needs of the patient, and we need to get beyond just audibility and solutions to meet those needs, and we need different measures other than the speech tests shown here in order to demonstrate the benefit that people are getting or not getting from provision of technology.

So here are some of the technologies that the hearing aid industry has developed over the past decade and longer to meet those unmet needs. I'd like to

highlight just a few here that in my experience have really resulted in competitive advantages for the companies that first brought these technologies to market.

So when one of the major companies brought a significantly improved feedback cancellation to the market, they obtained a significant market advantage and started capturing market share. Same with the same company that introduced frequency lowering. Dynamic increase in market share and patient capture.

Wireless ear-to-ear, we're seeing beamforming capturing advantages today. Made for iPhone has been quite significant. And teleaudiology, maybe I'm a little optimistic there because that's just being introduced. I think that's going to really help as well.

So technology is also developed in order to compete among the companies, of course. And we do see this played out in the marketplace in terms of acceptance of the technology and sort of the gathering towards it.

So in addition, as I said, to new technology, we also investigate new diagnostics and new outcome measures. I'm just going to give you a couple examples here of what the hearing aid industry does. This is one study, funded by one of the major hearing aid companies, looking at the benefit from a brain-sensing perspective. And here you see in the normative condition here, for poor speech-to-noise condition using EEG, they're measuring I think the alpha waves here of the activity of the brain. And you see what the general level of activity is to understand speech-in-noise for different condition.

Now, the top panel, you see the improvement, the change in the brain activity, when you improve the speech-to-noise ratio. You have less activity, suggesting less cognitive load and listening effort just by improving speech understanding in noise.

In the bottom panel, you see the benefit of not improving the speech-to-noise ratio, but by adding a binaural algorithm that goes from unilateral to bilateral hearing. You see the same amount of reduction in brain activity. You see presumably the same improvement in cognitive load by the provision of this technology.

So this is an example of how we're getting beyond speech tests, and understanding how hearing aid technology is affecting brain function. I was involved in this study many years ago with UC-Berkeley to look at the impact of hearing aid technology on cognitive load. And using a dual-task paradigm, we measured the reaction time correlated in association with different hearing aid technologies, and showed that listening effort, cognitive load were reduced with the provision of noise reduction and directional technology. And this was also replicated later on with hearing-impaired subjects and with actual hearing aids.

Also, one of the researchers at one of the big six companies many years ago showed that the benefit from hearing aid technology depended on your cognitive ability. On the left hand side are people who score low on cognitive measures, and they did much better with slow-acting compression, whereas on the right hand side, people who scored better on—who had high scores on cognitive function did better with fast compression. So by getting better diagnostics that represent the individual patient—in this case, diagnostic ability—you're better able to provide technology.

And this also is a representation of how the industry has funded this kind of research. These are the areas of funding for the hearing aid industry research consortium, which has so far totaled about $1.5 million.

So I work in Silicon Valley. I've worked at hearing aid companies there for over 22 years. And I can say that innovation is alive and active there and around the world, specifically in the Bay Area. We have the following companies that are startups, or were startups, that are in the hearing impairment space that are very successful in their development. We've also seen the big six, the major manufacturers, working with hearable startups—in this case, Starkey working with Bragi to try to collaborate together.

My own company, Earlens, we put a laser in your ear canal, and we put a motor on your eardrum, and with a combination of those two, we get to much higher levels of performance in hearing than a traditional hearing aid. So I think this is a pretty good

example that innovation is alive and well in the startup world and has not been impeded by some of the competitive or other factors that exist in the industry, including the FDA regulations, which, in my experience working at two of the big six hearing aid companies and two hearing aid startups, I have not experienced any impact of regulations on bringing innovation to market. And in my discussions with other hearing aids startups, at least in Silicon Valley, they share that view. So I'd say, if you have a good idea, if it's a technology that can bring benefit to patients, you know, the money's going to be there to support that business, and the regulations are going to be easily overcome by lots of consultants out there who will help you, guide you, and bring your technology to market to help patients.

So in summary, innovation is strong, not just in technology, but diagnostic and outcomes. It's very alive in startups. And in my opinion, the FDA has not impeded innovation one bit. Thank you.

[APPLAUSE]

DANIEL WOOD: Thank you, Brent.

KAREN GOLDMAN: And now, our last panelist, Jani Johnson, will begin her presentation.

JANI JOHNSON: Thank you. OK, so today I'm going to present some research that I completed with my colleagues, Jingjing Xu and Robyn Cox. So Jan has already presented some of this, but as a reminder, traditional hearing aid products typically are introduced into the market at successive levels of technological advancement, so that compared to basic hearing aids, mid and premium levels have more advanced technologies and more sophisticated features. Each advancement, of course, comes at an increased cost to the end user.

Hearing aid features are created by focusing on device capabilities. Manufacturers capitalize on those capabilities to target improvement in real-world domains. Some of these features either are present for premium hearing aids but not

basic-level hearing aids, or else they differ in sophistication between premium and basic hearing aids.

As a result, it might be assumed that user outcomes would be better with all of the most advanced features working together in the premium aids compared to the basic-level hearing aids. However, independent research has not demonstrated that use of premium-level technology results in better everyday user outcomes than using basic-level technology. Therefore, in spite of large cost differences, hearing health practitioners have no scientific basis for making the recommendation for premium hearing aids, and instead are forced to rely mostly on unverified marketing claims about future benefits when they decide on which hearing aids to recommend to patients.

This research evaluated examples of basic and premium hearing aid technology from two of the major six hearing aid manufacturers, with the goal of evaluating outcomes in the laboratory and in the real world. We explored outcomes from the perspective of the patient with hearing aids fitted as they would be in a typical audiologic fitting, and we tested four domains of user outcomes that have been demonstrated to be important for daily listening with hearing aids.

So the research questions for this study were, in the laboratory and in daily life, are outcomes better with hearing aids compared to without—it's important to show the effectiveness of hearing aids before looking into differences between premium and basic—and then compared outcomes with examples of premium aids and basic hearing aids.

Forty-five typical hearing aid wearers participated in the study. These were older adults with acquired symmetric mild to moderate sensorineural hearing loss. The study was a single-blinded repeated crossover trial. This is an example of one participant's journey. Participants wore four different pairs of mini, behind-the-ear style hearing aids in their daily lives for one month each. The presentation order of the manufacturer and the technology level were both counterbalanced, and outcomes were evaluated at the end of each one-month trial.

All hearing aids were fitted bilaterally using best clinical practice protocols. So the term "fitting" in this case includes individualized selection of acoustic coupling, individualized electroacoustic programming, and verification of the output of the devices in each participant's real ear. Participants received comprehensive face-to-face training on the optimal care and use of their hearing aids in various situations. In addition, participants were encouraged to come back for follow-up appointment to address outstanding issues or concerns and to make adjustments when needed.

So this is a summary of the results of the study. We began by investigating this question from the perspective of the patient. We found that participants reported substantial benefit with hearing aids in terms of hearing-related quality of life and everyday hearing. However, on average, they did not report better outcomes or preferences with premium processing compared to basic.

For these participants, hearing aids maintained or substantially improved performance in all of the domains we tested in the lab and in daily life. So you can see there that we tested speech understanding, listening effort, localization, and sound acceptability. However, premium-feature hearing aids mostly did not result in further improvements compared to basic-feature devices.

We found these results to be extremely compelling. We implemented a broad scope of outcomes, paid careful attention to optimizing all of the hearing aid fittings, and designed tests that favored premium capabilities when possible. Yet there was only one difference when performance with premium was statistically better than basic. This small effect, found in the lab, did not translate to perceived benefit in the real world.

Please keep in mind that these findings apply for older adults with uncomplicated mild to moderate sensorineural hearing loss, and for devices like those included in our study. I recognize that this is a comparison of select technologies at a given moment in time. We looked at two brands of BTE aids from two manufacturers that were released into the market in 2011.

However, currently, the cost of premium devices is greater than basic devices. But I presented evidence here that these devices did not result in better performance for typical older hearing aid candidates. We don't claim that this outcome will hold for all brands of all manufacturers at all points in time. However, payers should remain skeptical about device benefits without independent proof of real-world effectiveness.

We're not attempting to claim that there is no value in researching and improving on existing hearing aid technology. In fact, there is evidence of improved patient experiences with hearing aid technology over time. Yet, for our study, differences in technology made very little difference in terms of daily life outcomes.

It was our experience that the audiologic hearing aid fitting process, including face-to-face training in the optimal use of hearing aids, provided the knowledge and skills necessary for participants to obtain optimal outcomes with their devices, regardless of the technology level implemented in the intervention. In my opinion, this is the most important ingredient in optimizing hearing rehabilitation with hearing aids.

Yet, today's hearing aid fitting practices are shaped by reliance on hearing technology in and of itself to manage hearing problems, a lack of current independent evidence about the effectiveness of different hearing health devices, and concerns about the financial practicality of providing evidence-based rehabilitative services, primarily because reimbursement is tied up with the cost of devices. For patients to obtain maximum benefit with hearing health care services, change is needed. And as always, we're grateful to NIDCD for supporting our research.

[APPLAUSE]

KAREN GOLDMAN: Thank you very much, Jani. So we thank all of the panelists for their very interesting presentations, and now we're going to move into the discussion portion of this panel. Since we just heard about premium hearing aid features and their value and effectiveness, we thought we'd continue a little bit more on that topic. And in particular, we want to ask the panelists, and if they want to respond to these questions, please turn your cards on edge.

So how does a hearing health practitioner decide whether premium features would benefit a patient, and what level of technology is best? And if it's not the degree of hearing loss, then what factors come into play? It would also be interesting to know a little bit about the percentage of hearing aid sales that are of premium versus other levels of technology, and also the cost differences between the basic and premium technologies.

BRENT EDWARDS: So I think I can start out. There are several questions there. In terms of determining what to provide to a patient, it's multi-dimensional. As I said, there are a lot of different unmet needs for people with hearing loss. I can give you a couple examples.

Frequency lowering, for example, is going to be dependent on the shape of the audiogram—not the overall hearing level, but whether someone's going to benefit from frequency lowering, and also whether they tolerate the difference in the sound quality that results from that, because some may hear a difference but not want to put up with it. Same with some of the other features, like noise reduction, depending on their level of tolerance for noise.

And we do have some ways of measuring that, with acceptable noise level as one example of a test. You might provide different strengths of technology. Depending on their lifestyle, you may choose to give them more aggressive speech-in-noise tests than you might with someone else who has a more quiet lifestyle. And maybe I can let some of the others answer the rest of your question.

KAREN GOLDMAN: All right. Thank you very much. Jan?

JAN METZDORFF: OK. So I think Brent is touching on some of these things, right? I think lifestyle is very important in detecting what is the correct hearing solution for a patient.

So I'm not sure when Jani, she talks about these 46 individuals who are in that test, what kind of lifestyle? Do they have an active lifestyle? Are they in business? Are they in meetings? Are they active out in restaurants? Or are they sitting mostly at home

in front of the TV? Because if you have a fairly passive lifestyle, I would agree you will probably not get a lot of additional benefit from sophisticated technology.

So I think that's a big part of what the hearing health care professional have to assess. Of course, hearing loss on the audiogram is one piece. Lifestyle needs of the particular patient is another piece.

When you talk about what is the percentage of different technologies, I don't think we have exact statistics on this. We know, for instance, the VA, they only fit and choose premium technology for your veterans. If we take that out, we believe that the premium market is around 20%. And maybe the advanced segment is something similar to that. The majority of hearing aids are probably sold in the mid segment, maybe around 50% or so.

KAREN GOLDMAN: OK. Thank you very much. Jani?

JANI JOHNSON: I would say that ideally, providers implementing evidence-based practices would be basing their recommendations on the current best effectiveness research. However, the rapid innovations in the competitive marketplace do not allow third-party researchers to continually keep up with timely best evidence in controlled field trials. As such, hearing health practitioners do not have, necessarily, a very good evidence base to make those kinds of recommendations, and as I said, mostly are relying on unverified manufacturer marketing claims to make those kinds of recommendations.

JAN METZDORFF: So I just want to make the point here that we as manufacturers, right, we're sending out demo aids of our various technologies by the truckloads. I mean, nobody's buying a hearing aid without trying it on first, right? And I know at least one manufacturer has a program in place, actually in our own group, where you can try the hearing aid at home for a period of two, three, four weeks, and you can trial it at different technology levels before you decide to buy. So here's a great opportunity to try out, in your own lifestyle, what is the best and most suitable hearing for you. And even, again, in that program, when you decide to buy a hearing aid, if your

lifestyle changes or if your hearing loss progresses and so on, you can actually also upgrade from that technology.

When we introduced this concept some years ago, there was a consideration, well, maybe everybody's now going to start at the lowest, basic level, and then just see how it goes, and maybe upgrade from there. But the reality has been, actually, we are selling hearing aids exactly with the same product mix as we always did, and actually also generating significant revenue from upgrades. So again, before you do an upgrade, you can actually try out that increased technology in your own hearing aid, again, for a couple of weeks before you take a decision to buy that.

So I think we give consumers a lot of opportunity and chance to try out the technologies. It's not just marketing claims from us as manufacturers that are selling the products. I think everybody have a chance to try it for themselves.

KAREN GOLDMAN: Thank you. And Stavros, did—and then we'll move—after Stavros, we'll move on to the next question.

STAVROS BASSEAS: Many of these extra features, they are lifestyle-related. But yet, they are decided by an audiologist sitting in a room, and the user does not have a way of actually trying these things. It's usually people who have—who really will be the greater beneficiaries of all this advanced signal processing, and they are active people, they will be able to actually do things by themselves, better than audiologist would be able to do in the office. So then we should give the people access to that technology.

And during my 25 years in the hearing industry, I felt many times has been a terrorist, because I was introducing technology and the audiologists have no way of evaluating it or even making a decision how to use it. It felt like it was impulse. It was not really—this is an interactive process that you have to have with the end user. And the end user should be—actually would be the best judge as to what of this technology will be beneficial to him, especially if he is an active user.

KAREN GOLDMAN: Thank you.

DANIEL WOOD: OK, so moving on a little bit, as Dianne told us, the target market for hearables is often much broader than the market for hearing aids. Hearables, on the other hand, offer capabilities for entertainment and fitness tracking as well as sound enhancement, and may not offer all the sound processing techniques that are available in hearing aids. To what extent do hearables have the capability to substitute for hearing aids? Do you want to—Stav? Brent?

BRENT EDWARDS: Yeah, so, I mean, I think there is a merging of those two fields. I mean, you're going to see a hearing aid that has heartbeat measures and is able to play music while you run. But because it's intended for use to compensate for hearing loss, primarily it is a hearing aid, and that makes all the difference.

So hearing aids already stream podcasts and music to hearing aids. But they're a hearing aid because they're intended for use for hearing loss. And that's what really differentiates a hearable from a hearing aid, even though they could be identical technology and have many of the identical features.

DANIEL WOOD: Stavros?

STAVROS BASSEAS: The platforms available for hearables now are really, they have immense computing power. We are at this point paying the cost of the largest size, but this is, as Dianne mentioned, it's not—it's going to change. And it's changing. So then having all of this available capability in the hearable, we don't have proprietary hardware which has to be updated every three or four years, and it's highly expensive.

So the possibility, the potential of growth of the overall hearable market is huge. And it will far overpass a limited platform existing today in the industry.

DANIEL WOOD: Dianne?

DIANNE VAN TASELL: Well, you know, I think Brent put his finger on it. And as I got to thinking about this, and I did a little background reading in preparation for this, in 2014, that was the year the term "hearable" was coined. And there may have been a

few devices that were capable of doing—that fit the definition of something you put in your ear that has a wireless connection.

It's three years later, and the last time I looked at that website, there are 30 to 40 products that are now doing at least one of, and most of them doing more of, the functions that I talked about in my talk. So what's really happening is a big convergence, and as I said, the things that—the things that you put in your ear do to help people with normal hearing hear better in noisy situations or in situations where they need some amplification of a quiet signal are the exact same things that hearing aids do. It's a well-known science. The technology is widely available.

So even though hearing aids are unique within the hearable space because they are the only medical and medically-regulated device, we're getting to the point, as Stavros said, where any of the hearable devices can have a check mark on the box that says they do hearing aid processing as a feature. That's now possible. But they are not now hearing aids, and they cannot be hearing aids, unless they are and they can conform to the FDA regulations that govern hearing aids.

DANIEL WOOD: So just a quick follow-up question. Maybe this is intended for Dianne. To what extent would hearables companies market their products as intended for hearing loss if FDA and state regulatory requirements were relaxed?

DIANNE VAN TASELL: I believe that there are several companies that would do that, that would be anxious and happy to do that.

STAVROS BASSEAS: I think the problem is—the regulatory structure that we have in this country and in the developed countries, it's really very significant for the developing countries, because they tend to mirror whatever regulatory structure we have here. And so you have the situation where in India, for instance, you need to have an audiology degree in order to dispense a hearing aid, which is even stricter than here, because they just follow what FDA does or what we do here, and even though the realities are very different.

So really, the regulatory structure needs to change in order to allow the growth that it is possible given the technology.

KAREN GOLDMAN: OK, so thank you. Now we want to talk a little bit about some recent or upcoming innovations that could contribute to greater access and affordability of hearing aids. And you could discuss any innovations, but I thought we might focus on self-fitting, which we heard a little bit about from Stavros, and alternatively, remote fitting of devices by teleaudiology. Dianne?

DIANNE VAN TASELL: Well, I just personally have always thought that self-fitting is the area of greatest opportunity for innovation. And it's actually—the fitting of hearing aids, if you think about it, the fundamental paradigm that we've used for doing that hasn't really changed in 30 or 40 years. I'm old enough to remember that David Pascoe publication in 1977 that finally convinced us that yes, we had to provide more gain in reasons where hearing loss was more severe. I see you nodding out there, Alison. That was—believe it or not, that was not agreed upon—not always agreed upon.

But we've gotten an audiogram, used the audiogram as a starting point for a hearing aid prescription method, all of which have been developed in the last, I guess, 20 to 30 years or so. We use it as a starting point, and then we—the dispenser adjusts from there. Hasn't changed.

But think of the things that we know about hearing loss—the demographic nature of hearing loss, the things that cause hearing loss, what audiograms look like. We had a really nice presentation about that early this morning. And the fact that—I love the guy, I guess he was from Qualcomm, at the last NASEM meeting who held up his smartphone and said, people, there is more computing power in here than sent Apollo 13 to the moon and back. There you go. That guy.

So we have the opportunity to figure out how to make it possible for people to get—very quickly, without any knowledge of hearing or hearing loss or the nature of their own audiogram—to get to a setting that will provide benefit for them very quickly.

So I think there's a lot of innovation that's happening in that space. And once more competitors get into that space, we're going to see a lot develop there really quickly.

STAVROS BASSEAS: Most of the time, the audiologists are just doing the auto-fit, you know. And of course, the adjustment of the device, it's happening out in real life. Giving access and control to people, they would be able to do much better optimization.

But the issue here is not to really go away with the existing channel. It's just to open up possibilities, because we do not need to have one solution for everybody. We need to open up and allow possibilities, because the technology allows us to do that. That's basically what the issue is here.

KAREN GOLDMAN: Brent?

BRENT EDWARDS: So I think also, technology to facilitate accessibility is teleaudiology, which we're seeing introduced by hearing aid companies, where audiologists can remotely program devices. They can get better connections with the patient on the difficulties they're having and either counsel them or change their technology remotely. And you know, I agree with Dianne that self-fitting can be beneficial for some patients, and people that have a desire to do it themselves, by and large, and they get better outcomes because they're satisfied that they've done things themselves. And, you know, the major hearing aid companies have come out with self-fitting tools for patients.

I also know from data logging that when they have these self-adjustments for the field, using an app, for those that have hearing aids that connect with their iPhone, there are a large number of people who don't even touch that, in the same way a large number of people don't ever do anything but leave the hearing aid in program number one, because that's—whether it's a lifestyle, cognitively, they just don't want to be bothered. So I think everyone is different, and you have different needs and different approaches that will be successful.

KAREN GOLDMAN: So in addition to self-fitting, another area is perhaps self-evaluation or self-screening. And have there been innovations in this area that would

improve access and facilitate the use of hearing devices without practitioner involvement? Dianne?

DIANNE VAN TASELL: Yeah, I guess I don't know the particulars, but there have been several very clever and very valid ways, advanced, to at least do hearing screening over the telephone. There's that technique developed by Chuck Watson and his colleagues that gives a pretty accurate estimate of severity of hearing loss using, I think, it's the triple-digits test in noise over the phone. And I believe that there's been one company that Brent mentioned, iHear, that has gotten FDA approval for a home hearing test that's valid. Is that right?

BRENT EDWARDS: Correct.

DIANNE VAN TASELL: So I think there's a lot of innovation going on in that space, too. But I would just like to mention that once again, if we can get away from our—that an audiogram or even a self-test to the severity of your hearing loss is not the only pathway to satisfaction with a hearing device. So that part of the innovation is going to be to allow people to try and adjust devices without having an audiogram, or without even having screened their hearing.

KAREN GOLDMAN: Thank you. Brent?

BRENT EDWARDS: And one thing I'd like to point out is there is evidence that self-assessment of hearing loss severity is not accurate. The sensitivity and specificity is not terrific. So we shouldn't rely just on self-assessment, in terms of need. A lot of people who say they have a hearing loss actually have normal hearing audiometrically.

And also, the audiogram isn't a good predictor of benefit, or if you're going to use the hearing aid, either. So we can't rely just on one thing to guide the patient to a device selection and use. Again, I think it's multi-dimensional here.

KAREN GOLDMAN: Thank you. Jan, did you want to—

JAN METZDORFF: I think, Brent, you covered it quite well. But I think all manufacturers today are working on some sorts of apps, for instance, where you can do a self-assessment. I think we all have those.

And again, it's a good indication. But as we also already discussed, the audiogram in itself is not the be-all. It's only a part of the solution here, or maybe even a trigger just to go and see a health care practitioner and get a better evaluation of the total situation.

I still think it's a high ask of the patient or the consumer to be able to do self-diagnosis, self-assessment, self-programming of a hearing aid. I don't think we have any evidence in any markets around the world that are open to OTC, for instance, that this has really been successful, and that that has been driving up satisfaction rates or penetration rates—rather the opposite, I would suggest at this point.

KAREN GOLDMAN: So I know we have more people who want to chime in, but I'm going to ask a question that I think will put this in a context. It's about the same issue. So the Warren-Grassley Over-the-Counter Hearing Aid bill defines an over-the-counter hearing aid as a "device 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, and that may include tests for self-assessment."

So I would like to invite the panelists to give their views on whether currently-available devices meet this definition and don't require input by a hearing health practitioner. Are those devices available now? And if not, do you think they will be available in the near future? Stavros?

STAVROS BASSEAS: Go ahead.

DIANNE VAN TASELL: Well, let me just say that there are—now we have to do the funny little regulatory speak thing. There are definitely devices that have those fundamental capabilities. They're not being marketed as hearing aids, because there exists no category of over-the-counter hearing aids. And so they can't be—many of

them can't be messaged properly. And that was kind of—I didn't want that to be a slippery answer, but that's the truth.

And I just want to say one other thing that I think is pertinent to your question. And that is that, Stavros, I think you had a really good—I hope you got to mention it on one of your slides, that when we start thinking about over-the-counter hearing aids, they are systems. They're not just the thing you put in your ear. But they, by definition, will have to include some method, as the bill says, for people to be able to customize them to their own hearing.

So I think, Jan, that although there may be some markets in which hearing aids are available over the counter, I don't think we have had a situation yet in which devices that have been designed specifically to be used start to finish by the user here have been widely available.

STAVROS BASSEAS: That is true. I mean, the over-the-counter hearing aid doesn't exist today. Yeah. But it's a system that you—and I think the most difficult test will be to actually satisfy people with mild hearing loss. It's much easier to satisfy people with severe hearing loss with a hearing aid, an over-the-counter hearing aid, because people would get a benefit which will be obvious. And in fact, our most satisfied customers for our products, even the personal amplifiers, are the existing hearing aid users, because they understand the value they are getting, and they have the capacity to actually adjust the device.

So then the over-the-counter device will be a great test, because if it's not done very well, if it's not a complete system that is supported—by not just the device, but all the necessary interface to allow the user to optimize the performance, it will not be a successful product. This is a difficult test, the over the counter. I wish that there—I think we are doing a disservice to the end users by limiting the over-the-counter hearing aid, that it is discussed right now, would have limited gain and possibly limited output, and possibly it will be directed—will allow us to do claims only for mild hearing loss or possibly moderate hearing loss.

But the biggest need out there is for severe hearing loss, and even the study of Harvard was done in 1947, sometimes optimization of the performance, of the response, is really good, but audibility is much more significant. And this is where the greatest need is. So then we should not really fool ourselves by trying to keep everybody satisfied at this point, that the over-the-counter—limiting the use of over-the-counter hearing aid that we are serving the market at the end of the day, the needs of the impaired.

JANI JOHNSON: I think that there is a great opportunity for over-the-counter devices to meet unmet needs for a large variety of people. But I do think that it's important to consider that—I mean, I think some of the research that some of you even mentioned was that there are many people who are unable to do self-fitting and do self-diagnostics really reliably. So I just want to make sure that we're being cautious about applying this to all populations, when there definitely are those individuals who need significant intervention.

I was thinking about this and it kind of reminded me of someone who's fitted with a prosthetic limb. You don't just send them out to use it, just have it, and individualize it. And then you have some follow-up therapy to learn how to use it, to maximize their ability to use that medical device in their own lives. Some people could probably get by with something less individualized in an exercise video, but a lot of people would need that personalized, individualized follow-up care. So I think that there is some concern there.

BRENT EDWARDS: So I'll say, I'm happy with everything I heard in response to this. I agree in large part. It is a system. It's not easy. It's not going to be easy to do OTC.

I would like to point out that there is evidence to be concerned about, which is that satisfaction with technology is related with the level of care that the patient gets from their audiologist. And we've seen that in MarkeTrak. We also see that right now with the Swedish quality of satisfaction database that's being gathered with over 200,000 fittings, that you get big changes in satisfaction with the same device

depending on who you go to see, which tells me that, again, the practitioner is playing a big role in satisfaction with the technology. So that has to be considered.

Finally, I would say the more significant your loss—I agree that any technology will be obviously beneficial the more significant your loss, because you're getting something. But it becomes a lot more challenging to provide the best solution for that patient, the more significant the loss, because the smaller the dynamic range, the trickier it is to get that fitting. And so even though you can get someone partway there, you may not get them to the point that they could get with a professionally fit. And that would be my concern.

STAVROS BASSEAS: I agree. And it's very—we have to be careful with severe hearing loss. But the problem here is value. If getting this satisfactory, optimal performance is so expensive that it forbids people to even get to it, so then we have to find the trade-off here.

And I believe that if we allow the over-the-counter device, this thing will do two things. One thing, which is very important, it will really introduce people to amplification that are very reluctant to actually go in the existing channel—access, price, all of these things. So people—the same thing, I started with the reading glasses and very quickly I moved to prescription glasses. I became aware of my problem. The same thing would happen with the over-the-counter hearing aid.

That will allow people to become aware of the need that they have for a professional at times, because they might not be able to do it by themselves, and they don't. I have also a dispensing chain of hearing aids that I dispense regular hearing aids and I see the value of the professionals there.

Also, the second thing of the over-the-counter hearing aid, it will drive the price down, because people who experience amplification and they can get it at a reasonable price, it will be extremely difficult then to be able to be asked to pay this huge amount of money for performance that is not so different at times. So it will be—it has—and the third effect that I did mention is that innovation is happening in this field, in the

hearables field. I mean, there's only one hearing aid company in the United States. All innovation is happening in the hearable fields. We should really allow this channel to blossom. Everybody will be benefiting from this.

KAREN GOLDMAN: Thank you all for the very interesting discussion. I'd like to follow up on this with an audience question, which is, what is the return rate of those hearing devices purchased directly by the consumer, versus those hearing devices that are provided by a hearing professional?

STAVROS BASSEAS: Well, I know what is happening in the hearing industry. I mean, basically, we used to have—I am not in the hearing industry anymore. Therefore, there used to be a high return rate. Now, it's much lower. And it's much more manageable, because the quality is better.

And now I can only speak for my own company, because we have the personal amplifiers. The return rate is almost the same as it is in—right now, our return rate, it's about 16% to 17%. In other words, people that return the device, even if the device works well, it's because it's too big, because we have that problem.

So that is our return rate, which is not really that bad. Many times, people, when they buy a device like ours, they do get the value. It's a value proposition. They don't pay a lot of money.

So if they get some value, they appreciate that. They don't return the device. So the chances of them returning a very expensive hearing device is much higher. So it's all price and benefit related.

KAREN GOLDMAN: Thank you.

BRENT EDWARDS: I mean, that's a great return rate. In the industry, it's about 20% return rate. And I know of some direct-to-consumer type of devices that have much, much higher return rates. So that's something that I would be concerned about as well, with some of the products that might be offered to people, to make sure that they're not left holding the bag.

STAVROS BASSEAS: May I add something here? I mean, the hearing aid devices, they are tested with a very good process. They are not cheap devices. The performance is good. The over-the-counter, or devices that you can—or personal sound amplifiers, you get some devices that they have a very wide performance. There's no regulatory restriction. They are all—even some of these cheap hearing aids, personal amplifiers, sometimes they say they're registered with the FDA, because they do—they register with the FDA means that they follow good manufacturing practices.

That doesn't mean that their performance is good. Even in the hearing aid industry today, the devices are required to be tested by ANSI. But there are no restrictions as to the range of the performance of the device would be.

So the over-the-counter hearing aids, and the devices that are for mostly for consumers, not only we should really have some testing, but also we should have some limits in performance. Distortion, for instance, which is very important, maximum output, and probably frequency response, because then the consumer will not be in position to actually evaluate the performance, where right now, the audiologist, supposedly they have the capacity to see the test results and make the evaluation if the device is good or not, even though the hearing industry is not required to meet any particular standards by the ANSI.

DANIEL WOOD: Dianne, did you—after this, we'll move on.

DIANNE VAN TASELL: OK. I just wanted to point out that I think a lot of—I've been in a lot of these discussions, and I think sometimes we kind of take a left turn when we think about the fact that there are a huge number of unregulated devices out there, some of them really of very poor quality, like you mentioned, Brent. But I just want to remind everybody what we're contemplating in establishing an FDA-regulated class of over-the-counter devices is a situation in which the quality of these devices would be—now, as a matter of fact, the bill charges the FDA with figuring out how to label the devices and how to establish standards that would result in their being safe and effective.

DANIEL WOOD: OK. Well, thank you all for that. That was a very interesting discussion. So moving on to a topic near and dear to my economist heart, what are the main hurdles to bringing to market new technologies and products that would improve hearing health care? Dianne?

DIANNE VAN TASELL: This is kind of like Johnny One-Note here, but once again, it's a situation in which the technologies—the science is known, the technologies are available to provide much wider—much more widely available hearing assistance in consumer products. But the big hurdle is that we cannot message those products. If we wanted to make those products, we can't message them properly to our customers.

I'd say that's the biggest one. And the other thing I want to mention, I was thinking about what you said, Brent, about the good manufacturing practices and whether that's a hurdle for innovation or entry into the market. And I think that we shouldn't dismiss that as being not meaningful at all.

So for example, one of the things I've learned is that established consumer electronic companies have established quality systems, quality manufacturing systems. And the quality systems that FDA requires also extend to development, manufacturing, and even customer service. Companies have established systems like that. But the corker is that the established systems they may have might not be the ones that are sanctioned or approved by FDA. So companies who are already experienced in making safe and useful products for their customers sometimes will have to dismantle those systems or start all over with FDA-approved systems. So I think one of the things that could help would be for FDA to work with companies that already have—consumer companies that already have very well-established systems to be a little more flexible in accepting the current practices in consumer industry.

BRENT EDWARDS: I think you make a good point. It might be worth a separate workshop just on that topic. I guess my perspective has been if you have good engineering practices in building a quality product, you're doing 90% of what the FDA wants you to do. And you just have to call it a design history file and so on. So I guess

that's part where I say, shouldn't be a big burden if you're already a quality company. If you're a guy in his garage, you know, it's going to be a burden, and maybe they shouldn't be making medical devices in the first place.

But to answer your question about barriers to innovation—let me take a step back beyond just OTC and just say the industry in general, my experience—and working with people who come in from the outside industry into our industry, it becomes really surprising how difficult it is to fit technologies to different types of hearing loss, and the amount of clinical testing that is necessary to validate that the technology is providing benefit to the patients, as opposed to it works on the bench, ship it. In the hearing aid world, I can tell you, in the major manufacturers, we do a ton of clinical testing on patients of different types of hearing loss, different outcome measures, trying to get measures of benefit.

And I know it's been mentioned a couple times that technologies are only issued with marketing claims. There's a lot of data behind benefit internally generated, not by independent universities, that go into ensuring that the technology is going to have some benefit in some situations for some patients, and to try to understand that. So that level of burden on understanding the patient benefit before we ship the product that I know all the major companies have, I think has always been the biggest delay, and may be even keeping technology from being released to market.

KAREN GOLDMAN: OK. Well, we've gotten a lot of interesting questions here. Some of them focus on costs at different stages in production and by the delivery by an audiologist. Some of these may be covered in subsequent panels, so we won't necessarily cover all of these questions at this point.

But just one theme that we've heard in all the discussion and presentations is that innovations in hearing technology, including hearing aids, PSAPs, hearables, and other products and platforms, might be changing the competitive landscape. And so the question really is, is this blending of hearing aid technologies and consumer electronics

that we've heard about, do people think that will result in greater price competition and perhaps reduce the prices both of hearing aids as well as PSAPs and hearables?

JAN METZDORFF: Yeah, it's a good question. I think all manufacturers are looking at, where is the market going? What are new technologies that are being available? And how do we apply those to our hearing instruments, for instance?

And potentially the market is coming together. I would say I'm not sure all of this, necessarily, will drive prices down. A lot of the features and new technology we introduce now in hearing aids is more about adding value and providing a better health care system or better health care product versus necessarily going for lower prices. As I showed in my introduction, we do have a number of price points in our product range. So we do actually try to cater for both the most sophisticated end of the market with the most difficult hearing losses or active lifestyles, down to the basic level. So we also provide products at reasonable prices for those who need that.

KAREN GOLDMAN: Thank you.

DIANNE VAN TASELL: Yeah, I think that although we've been talking about regulatory issues, there were other recommendations made by the National Academy, and even by PCAST, one of which has to do with unbundling of prices. And I think you're going to hear a lot more about this this afternoon.

But it strikes me that as those implementations are implemented—as those recommendations are implemented, and I hope they are, consumers are going to get a much better idea of what the technology costs and what the services cost. Add to that mix a regulatory change that allows consumer products to be available—good consumer products to be available at competitive prices in the consumer marketplace. I don't have a crystal ball, but I can't help but think that that makes for more competition. That makes for products that will be available at more affordable prices for everybody.

STAVROS BASSEAS: It's more choices, and it's not just the price issue. It's access. We have to design models that technology allows us to make amplification and hearing

aids accessible. And as I said, even in this country, even if the price is right, sometimes people do not have access to it, to amplification.

And there are many issues involved. If people need amplification and they're not get it, we have all kinds of other side problems that will be discussed later on. But in the models that we have, if we really need to make a difference, and since we are leaders in technology, we have to think, as I said before, on a global perspective. Our models here, yes, if we address the price problem, it's good. But access, I mean, we do not require all of this necessary for—and choices. And that will allow the problem of amplification to lead to a better solution globally.

KAREN GOLDMAN: Thank you. Brent?

BRENT EDWARDS: Yeah, I'll say I'm very excited about all the interest in the hearing aid space from innovators around the world. And I think that'll just make things better for people with hearing loss. You know, I've said for years that I think the big opportunity here for this merging of consumer electronics with hearing aids is that untapped mild market—people, professionals, in their 50s who just reject the whole hearing aid experience and channel. But they may accept something different.

We don't know if that's true or not, but I think that's where the potential is there. I think we do a really good job with the people who have more moderate and severe losses through the traditional channel. And I would want to make sure that whatever happens doesn't affect the people who are succeeding there. But I think it's fantastic that we're getting new ideas and technologies in place, and they may trickle across the whole spectrum here. So, you know, let's go.

KAREN GOLDMAN: Thank you.

JAN METZDORFF: Is this your card?

DANIEL WOOD: Oh, sorry. That was my fault. OK. So why don't we circle back a little bit to OTC? How would the introduction of an over-the-counter hearing aid

category affect products in the other current categories that are out there? How would it affect industry business models?

STAVROS BASSEAS: Well, I mentioned before that the consumers will be aware. First of all, it will be easier for them to have access to it, because many times people do not think that they have a medical problem because the existing channel somehow makes it, you know, that you have to admit to your problem. I mean, with the over-the-counter hearing aid, you might be able to try it in your own privacy, just to see how bad the problem is.

Also, it will create price pressures to actually rationalize the price. It should allow also the unbundling of the existing channel, I mean, where the price includes services and the cost of the device. And of course, innovation and all of these things. So the over-the-counter hearing aid, I mean, the reading glasses is the example. The over-the-counter hearing aid opens up possibilities to actually drive customers to the existing channel, because they will become aware of their problems.

DANIEL WOOD: So how would it affect products in the existing channels?

STAVROS BASSEAS: How?

DANIEL WOOD: How would it affect products in the existing channel?

STAVROS BASSEAS: Well, I mean, right now we have existing products—I mean, there are quite cheap products out there. They call themselves—they sell mail order. They are personal sound amplifiers. There's a huge range of performance.

And if this is not regulated, I mean, the reason we want to have an over-the-counter product is to put some regulation and protect the consumer. And the regulation, meaning we do not want to have barriers to entry, but we want to have guarantees that the performance of the device meets some minimum standard.

And first of all, that is critical for the channel itself, because it will become a credible channel. You know, I test all of my products using the ANSI standard because I

want them to be credible. But then having a performance standard that they all meet, then it will wipe out the bad products.

And by the way, I could sell my products cheaper than what I'm selling them now. My margins allow me to do that. But if I go any cheaper, I will have credibility issues, because people have identified a $100 product to be a cheap—I shouldn't say that. Cheap products, you know, that they have bad experience with. So then it's good for the over-the-counter industry to actually have some kind of—to make it—to take it from underground, in order to really manage it well and allow technology to blossom and possibilities.

DANIEL WOOD: Jan?

JAN METZDORFF: Yeah, so I'll say OTC is obviously a new debate and discussion here in the US. But there are many markets around the world where you can sell hearing aids OTC today, and mostly markets where they don't have a good hearing health care infrastructure. And I would say again that there are no indications that either penetration or customer satisfaction is higher in those markets.

Actually, as manufacturers, if you take some of the markets out in Asia, we have spent a tremendous amount of resource and time to try and build a professional infrastructure. We spent a lot of resources on training people and so on so we can provide a professional hearing health care system where people can get advice and counseling and so on. So it may be that an OTC category will actually not have a tremendous impact on the more medical side of the hearing instrument business. I still believe that for most people, the counseling, the recommendations, the advice, the programming, and so on is a very key factor in getting to a high customer satisfaction ratio. So—but to be seen, I guess.

DANIEL WOOD: Well, it looks like we're out of time. So we have to end this very interesting discussion. We want to again thank all of the panelists for participating and contributing to this panel.

Now we're going to take a 15-minute break, so we will reconvene at 11:25.

[APPLAUSE]

[SHORT BREAK]

PANEL 2: INNOVATIONS IN HEARING HEALTH DELIVERY

Panelists:

- **Rupa Balachandran, Program Director, Doctor of Audiology Program, University of the Pacific**
- **Lucille Beck, Deputy Chief Patient Care Service Officer for Rehabilitation and Prosthetic Services, Office of Patient Care Services, Department of Veteran Affairs**
- **Kim Cavitt, President, Audiology Resources, Inc.**
- **Scott Davis, Chief Executive Officer, Sivantos, Inc. (formerly Siemens Hearing Instruments, Inc.)**
- **Gary Swearingen, Corporate Counsel, Costco Wholesale**

Moderators:

- **Daniel J. Gilman, Office of Policy Planning, Federal Trade Commission**
- **David Schmidt, Bureau of Economics, Federal Trade Commission**

DANIEL GILMAN: I'd like to ask people to take their seats, we'd like to start with the next panel.

My name is Dan Gilman. I'm in the Office of Policy Planning here at the FTC. My co-moderator is to my left, Dave Schmidt, from the Bureau of Economics, also here at FTC. As throughout the day, we're going to do the briefest of introductions for our panelists, and we have bios, as handouts and on the web, where you can read more about each individual panelist and speaker. We're very glad to have the panel that we do, and I'm just going to briefly introduce people. Each of our panelists will have some brief opening remarks, just a few minutes, and then most of our time will be reserved for discussion.

Joining us today are Rupa Balachandran, PhD, the program director in the Doctor of Audiology Program at the University of the Pacific.

Lucille Beck, PhD, who is Deputy Chief Patient Care Service Officer for Rehabilitation and Prosthetic Services, Office of Patient Care Services at the Department of Veterans Affairs.

Kim Cavitt, an audiologist, who's the president of a private firm, Audiology Resources Inc.

Scott Davis, Chief Executive Officer of Sivantos, Inc., formerly known as Siemen's Hearing Instruments, a major manufacturer.

And Gary Swearingen, Corporate Counsel for Costco Wholesale.

We have a number of overlapping panels and interweaving themes, and now we're going to focus on delivery aspect of hearing health care, including devices. And I'll just start by saying, Rupa, would you like to [INAUDIBLE] go up here? There's a little device for the slides, and then there is a timer here.

RUPA BALACHANDRAN: Good morning, and I wanted to thank the FTC for the invitation to share some of my ideas and my passion for this area.

So in thinking about the topic that we're discussing, I'd like to put it in the framework of the triple aim that we look at in health care improvements, which is every innovation would need to address three big major areas, which is improvement in patient satisfaction and quality of care. The second one being reduced cost to the health care system. And three, improving the overall health outcomes for the population that we serve.

In thinking about it, I think the proposed over-the-counter hearing aids will very easily address the issue of cost, I hope. Two, it does offer very exciting opportunities to really address the health care needs of a very large population. I think one of the greater concerns is patient satisfaction and improvement in the actual quality of life as a result of that.

Typically when we're looking at improvements in health care—in the health care world, on the medical side of things—it really is looking at improved patient satisfaction, reduced hospitalizations, increased patient engagement in their plan of care, and improvements in patient safety, and adherence to care plans. In looking at solutions to all of these, it comes down to the fact that you need to have improved communication with the patient.

And ta-da, that's where we come in, as audiologists. Better hearing really does play a very big role in improving all of these desired goals. There is a lot of good research that would say that hearing really results in positive health outcomes, lowers the risk of depression, increases social engagement, improved personal communication, and just a very deeper degree of engagement – all of which can be achieved with better hearing.

In looking at our discussions today, and in trying to present the framework, I wanted to do a quick comparison of what is traditional hearing aid models versus over-the-counter models. And at this time since the over-the-counter hearing aids have not been very specifically outlined in terms of each part of how they will be implemented, I'm going to use it as a very broad umbrella term to include devices that are fit without an actual professional being there offering guidance at every step of the way.

Traditional hearing aids are still the gold standard in hearing health care, and we all need to recognize that hearing health care is a very complex and a highly customized solution for hearing loss, and it's that degree of customization that essentially drives the cost.

On the other hand, other technologies, or over-the-counter technologies, can greatly improve access to amplification. And it is not a treatment for hearing loss. Not as it currently stands. It can be seen more as a personalization of hearing. It is not a prescribed treatment. It can help you hear better in different situations, but it's not a treatment.

There are opportunities when you think about an over-the-counter hearing aid. Some of the opportunities it does provide, and we could hopefully take advantage of, is that it would provide greater access to devices with lower costs and more delivery channels. It can create a consumer-driven channel for hearing health care. And with more options you could be able to engage the innovative technologies to improve hearing, especially with the new opportunities that smartphones present, with different hearing enhancements available using smartphones as the driver. It allows adults to really engage and participate in their own health care.

Over-the-counter hearing aids also pose challenges to us. The greatest one, which has not yet been discussed, is really the comfort of these devices in the ear. You're looking at a long term—wear a device for eight to ten hours a day. We have to consider the anatomy of the ear in a device actually sitting in that ear for that long, and what does that mean in terms of innovations to address the fact that it's there for such a long period of time? And what will be the comfort? What would be the challenges in terms of managing repairs and warranties? What happens once the consumer has bought them? What are protections afforded to them in terms of repairs exchanges and warranties? And I'm out of time, so I will pass it over to the next presenter. Thank you.

LUCILLE BECK: Good morning, can everyone here me? Great. I really want to start with a comment that you made, Dr. Balachandran, and that is that I want to talk a little bit about adults engaging in their own health care. I think that's really an area that we should be thinking about this morning.

I'm with the Department of Veterans Affairs and we have a large comprehensive health care program. I'm going to make a couple of comments about that, but I would direct you to various websites from the National Academy of Sciences and other reports that really describe our health care system.

But I want to put this discussion today in the context of patient-centered care, which we're all talking about a lot, and also talk about the innovation in health care where we're moving to patient-driven health care. I think that's a key issue as we think about adults engaging in their own health care.

Veterans, as you know, served in the military, and hearing loss and hearing—let's start with hearing. Critical function for military service. If you can't hear you can't communicate, you can't be on the battlefield, you're likely to lose your life, you can't tell where sounds are coming from. Think about if you're on a Navy carrier. It doesn't matter where you are. You are in a chaotic, noisy environment and you are required to communicate.

So hearing is a very critical function. I would submit that it's a critical function for your entire life, and as part of health care. Veterans, who served in the military, were exposed to lots of hearing conservation. They had their hearing tested every year, they know audiologists, they know the critical importance of hearing, and they expect, when they come to VA, to have hearing related services.

We have a long history of providing a comprehensive hearing health care system. And I want to emphasize that system—it starts with prevention, it includes awareness, it includes evaluation, it includes in-treatment, rehab, follow up, and most importantly, integration with the rest of the health care services and their providers.

The system is very mature. It's been around since World War II. Many of you may have seen in your audiology history books people like Raymond Carhart, Ira Hersh, and on and on, who participated in the development. So audiology is a long term service.

I was asked today to talk particularly about two things. Hearing loss is of course an occupational injury, it occurs whenever you're working around noise. We're particularly devoted to veterans, but I think what you heard this morning from the CDC, I'm very pleased to see that we're getting some really good epidemiological information, because with that noise-induced hearing loss, that loss in the high frequencies—very critical to communication, huge issue for veterans, and one that we're addressing.

I was asked to talk a little bit about access, quality, and telehealth. And so, in 2010, VA, as part of an overall initiative in the Department of Veterans Affairs to really develop a telehealth channel to improve access to get care to our rural veterans, allowed us to engage on a journey which is now in the evolving stages but maturing.

So I wanted you to know that some of the questions I heard in earlier panels—use of smartphones, we are now, and many of the companies here today, have great technology, which allows a user to adjust the settings of the hearing aid in their own environment. One of the most popular high technology pieces. Jani, I think, commented on VA using so much high technology, and we do. That's one of the reasons. Another is connectivity to your personal phone. So that connectivity, that wireless connectivity, is

critical. We're very focused on people being in the workplace. But as we have, and I'll talk with you more about automation of tests, which we are doing, remote programming of features, and working with our partners in the industry to develop capabilities that not only allow us to deliver services in our remote clinics, but allow us to deliver services in our patients' and our veterans' homes. Thank you.

KIM CAVITT: Hello. I'm Kim Cavitt and I want to thank the FTC for inviting me to participate today. My part is on bundling and unbundling, so I'm going to give a brief tutorial today on the bundled hearing aid delivery. And this is really based on a traditional hearing aid delivery, not an over-the-counter delivery, a provider driven delivery.

Why was bundled hearing aid pricing? This pricing has always really existed in the hearing health care space. Prior to 1977, audiologists couldn't legally dispense hearing aids. And so, in that world, audiology was unbundled. We were charged separately for the evaluation and for the treatment after the fitting, and in the middle, the hearing aid dispenser charged for the actual procurement of the device. When audiology entered the marketplace we just took up that bundled mantra at the time.

So really, this is what all is included when someone buys that single line item, single HCPC code, bundled price. It's from the evaluation, really, through long term care, is all in that bundled model. Earmold impressions, electroacoustic verification, pre and post fitting evaluation, accessories, manufacturer warranties, and then long term follow up is really all included in that bundled price. So we've done a poor job: we're representing to the consumer only the product. But they don't get to see really what is behind that product when it's delivered.

There are pros and cons of unbundling. So here are the pros of unbundling for the consumer. The pricing model is very easy for the consumer to understand. The consumer gets an unlimited amount of services for a finite period of time. The consumer typically doesn't have to pay up front for a hearing test if you're in a dispenser's office,

or for a hearing aid evaluation or consultation, if you're in a dispenser or an audiologist office, even if they don't opt to pursue amplification.

So they get evaluated and told what their recommendations are, and they have had no out-of-pocket costs typically at this point. As the consumer pays at the fitting, the cost of the evaluation, the fitting, the orientation, the treatment, long-term follow up, there is a continuity of care without worrying whether or not the patient or consumer would still be willing to pay for long term or additional costs. The lower the cost of trying amplification, as the restocking fees when someone returns for credit, typically actually don't reflect the cost of the time that was lost to the provider. Because of state laws, like California, all the money has to be returned. So it does really lower the cost of trial.

But with that come cons, and I like to call them rights and responsibilities. The cons of the bundle model is the greater upfront costs to the consumer. The consumer is actually paying for care they may or may not use. Another part of my work, I do a lot of insurance work, and this is why insurances, they don't pay for three years of something that may or may not happen. So again, this is what's happening to the consumer. They're paying upfront for a long term care that they might not use. Also, the lack of portability of that service. You are prepaying a provider to provide you care. So that means if you want care at no cost you are now stuck with that provider, because another provider is generally going to charge you for additional service, unless they're in some franchise arrangement where they share patients across.

And again, if the device were proprietarily locked, that means every provider can't adjust a proprietarily locked device, then you're not only locked with that provider, you're locked with that class of providers. You can't take that hearing aid to just any provider. Lack of price transparency, they don't know the difference between the price of the device and the price the evaluation. The lack of control of the costs—the consumers are forced into paying upfront for long term care they may not want or need. It's inconsistent with how insurance covers things. Insurance doesn't cover something that may or may not happen. The consumer who purchases amplification is ultimately

paying for the people who don't purchase because the evaluation was at no charge. And it's not financially feasible for providers to opt to accept insurance in a bundle model because of the way that it works.

I'm going to go real quick. There's really no data on unbundling. It's very subjective because people are very reluctant to talk about price because of anti-competitive behavior. But again, the data is about 20% to 40% of practices are unbundled. If you want to see, you'll see the next slide of what an unbundle can look like in a clinic. So again, provider driven. Thank you.

SCOTT DAVIS: Dan, David, thank you for having me today. I'm lucky to get to go after Kim today. I wanted to spend a little time and put some numbers maybe on the table, and a little bit of data as well. And I would say most of this is publicly available information from financial analyst reports, from annual reports for many of the publicly traded companies within the industry, as well as internal estimates that we've made and research that we've done within our company. And so there are three exhibits that I wanted to speak to today.

The first is around the value chain within our industry. The value chain was created by Michael Porter in the 1980s, and basically what it does is it takes the price that a consumer pays for a good and breaks it down into all the individual components that go into making that. In our industry, about a third of the cost goes to the hearing instrument—in actually manufacturing and servicing the hearing instruments. And about two-thirds of those costs are actually part of the dispensing and care associated with it. And so what consumers are really paying for, and what they really value, and what was shared so much in the last session, is the importance of the professional within the process. But to Kim's point, it's not always transparent to the consumer what they're actually being given, and the portability of those services that are associated with it as well.

One thing I do want to note within this, we conducted a study with the American Opinion Research Institute to look at what the margins were for an independent mom

and pop operation, and that's where this 30% comes into play. I would say that's often some questions on the retained earnings or owner margin associated with it because different things can be included within that. But if you take a look at the largest publicly traded retailer in the world, Amplefone, last year reported 17% earnings from an EBITDA perspective. So that gives you some perspective on the range that could be within that area as well.

But generally, about two-thirds is within the dispensing and care segment and about a third is related to the hearing instruments. And one of the things that's interesting within the hearing instruments side is over $125 to $150 goes to the warranty associated with those for three years of care.

The second thing I wanted to share today is what the distribution system looks like here in the US. This data goes back to our fiscal year '15. In the US we sold about three and a half million hearing aids and there are about 15,000 points of sales within the US. Now, that number is often debated—is it 12,000 or is it 20,000? I think no one really knows. But I think it's good to put some point of reference on the table so that we can start to see where hearing aids are actually sold today within the marketplace. About 20% of the hearing aids actually go through the VA, so we're lucky to have Lucille here with us today on the VA. But as you start looking into the commercial side of the marketplace, there are really four major channels. The first of those are independent private practice and medical office. The second is manufacturer-owned, financed, and affiliated organizations. The third are national retailers. So these are people that either specialize in hearing and have broad based coverage across the US, or other national retailers such as Costco and Sam's Club. And then the last and new channel that's actually growing quite a bit is what we classify as virtual retailers, and this is our online sales, mail order, and then managed care that's starting to emerge more and more within the industry.

You'll see that of that 80% of where hearing aids are actually sold, on the commercial side about 25% are going through independent private practice. Some of those are local mom and pop shops, some of those are within ENTs, others are within

medical offices. On the manufacturer side, there are basically three different models that exist within this category, and the first is actually what is owned, the second is what is financed, and the third is what's affiliated. Within that, about 50% is actually owned, so 16%, 17% of the marketplace is actually owned by manufacturers, 9% is approximated to be financed, and 9% are actually independents who are affiliated with organizations that are associated with a manufacturer. On the national retailers, this is one of the largest growing segments currently, about 15% of the marketplace is there. And then under virtual, which is a new emerging segment in many ways, it's a little less than 10% as of 2015.

Before I wrap up, I just wanted to comment on satisfaction levels both here in the US and in Europe, and adoption rates. We are very close in the US from a satisfaction level, even a little higher in Europe, where many times hearing aids are actually for free. And our adoption rates are also pretty close. But in Japan, which is a completely over-the-counter hearing aid marketplace, it's about half of that. So I think our purpose really today is thinking about as we move to an OTC market, how can we do that in a way where we actually can maintain the current satisfaction levels and actually drive our adoption rates?

GARY SWEARINGEN: This only has one button on it, so I'm in good shape. I'm going to tell you a little bit about Costco, for those who may not be familiar with us, or haven't been into a location for a while. We're the second largest retailer in the world. We've actually been selling hearing aids since 1989. In 2005, we made a business decision to grow the hearing aid business. So now we're in 482 warehouses in the United States. We also have a worldwide presence. Our hearing aid centers look a little different than they used to. New warehouses are three, we call them lanes, there are three soundproof booths equipped with the latest technology.

We knew that in order to grow and be successful we'd have to dramatically increase our products and services. Costco's model on all products is to sell the highest quality product for the lowest possible price, and that's a tough balance sometimes.

So here's our pride and joy in the hearing aid world, our Kirkland Signature series hearing aid. This is the evolution from 2007 to the present. You'll see the price is actually going down, and the quality and features are dramatically increasing. Our KS7 that we launched last year is a top tier premium quality hearing aid at a pretty extraordinary price. It comes bundled with all services, so we are a bundled model. It doesn't come with a custom mold if you need that. For 20 bucks more, you can throw in a year supply of batteries with that. It comes with a 180 day no-risk guarantee. That's in addition to the three year manufacturer's warranty. We sell a lot of them, business is booming, and it's really only constrained by our need to have more licensed professionals. Thank you.

DANIEL GILMAN: Thanks very much to all of you. We'd like to ask some follow up questions to get the discussion running and maybe start with Scott Davis, who had some interesting slides on the supply chain relationship and integration along the supply chain—what we in competition policy might think of as vertical relationships, vertical running from manufacturer, distributer, retail, and so forth. You had some slides on what seemed like a significant degree of integration. Manufacturer-owned practice, financed practices, and then independent, but affiliated, practices.

I guess the first question would be, where the trend is going. It's a powerful snapshot, but what kind of trend do we see? And then, I think the follow up to that was—good manufacturer reasons for pursuing one model or maybe for several models—what are both some of the benefits to consumers from this model, and then maybe, also, some of the costs, risks, or drawbacks for consumers?

SCOTT DAVIS: I think the trend is TBD at the moment. I think when you look at where the different manufacturers are actually competing within that space, or within all the channels, there are several different strategies that are underplaying. So you see some manufacturers that are actually exiting retail so they had made acquisitions and tried to run the retail side of the business, decided that was very difficult, to actually now selling parts of that. You see other people that think that that's part of their corporate strategy and are actually growing the retail side of the business, and you see

other people that have clearly stated they will not be within the retail space and are looking at other avenues in order to distribute.

So I think there are a lot of competitive dynamics that are actually happening across all the distribution chains and different manufacturers are doing different things across all of those. I don't know if the trend is going to be that it's going to continue at this point, or whether … you're going to see manufacturers that may even exit from being on the retail side. I know personally, within the company you know that I work for, we had a small retail footprint, and we actually sold quite a bit of that over the last few years as well. So I think it's a little bit of TBD at the moment for what the trend is, but what's actually owned is less than 20% of where hearing aids are distributed in the US at the moment.

I think some of the benefits on the two other sides where manufacturers are actually working. On the financing that actually is mostly for audiologists or hearing care dispensers to start up in their own practice. So often that's financing to help them start their own business. I think that it's also very useful for people that want to update, buy new equipment, be able to offer new services. Often they may be looking to expand within a certain geography as well. And then, I think from an affiliation standpoint, it provides scale to many mom and pops to be able to have national advertising or to have a really great web presence to be associated with. It enables consumers to be able to, if someone's a snowbird and they're in New York in the summer, they're able to go to Florida in the winter and be able to have service in both of those locations, rather than just being with someone that's local as a result.

I think there are also several other benefits that are associated as you look that you get a lot of expertise associated with it. I also think it helps manufacturers getting closer to the consumer so they can actually start to learn more about what's really important for the consumer in order that products can be developed along those lines.

On the risk front, I think it's pretty obvious the risk is always, oh, if it all goes to consolidation and everything is just the only product that's actually being sold, then that

of course is a risk. What I have seen in what's manufacturer-owned is that the providers still buy products from all the other manufacturers to fit what is best for the patient and what the patient actually wants. So I would say all the manufacturers sell to the retail chain of other manufacturers, and vice versa, because it's really about what's best for the patient there.

DANIEL GILMAN: This is a holdover question from the last panel, but it had come from the audience. There is this interest in other manufacturers' products, but also wonder, people, if you have thoughts about the impact of integration on the interest in, or ability of, a retail vendor, who is also a practitioner—I guess, first of all, to recommend another product that they're familiar with, but also another category of product. In other words, as we see development of whatever an OTC category might look like, as we see development of consumer tech, of hearables, of PSAPs, what's the impact on the development of that space, and in turn, what's the implication of that space for this kind of integrated model?

SCOTT DAVIS: I think there are a couple of things from my perspective on that. One is, most of the retail entities are managed separately from the wholesale side of the business. And so, I think, if it's what consumers are actually wanting, then that's what the retail organizations are actually going to supply.

I think the second thing is one of the things mentioned in the last panel is that many manufacturers are actually working with curable companies, so it's looking much broader at providing holistic hearing health care within the retail settings as well. Many retail organizations also offer hearing protection, for example. So one of the things that we were talking about with occupational that Lucille mentioned. We have many devices that we manufacture that go for musicians, that go for people that are working in industrial environments, to ensure that their hearing is actually being protected. So I see something very similar that if hearables come into that space, then it will be something that if that's what the consumer was looking for, then the consumer would actually be able to get there.

KIM CAVITT: And again, one of the issues, I'm going to speak from a provider's perspective, an independent provider's perspective, that there's been a lot of misinformation in the marketplace about the legalities related to an independent provider dispensing a hearable, or a PSAP, or an over-the-counter product to someone who was hearing impaired. And so I think we would really need to make sure to have all the regulatory language be very clear about that fact because while I've heard Eric Mann, Dr. Killion point blank asked Eric Mann at the second NASEM meeting, could an audiologist dispense a PSAP, and he said yes.

There was still a lot of misinformation being spread in the community that it was not legal for providers like myself to actually dispense these products to consumers even if they did want them.

RUPA BALACHANDRAN: I think one of the concerns would be if a provider provided hearing aids in the traditional model and was considering doing what potentially would be over-the-counter, that should be very well differentiated in the eyes of the consumer. Because in the over-the-counter model we're looking at taking away some of the costs of services. But if, in the minds of the consumer, they are here at this provider they picked up something in a box, but then they expect to keep coming back for the same traditional services that they're used to for a traditional hearing aid, that, then, creates a lot of difficulties for the provider. It's revenue negative for the provider, and it defeats the purpose. That has to that has to be in the equation.

KIM CAVITT: But that can really be solved with itemization. If we had price transparency and itemized unbundled practice—that every consumer was only paying for the care they need—that would really be a non-issue.

DAVID SCHMIDT: I just have one follow-up question, and this is actually going to Lucille, so maybe you can follow up with what you were going to say. But I had a question. We've heard a lot that a lot of dispensers and audiologists tend to focus on one, two, maybe three brands of hearing aids, and there can be good reasons for that. It can be they're getting volume discounts, and that allows them to provide those brands

at lower cost if they specialize, or it could be that they've got more familiarity with those brands and they're trying to prescribe the brands with which they're most familiar, or they've got good command of the software that's used for those brands.

I know the VA, or at least I've read the VA, has contracts with all six major manufacturers. I was just wondering what was the experience in the VA has been, whether VA audiologist, any individual audiologist, do they tend to specialize within just a couple of brands when they're dispensing? And if so, would that tell us anything about whether it's the specialization explanations for why we might see these patterns, or would it tell us something about contracting?

LUCILLE BECK: OK, I will try. So we have 1,200 audiologists in our system, and what we find is that we have clinics that some of them have 15 audiologists in them and some of them have one audiologist in them. I think my experience over the years has been that every one of our clinics uses more than one manufacturer. Most of them use three to four. I think those choices are made on a number of things—their patient needs, to begin with. Although we sometimes don't think of the differentiation in technologies and quality in technologies, the people who take care of, and provide services and get feedback from our veterans, have very legitimate clinical experiences which drive them to use certain technologies for certain kinds of losses and conditions. And that's part of the expertise that you bring to the table as an audiologist.

The second issue, I think the software, programming, ease of operation, and the user control features drive you in a certain condition. We see 20-year-olds up to 104-year-olds. So the variation and the need is there.

I think the third thing is training. I think every clinical health care provider in this country, from surgeons, to primary care docs, to audiologists, to therapists were trained with certain technologies and in certain ways. And you want that. You want to have someone who is highly trained and knows how to use that technology. I think really when we talk about professional services, what we're talking about is folks as

individuals, and clinicians who are well trained and have the intellectual property to match the technologies and use the technologies.

I do want to make a comment about the last questions though, because we are in the enviable or perhaps unenviable position of speculating quite a bit. We did it on the last panel and we're probably going to do it all day. Because we're looking at what has been in the past and we're trying to envision what is to be in the future. I think the to-be remains to be seen, but it depends on the innovation. I've heard that we're going to talk about systems which do everything in an automated fashion. We're going to talk about an over-the-counter product that you can touch. So I think it's pretty hard.

One of the things I will say, though, is that we are at the intersection right now of what we call in the technology smartphone hearable space, universal design versus technologies for people with disabilities. That's not only happening in our space, it's happening in visual impairment, it's happening in artificial limbs, where you're seeing computer control and things like that. So I think the opportunities are endless. But I think you've heard everyone here talk about where's the evidence? What's the evidence? And I think you're going to see a system like mine, which looks at the evidence, evaluate these technologies and look at the capability. I think the difference you're going to see, perhaps, at least from when I started in this field, that the consumer is a partner, the veteran is a partner, the patient is the partner. They are no longer someone who doesn't have a voice and a capability to be part of the process. Thank you.

RUPA BALACHANDRAN: For the question about why typically providers work with two or three manufacturers and not carry six or seven. From a very practical point, every manufacturer will have seven or eight products with different capabilities and different ranges, and they all have several parts and inventory. So from really an operational logistics point of view, and you want to support the patient with that product for a five to seven year period, and so it becomes a nightmare trying to keep up with six or seven. So you end up choosing a few.

SCOTT DAVIS: I wanted to support exactly what you were saying, Rupa, is that manufacturers have also chosen different strategies around technology so you will see some manufacturers that are very focused on connectivity and driving Bluetooth technology to connect with smartphones. You will find other manufacturers that are very focused on ear-to-ear communication, so that is the hearing aids actually communicating with each other. And you find other manufacturers that are very feature driven.

Depending on what your patient needs, this is what Lucille was saying, you will use each of those manufacturers. But you will specialize in one, and we see this in the VA, I see it in Costco. Every audiologist has one. I think it goes back to training and what you're comfortable on and I think that's actually a really good thing, because, if you think about your car at home, you want an expert on that vehicle to be able to work on it. You want to make sure you're getting the right earmolds, you want to make sure that you're trained on how to change the receiver, you want to make sure that, as you go in and do adjustments, you're doing it right. If it's automatic acclimatization, if it's data logging.

And there are so many differences between the hearing aids that you really need to be an expert in order to provide that care to your patients. So I think it's actually a good thing to have some of that expertise. But also to know other things that are available in case you have a patient that needs that.

DAVID SCHMIDT: OK, thank you. I think maybe we should move on to our next topic. Kim, you gave a nice presentation about bundling. I wanted to ask if you've had any experience, whether any audiologists or dispensers had tried to use unbundling as a marketing approach.

KIM CAVITT: Yes. I'm a consultant, so I deal with a lot of different audiologists, primarily, all over the country, and absolutely yes. Some as a marking approach against a third-party administrator who may have come into their area and taken over the insurance policy. And that third-party administrator is unbundled, and so they are now

creating a marketing approach to just go toe to toe with that administrator. Oftentimes, to be able to show that they're different in the marketplace. They call it their secret sauce, but absolutely.

I actually have a client in Colorado who asked people if they're a Costco member. If they are, in the recommendation in her plan of care, because she does a very complex communication needs assessment, if what she is recommending they could get less expensively at Costco, she presents that as an alternative.

So there are some people doing some very innovative things and going out and marketing that difference in innovation. Absolutely. Especially on the price standpoint.

SCOTT DAVIS: I think it's also interesting to look at other ways besides just the bundling and unbundling about price within the marketplace. I want to talk about Costco for a minute if it's OK with you. Because I think it's interesting how Costco has disintermediated the value chain and Costco has done some very interesting things. Gary had shown the price point. I think it was 1,799 for two, if I'm not mistaken. And earlier today, we saw in the presentation 4,700. I think that was actually for two, and not just one in the initial presentation. From our research we showed about 1,950 so how does Costco actually get that? I mean what has Costco actually done within the value chain?

DAVID SCHMIDT: That was for one or for two? You're 19?

SCOTT DAVIS: 50 was for one, and Costco's actually for two. So that's 850 per hearing aid. And so Costco, I think, has done some very interesting things. You think about it, it's a little bit about having a fixed asset, with all the equipment that's required to do audiology. And maybe it's not fair to compare it to the airlines, especially with what happened with United, but maybe it would be a great thing if we were pulling patients out of sound booths, and people trying to get in the sound booth.

But Costco has gone to a six day model everywhere. They're open the same hours that the warehouse is actually open. Costco receives all of its hearing aids on pallets, basically, and then handle the distribution of that. There's no marketing really

associated, because it's all of their members within. They've taken on doing all of their training to develop dispensers as well.

So there's a tremendous amount of cost that Costco has taken out of the system, and I would compare that a little bit to the VA as well, Lucille, because that's one of the things that I think you guys have done. We all have EDI transfer with you. The amount of order taking—everything else—it's all systematic now. And so I think as we start to look at this problem, it's not just a question, because I agree with you, Kim. I'm a big fan of unbundling and I think transparency is always good as long as we don't consume confuse the consumer. But I think there's a bigger topic as well about how can we take some cost out of the system and how can we drive more productivity within a lot of the independent practices, because I think by driving some of that productivity so that they're busier will actually help to reduce costs in the long run as well.

KIM CAVITT: The independent practitioner does not get to pay what the VA and Costco gets to pay for a hearing aid, and it is nothing at all anywhere near. I'll give my own practice, I ran a very large practice, one of the largest ENT practices in the country. We did about 250 aids a month, and I could not purchase a hearing aid under $300.

I would tell you, in price, what we pay for manufacturers is not based on volume. And I agree with Scott that can you take some of these things away from the cost that we independent practitioners pay? I have a client who tried and has been unsuccessful. That she said she did not want. She told manufacturers, I don't want your marketing, I don't want your training, I don't want any of this. I don't want your three year warranty, I don't want loss and damage. These are things I don't want. I want to pay for those in the private sector when my patient wants them, and she has been unsuccessful to date.

So, while I would love to pay what Dr. Beck and what Mr. Swearingen pay for a hearing aid, that is unrealistic in the private sector. We are not offered aids at that price, and as a result when we then dispense them to a patient, especially when you go bundled, I can't compete. I can't compete with him.

I would also disagree just a smidge with something Scott said earlier. We're not always two-thirds of the price, it depends on the product. Sometimes we might be 50% of the price—the service in a bundled model. Sometimes we might be two-thirds, but that's not always that we are the most expensive part. It depends on the product. Because what she pays 300 for, I pay three to four times for that same exact product.

SCOTT DAVIS: I'm just commenting really quickly. So those were averages, so I don't disagree with that. I presented the averages, not by product, number one. Number two is the average price that an independent pays is under $700 for a hearing instrument. And that's on average, and you can dig into some annual reports and you can sort of back into those numbers. Different than what the VA pays because the VA is also very much in bulk. And that's my point is about taking the cost out of the system.

This is not a hearing aid specific topic, it's across all independent mom and pop practices. Whether we're talking about pharmacy chains, whether we're talking about local stores, restaurants, anything, this is a challenge that actually faces that group because the cost to serve is actually higher. And because there's a higher cost to serve, there is a group of consumers that want that, but what they want is that high-touch service that comes along with it, and they're willing to pay the price point for that service that they're actually getting. And I think it's really important that on the independent practitioner's side that service really, really comes through on it.

KIM CAVITT: Having the space to care.

SCOTT DAVIS: Yes

LUCILLE BECK: So if I could just add something. This is an interesting discussion because we just had our national meeting several weeks ago, and one of the discussions that I was hearing a lot among the private practice community, which I am not part of and have never been part of, let me do that as a disclaimer to start with, but it was about unbundling the manufacturer's costs.

We talk a lot about unbundling the clinical costs and we've had a huge focus on that. But I think some of the things—and we may as well put it on the table—because

some of the things that you talked about, Scott, related to financing and services and various things are really great, but maybe there are costs to be negotiated or that could be on the table on both sides as we look at this.

We have a huge system now, as you know. I think I saw your numbers, thank you. We bought 706,000 hearing aids last year, but we work with our industry partners very closely. We don't make you collect from 400 sites of care. We don't make you get purchase orders from 400 different sites. We do everything electronically, we automate, and we work with our partners to say our return for credit rates are under 3%, et cetera. Those are a lot of things that we've worked on over the years.

Now, to be sure, veterans who get to us, who come into our clinics, they have hearing services, including technologies, whether it be a Baha cochlear implant, an assistive listening device, or a hearing aid with connectivity, is part of their rehab technologies for services. But as I said earlier, they are aware of their problem, they have usually had it for a while, and then, when they come to us, they are seeking assistance. They don't make appointments to come to us. So we have a different situation, if you will. And they have a longstanding understanding that it's part of their uniform benefits package, and many of them get their hearing evaluated every year. Even if they don't want any kind of an intervention they do have an awareness, and they do want to know.

DANIEL GILMAN: Can I just ask Kim a follow-up question? You raise an interesting point, and I don't know the exact details, but it was very plausible that an independent small practice audiologist will not be able to purchase a small number of devices at the same cost as a large retailer, a large multi-state retailer. And so we want to understand that. To shift to not just the audiologist's perspective but the consumer's perspective, we heard about advantages of integration, advantages of bundling, but with an audiologist being both a health care practitioner and a retailer, I want to ask about the disadvantages of this kind of integration. Is a small audiology practice an efficient retail outlet? Is it an efficient model? What are the implications of your

observation, if any? And maybe very different models are to thrive here, but what are the implications for the consumer and for the development of business models?

KIM CAVITT: So are you talking about the disadvantages of unbundling to the consumer or to the provider?

DANIEL GILMAN: If the cost differences are very different on the devices, I want to know if there are disadvantages to bundling—advantages to unbundling. In other words, are these small practices efficient retailers?

KIM CAVITT: Yes, they can be very efficient retailers. But they have a lot of different challenges that I don't believe that, well, corporate owned clinics actually have, if they're in insurance, have some of the same challenges. Insurance is a crazy ride that the only insurance that you ever really know what you're going to get paid from is Medicare and Medicaid, because they're the only ones that publish any information about what you're actually going to get paid. The rest of them keep it as some secret that they're never going to share with you. So insurances make things kind of difficult in their practice.

But what itemization does for a provider—and in a world where the consumer understands that nothing is free, that they have to let go, that the evaluations, and this, let's use the eyeglass rule model, that a prescription or a plan of care, which is what I would call that, carries a cost that either you or your insurer is paying for, that would add a more consistent revenue stream to a clinic that's not dependent on the sale of a product. You would then be back to where we started, was where we provided care. Where we were giving evaluation and care.

I think that can be very valuable to the consumer in the end and very valuable to the practitioner as well, because we would be valued for our expertise and paid for it when it's needed and not when it's not, and really be able to give a patient a plan of care that may or may not include a device. Or may include a disruptive, or different device. And there are models—there is an audiologist in this room that that's how she practices and is doing things very successfully.

So I think there is some great opportunities for everyone to be more open to a change. And also, what could be really good—and I agree with Dr. Beck wholeheartedly, and I think Scott was saying the same thing—if we could unbundle the cost of what we pay, as well, could be valuable.

LUCILLE BECK: So let me just add one thing here that I think everyone and you probably want to get on the agenda; and that is, we're talking a lot about professional services and the value of professional services. What we're implying is that there is not really much coverage for professional services, and when you do have coverage it's highly variable and it's around coverage for the product.

Unlike some other areas in health care, where you do get some reimbursement—and of course we know all of that is changing as well in health care—but this field, traditionally, has always been a private pay field for the most part. I think you're seeing some other players come into it, you're seeing some very different models in terms of, I want to cover the hearing aid, I want to cover the services, I want to cover both, and so, I think the NAS report talks a lot about professional services, the value of them and the efforts that need to be underway to talk about professional services being part of the coverage model. I think that's a factor that you can't ignore as you talk about this.

The other thing I would also say is to remember, FDA's role here is a regulatory role of the device. A hearing aid is not a prescriptive device, according to the Food and Drug Administration, and all of the consumer protections and licensing and other kinds of things are done at the state level.

Now, if you want to use the eyeglass analogy, you can. Obviously there are highly variable ways that that's covered, but the Food and Drug Administration says you can't get new eyeglasses and you can't get prescription eyeglasses or contact lenses unless you see an eye care professional, defined as an ophthalmologist or an optometrist, once a year.

We're talking about apples and oranges, and we need to remember that. You have a long history of—and we've talked about this—there are so many different ways to get into the system through so many different—and even, do you know if you have a hearing loss and what kind of a loss? Do you need to know? I've heard people say, well you don't really need to know. But you have so many factors here, which are affecting the delivery, and we're very focused on the hearing aid—that's very important, it's a very important technology—but there's a bigger issue here in terms of managing your hearing needs.

KIM CAVITT: It's about the evaluation. The road to an evaluation is a treacherous one. If you're Medicare age, you have to have an order. If you're Medicaid, and you're an adult, you may not have an evaluation covered. Or, if you are in an HMO, you have to go through primary care first. Some will only cover the evaluation, not routine. Not to see if you have something. We're not in welcome to Medicare, so there's no evaluation as part of that. Primary care just doesn't have the time to add this into their realm of things that they're dealing with.

I totally agree with Dr. Beck that the evaluation really starts someone on their journey, and then gives them the capacity and the knowledge to know where do I go next? Do I go to an over-the-counter offering, or do I need a provider driven delivery because of my needs, and my lifestyle, and everything about me? But the evaluation is not covered. And the treatment? Treatment in the Medicare system, if provided by an audiologist, is non-covered. Period. Always. End of story.

SCOTT DAVIS: I think one of the main things that we hear coming through is the professional has a role to play in this no matter what. Back to your question, how can an independent practitioner be successful within this marketplace? It's that expertise which is going to deliver that. It's about the service that's actually going to be able to be provided, that's actually going to deliver that. Whether that's on helping to navigate managed care, because it is a very cumbersome process today of are you covered? How much are you covered? What are you covered for? To help navigate through that field.

I think it's other ways that you can also be competitive, too. There are many successful independent practitioners, many of them are in the room today and online as well, who are actually providing that and are actually helping to drive really great patient care. But I think that as we talk through the different potential models that we really have to keep the professional in mind because we see it in the satisfaction levels across countries where the professional has an active role, not just in evaluation, but also on the counseling side of it.

KIM CAVITT: But I also think that the professional isn't always needed for every patient and every hearing loss. I think they're needed on the evaluation side, but then I think that the consumer should have the right to take their journey. Because how many people have we tested that ultimately have a hearing handicap, but not really? Because we have measures to measure hearing handicap, but not really a hearing loss that's a $3,000 problem, but rather a $300 problem, that then they could access on their own.

I think we're going to also encounter a different type of consumer as they start to age that just then doesn't want to start their journey on our terms, they want to start their journey on their own.

DANIEL GILMAN: Before shifting gears, I want to work in a question from the audience. We've heard about some different models of delivery, or at least some variations on some themes. Getting back to some issues from the National Academies' report and Acting Chairman Ohlhausen's opening remarks, we seem to have a huge unmet demand for hearing health care in the United States, and of course, as we saw in the first panel, worldwide. What progress are we making? Current models on the ground, maybe some nascent, as opposed to just sort of pie in the sky in terms of meeting some of that on demand? Obviously there are cost issues and budget constraints for different people. But what are we seeing to fill that gap?

RUPA BALACHANDRAN: It's started, and definitely some of the work done by Dr. Franklin really helped jump-start that conversation. They have a study looking at involving community. Helpers training community, helpers to get amplification into

senior residences, and allowing them to use pocket talkers to really reinforce the idea that good hearing is for everyone.

We're also seeing efforts, and we do this at our clinic, is to reach out to primary care clinics and equip them with pocket talkers so they can start using it with their adult patients. This is to start engaging patients, engaging physicians, in really talking about hearing, providing opportunities for the patient to access a low cost solution to help them hear better. It's at a very grassroots level and will continue in terms of bringing that patient education piece and using technologies that are now available.

Now more than ever you have several technologies. You have smartphones that will do captioning for you at the dining table. So to incorporate these technologies into patient education—the work has started and there are audiologists who are doing this with their patient base, with senior centers in their areas. So, though it's young, it needs a lot more support but it has started.

KIM CAVITT: When I actually saw a great talk at AAA from the University of Pittsburgh, where she is taking PSAPs into inpatient hospital scenarios to help give them access to amplification while they're in that care and care coordination process. It was a really interesting project. Some of the work of Stephanie Sjoblad from the University of North Carolina, you're seeing some great movements.

I'm seeing a lot of movement in unbundling, or itemization. I'm seeing a lot of large institutional academic medical centers. A very large institution is going unbundled on May 1st, so a lot more interest. And as we have these conversations and we read Dr. Lin's work and we read Dr. Humes's work—both very respected—you're starting to see people have interest in these disruptive products, and I'm seeing more and more people bringing the disruptive product into their practice, whether it is a PSAP or a hearing aid, and really starting to integrate those solutions in a way that I never saw before.

GARY SWEARINGEN: So I think from Costco's perspective, what we offer is we offer something to take a little bit of the stigma out of it. There are two large drivers for

not accessing care: One is cost; and two is the stigma factor, or whatever word you want to put on it.

But we offer a different environment. One that people see every day. Most of our hearing aid customers are members, so they don't come to Costco just for a hearing aid. But they come by, they see it, they see people waiting. They may be nudged by their spouse, hey, we're here anyway, why don't you sign up? So we definitely see that. It's not a mystery to people. If you want to know the price, it's in foot high letters right there.

We think we've been very successful in growing our business, and we believe that a large majority of that business was not taken from anybody else, it was taken from people who did not want to get a hearing aid or didn't think they needed one.

RUPA BALACHANDRAN: I think the next biggest area of impact will come in working with our primary care partners in educating them about options that are available. You know in my network I have primary care physicians who say, you want me to identify hearing loss and then tell the patient it's going to cost you $4,000. Rupa, how does that reconcile? So in order to educate them about newer options that are available, because still, 80% of patients, the first point of contact is primary care, and primary care physicians are engaged, do want to be involved in patient care, and as a profession we need to include them in the education so they can help us reach out to more consumers and patients.

LUCILLE BECK: So if I could, I'd like to make two comments. The first one is about innovations in hearing health care delivery, and I think you're going to hear this afternoon from Franklin, and also Nicole Moroni and the work that she's been doing, but I think it begs the question of what other providers can provide certain services, and what should they be? And if we want to move hearing as a health care issue out into the health care community, we have to start thinking about how we do that.

I think many of us have done initiatives around primary care and geriatrics and other issues for many, many years. I think that the response that you get is something

like what you just heard, and I think our geriatricians in the NAS report said to us, it's not on our radar screen no one ever asked me about it. That's a much bigger issue than trying to go talk to a particular provider.

So I think we need to turn the tables and start thinking, this is going to be driven by consumers. You just heard Costco say their consumers are driving this. This is a model they trust, so they're not confused, and this is a product that they trust because they know the other things that they buy from Costco. And you all sitting here—you probably know some product you buy from Costco that you think's absolutely the best.

So you've got a system that—and because our system is so confusing it's a buyer beware system, because you just don't know. And when you go to your physician, and all the statistics tell us you ask your physician what you should do, and the physician doesn't know what to do. That's a big, big outcome from this NAS study, and that's something that we've got to change the driver. So every time another service provider, whether it's a technical support person in a primary care clinic or somebody, talks about it.

And that's where I'll go back to my awareness thing. You don't get your hearing evaluated just because you're going to go get a product. You get your hearing evaluated because it's important—you can't work in some situations, you can't communicate, you're socially isolated. We all know the drill. And so, until there is an awareness that maybe there is a problem—I mean, I was really struck by the CDC report this morning, which is showing 61 million patients who have high frequency hearing loss who don't even know. And yet, we all know that that's why they're having trouble in noise et cetera, et cetera.

I think this whole hearing loss is the number one public health condition—is it one or three? The number one public—third in this country significant for people particularly over the age of 65. I think we need many, many ways to look at this, and I think innovations in who becomes our partner in the health care model is important.

The second point I want to make is about innovation and automation, because again, we are already using, in the VA, an automated hearing test. It gives you a threshold test with masking—pure tone thresholds, air and bone. It's entirely automated. The patient sits in front of the screen and pushes a button. We've tested that. We are now moving it out to test it in a number of more clinics, but we're adding store and forward capability so that when you get that test result you can send it to your audiologist, your primary care doc, your wife, your husband, whoever you want. And those are the innovations that are going to happen, or are already happening, which is going to change the model, I think.

SCOTT DAVIS: I wanted to add on. I mean one, primary care physician has been on the radar for many, many years I agree with you Lucille. It is a huge challenge because they have so many things to do in such a short time frame as well, and trying to figure out a way to get that on the agenda is going to be a challenge, I think, to do.

But just to add, I think the other spaces just tele-audiology—you mentioned it briefly, but at AAA last week, there were a couple of companies that announced being able to do remote fittings from the provider, and actually being able to monitor patients use of their hearing aid to make sure they're actually acclimating. If they're having any problems they can press a button, and send a message, and get a reply back from their audiologist. The audiologist can actually make some adjustments.

I heard a comment this morning that there wasn't a lot of innovation from the manufacturers. Many are doing this because there is a crystal on the chip that actually causes certain vibrations within ultra-high frequencies that allows for these adjustments to be made. This is some pretty cool stuff that manufacturers are actually able to do that is now, instead of requiring the patient to come back into the office, when they are having problems they can instantly send a message, and then the provider knows exactly what was happening, and can actually start to make some of those adjustments for them.

This is where the future is headed and if you think this is only on doing adjustments now, it's so much more that we're going to be able to do as we move forward, including possibly fittings and everything else. I know, Lucille, you guys are doing this in the VA today in more of a controlled environment, but you can start thinking about this in a home environment and everything else, which then goes to unbundling as well, Kim—to what you're actually going to use and want to use.

KIM CAVITT: Right and you need—but then the issue that we have, because it's such emerging technology is that the licensure and the reimbursement aspect of that is not keeping pace. Medicare doesn't really—I think they disbanded their telehealth work group because nobody could decide on anything. That's how behind on that reimbursement front.

Then, from a licensure standpoint, I come from a very fairly large, active state, and we're just adding telehealth in Illinois to licensure. So you have to make sure the licensure is in place to be able to allow for these changes in technology so they can exist. Because without licensure, you can't go the reimbursement route.

RUPA BALACHANDRAN: I think one of the things we have to think about is, moving forward with over-the-counter technology, whether we're going to be a medical model or we're going to be a consumer model. Right now, hearing aids are very much within the medical model. Hearing care is very much in the medical model. I understand frustrations in trying to educate vast numbers of primary care physicians. However, they're still the ones who write the referral for a hearing test to be covered by Medicare.

So there is definitely that group that we have to continue to work with in our traditional care for hearing health, but moving forward, looking at some of the other technologies that we can leverage, we would have to think about whether we move it into a more consumer space, something that is outside of the medical model. I think some of the discussions today are looking at the viability of where some of these stand and where that intersection might be.

DAVID SCHMIDT: Do you have any sense of—just since I've started researching this topic, I've noticed on my smartphone, when I go into the app store, there are a ton of hearing tests on there. There are some other apps that have hearing applications that I don't want to go into, but as a consumer I'm looking at it, and I don't know whether it's any good or not, and I haven't been to see an audiologist. Is there a role for anybody in the health care system to help guide consumers through and say, hey, there's a good app put out by so-and-so. Make sure you have your earbuds set up right. Or if you're in a primary care physician's office, can they be like, no and use these earphones here, we know these are good? Is there a role for somebody to play in helping consumers navigate some of this new technology?

KIM CAVITT: Yes, but I think it needs to be completely independent of what doesn't exist in our space is an independent. That most independent things of that nature you see from NICDC or from CDC. That's the most independent. Everything else a consumer has to always question, is there an ulterior motive of the people funding this space? And so, we're very much in need of a great unbiased consumer site that has nobody on the background. Nobody. No association, no industry that's back there. Because there are some great apps—some great test apps and some great hearing aid apps on your phone that are free.

RUPA BALACHANDRAN: I think HLAA has been working on evaluating some of these features and I think that is a great organization. To not put all the burden on the audiologists, because a kid with some knowledge in coding can come up with an app faster than audiologists can do evidence based testing on each of them. Consumer groups like HLAA do recommend apps from time to time, and I think they have a very valuable role in partnering with us to promoting hearing health care.

SCOTT DAVIS: I was going to say HLAA is one, I think Consumer Report also does many and is trusted by consumers and could do some things. I also think the FDA has played a role with iHear, in that they have now proven the first online hearing test that has calibration. This is the biggest thing, is making sure that there is proper calibration.

And so, I think the FDA still has a role to play within these as well. Otherwise it's a screener versus a test.

LUCILLE BECK: And FDA is in that space now with all medical devices, not just hearing aids that have apps that serve the same function, as the medical device in this case would be the audiometer.

KIM CAVITT: And I have an n of one with iHear at my next door neighbor, I have iHear at my home. She had an audio that I didn't look at. She did the iHear, it got in the exact same range as did an iPhone app that we compared to that was also excellent. And the calibration on iHear was crazy in that it was sampling the noise the whole time. And so when I did it, mine was shorter than hers because there was more noise in the background. It was really very interesting.

DANIEL GILMAN: Can I just ask a follow up question, maybe to Lu, and also Scott? You've mentioned all these things that the VA has done—telehealth, automation, integration. We also heard that some of these things are developing in the commercial space or private sector. You talk about studying the VA, testing things, developing things. To what extent do we see that information working its way into commercial development in the commercial space? Could it go better? And then, what impediments do we see to some of these things emerging in the commercial space?

LUCILLE BECK: The automated audiometer that I just mentioned is from a commercial company and I think it's already available in Europe, and it will be available here. So that's work. I think two of the applications that we're doing right now that Scott talked about for direct connectivity using a platform to modify hearing aids, we are doing as partners with industry in a commercial space through our innovation projects.

We have done remote programming now for a very long time, that's our most mature. Connectivity, all six of the manufacturers who work with us, their software is remotely programmable. They all know it, they all helped us get there. So I think that's another problem in technology.

I think the other area we're working in now is the diagnostic space and doing something where we're able to do some very good diagnostic evaluations outside of the sound room using a similar technology, where we developed a microphone which can do constant surveillance of the ambient noise conditions and present the testing.

So we are moving some of those innovations. For us in audiology, in the private sector, I think it's a big jump. How do you get that T3 line? How do you have an encrypted—how do you start? The benefit we have in the VA is that we have a platform and a system. You've got to have platforms and servers and all kinds of technologies. Stop. But if you look at your big health care providers, a lot of them are using telehealth. You can go on the subway here in Kaiser. You can go to Kaiser, and you can have video clinical telehealth.

We're not well represented in big systems. And so we don't have the benefit of—for us in the VA, we made a strategic decision to address access, and hearing is one of the high reliance areas that our veterans want. So we were willing to put the funding into the innovation, but I think the licensure issue—now that's an issue not only for us, that's an issue for all providers; and how that's going to be addressed is still an issue, but it's going to be addressed.

Because right now, if you're not in the same state—you have to be licensed in the state where the patient is. That's the issue. But for a lot of people, they don't cross state boundaries. You can do some things. But I think now, real time messaging is—we're already seeing that in the space.

So that's why I say we're speculating on so many things that we will be able to do in the future. Automating the testing, you can automate the probe mic measurer and send that measure. There are all kinds of things that you can do to automate the functions so that the user can sit in front of it.

Smartphones, we already talked about that. The user can adjust that smartphone. I think audiologist count on it now, because they let their users go out, use

it, and they want to know, what was your situational listening environment? Did you want to change your gain, your frequency, your whatever?

So I think that the partnership is critical. And again, I'll just end by saying, we're seeing that in all health care systems that you are—the consumer is driving. So when the consumer says to the primary care doc or their geriatrician that they want to know about their hearing, that's when the marketplace is going to change. Because I've lived through sending audiologist over to primary care, giving primary care tools, doing all kinds of things, and just because you fail a screening doesn't mean you want help. I think that's the fallacy here, that we're saying, oh, well we got to get everybody screened, if we can get everybody screened—a lot of people that have hearing loss already know it, right? Including some of us in this room. This has got to be consumer driven. The consumers are going to draw change.

DANIEL GILMAN: Thank you, Lu. I hate to cut this off. We've run just a little bit over time. I hope we'll be able to continue some of this conversation offline, and maybe the regulations panel can follow up on some of the licensure issues, but I really want to thank the panel for a terrific discussion.

Those of you who are not panelists, we are breaking for lunch now and I would ask that people try to return by 2:10, when we're going to start the next panel discussion. Those people who are panelists, if they could just stop by the front of the room that would be terrific. So, thanks very much for discussion and we'll see everyone after the break.

[LUNCH BREAK]

PRESENTATION: FDA REGULATION OF HEARING AIDS AND PERSONAL SOUND AMPLIFICATION PRODUCTS

- **Eric Mann, Clinical Deputy Director, Division of Ophthalmic & ENT Devices, Center for Devices & Radiological Health, Food & Drug Administration**

DAVID SCHMIDT: Thank you. I hope you all had a nice lunch. I notice nobody has a large coffee in their hand, so apparently you were paying attention this morning. Thank you all for being here for the afternoon session. We're going to start first with a presentation by Dr. Eric Mann, of the FDA. He's going to tell us about FDA regulation of hearing aids and PSAPs. So, Eric.

ERIC MANN: OK. Good afternoon everyone, it's really a pleasure to be here, and thanks to FTC for inviting me to the workshop. It's a little perilous talking about FDA regulations immediately after lunch, but hopefully we won't lose too many people here in the next few minutes. But I would like to present, in the next 20 minutes or so, an overview of our risk based regulatory approach for devices, and specifically how hearing aids fit into that whole risk based process.

There are some additional hearing aids specific regulations that I'll go over. One for labeling, and one for conditions for sale. And then I'll mention a few recent developments that have probably been mentioned already this morning, but the PCAST and NAS reports. We held a workshop last year on GMPs for hearing aids, and last December we had an Immediately In Effect Guidance, which I'll also talk about. I'll finish up with some future directions at FDA, with respect to hearing.

So when we talk about regulation of medical devices, we have to come up with a definition to put a box around what we're regulating, and what we have jurisdiction over, and what we don't. We do have a very clear, but fairly broad definition of what a medical device is, and it's in the Food, Drug, and Cosmetic Act. The definition is—it's any kind of product that's intended to diagnose, cure, mitigate, treat, or prevent a disease or condition, or intended to affect the structure or function of the body, and it does not achieve its intended use through chemical action or metabolism. As you can imagine, that third bullet is what kind of distinguishes a medical device from a drug or a biologic

product. But for all medical products, pretty much, the first bullet applies. They're intended to diagnose, cure, mitigate, treat, or prevent a disease or condition.

So we do also have a regulatory definition for a hearing aid. A hearing aid is any wearable instrument or device designed for, or offered for the purpose of compensating for impaired hearing essentially. OK. So I think you can tell, it's quite clear, that it is treating a medical condition or we consider it a medical condition, hearing loss. Hearing aids, obviously, are medical devices, they fall under our regulations, and that's in contrast to personal sound amplification products, or PSAPs.

We have no formal regulatory definition for PSAPs, but the working definition that we've used is that they are to amplify environmental sound for non-hearing impaired individuals. And that could be in a variety of situations, either hunting—many of you are probably familiar with the Game Ear. Listening to different sounds, like a remote speaker, that sort of thing. That could be a challenging thing for even a normally hearing person. So that's what we consider to be a PSAP, and as such, they are not treating a medical condition or illness, and they do not meet the definition of medical device. So they're not within our regulatory jurisdiction. That's really about all I'm going to say about PSAPs since, again, we don't regulate them.

In terms of regulation of medical devices, in general, in addition to hearing aids in the lower left there, we regulate a wide variety of devices from Band-Aids and tongue blades, all the way up to tanning beds and breast implants, and at the high-risk end of things, something like an artificial heart or implantable neural stimulators. I think you can see, quite easily, that it would not be appropriate to regulate the Band-Aid at the same level that you would regulate the artificial heart, right?

So the question is how do we approach regulation of this wide array of devices? The answer is, when the medical device amendments were created back in 1976, they created a tiered risk based classification in which the requirements for the device were gauged to the risks posed by the device. So in Class I we have low risk devices. These are ones that we feel that general regulatory controls, by themselves, are sufficient to

ensure safety and effectiveness. I'll talk a little bit more about what those general controls are. But I will also note that most of these Class I devices are actually exempt from any kind of pre-market application. So as long as the manufacturer complies with the general controls, they can go to market.

Class II devices are moderate risk devices, and in addition to the general controls that we see in Class I, they also have some special controls. This can range from anything from a performance standard, or addressing of points in an FDA guidance document, or even some sort of post-market surveillance requirements. So that's moderate risk.

And then at the high end, we have general controls and pre-market approval, which is a very in-depth application, including a lot of pre-market information, manufacturing information, and the centerpiece is typically a well-designed controlled clinical trial. So that's at the high end.

So I put this slide in just to show you that we have hearing-type or hearing-related devices in all three classes. Your basic air conduction hearing aid falls under Class I; we consider that a low risk device. Class II devices include a variety of bone conduction technologies, but we also have wireless air conduction hearing aids in Class II, although they are exempt. The way we created the classification regulation, you don't have to come in with pre-market application, as long as you follow those special controls. I will describe those in a moment. And then at the high end, of course, we have things like cochlear implants, implantable middle ear hearing devices, and auditory brainstem implants. So we have the whole spectrum. For the purposes of today's discussion, I think we're going to really be focusing on the air conduction hearing aid, Class I and the wireless air conduction hearing aid, Class II exempt. OK?

So diving deeper into the Class I hearing aid, basic hearing aid, air condition hearing aid—the manufacturers only have to comply with general controls prior to going to market. That includes things like prohibition of adulterated or misbranded devices, which essentially means that the labeling has to be truthful and accurate and

not false or misleading, and basically the device is what it says it is, it does what it what it says it does, that sort of thing. They have to comply with good manufacturing practices, according to regulations. The manufacturer has to register their facility with FDA, and list the types of devices that they're manufacturing. There are certain record-keeping requirements, as well as repair, replacement, refund provisions.

Originally, Class I devices did have to come in with the pre-market application, but over the years we have really scaled that back to the point where it's only a very small handful of Class I devices require a pre-market application, and the rest are exempt from that requirement.

OK, so the second category that we wanted to talk about was the wireless air conduction hearing aid, and there was a lot of discussion about this kind of technology this morning. Anything that includes like a Bluetooth function or the hearing aids talking to each other across the head; that would be considered a wireless air conduction hearing aid.

So in addition to the general controls that I just mentioned, there are some special controls that apply to the wireless air conduction hearing aid. Specifically, there has to be testing to validate the electromagnetic compatibility and the safety of exposure to non-ionizing radiation. There has to be performance data validating the wireless technology functions, and then there has to be some labeling that goes along with all of those wireless functions as well. And as I mentioned before, when we crafted this regulation a couple of years ago, we exempted it from pre-market notification, or pre-market application. So as long as these special controls are complied with, the company can go straight to market with it.

I just want to emphasize that when you look at the regulations, and you look at what we've cleared, most air conduction hearing aids are technically not prescription devices. But they are restricted by two regulations, one with respect to device labeling, and the other with respect to conditions for sale. So we'll talk about these two specific regulations, that are on top of the regulations we just talked about that are gauged to

the class. OK, so there are the classification regulation requirements, and then there are these two additional regulations.

The first one is the patient and professional labeling regulation. It primarily describes what needs to be in a so-called user instructional brochure. This, of course, would include things like instructions for use, how to put the battery in, how to get it serviced, expectations from the device that it's not going to restore normal hearing. There has to be a section called "Warning to Hearing Aid Dispensers," in which red flag signs and symptoms are put out to the hearing aid dispensers, and if they see these, they should refer that patient to a licensed physician, preferably an ENT specialist.

There is an important notice for a prospective hearing aid users, and this basically emphasizes the importance of the medical evaluation, in terms of the overall best health practices for treating hearing loss. And finally, there is a technical data performance section. This was mentioned this morning as well. It doesn't require a level of performance, but it just requires that the results of certain tests be published in the brochure, so that the hearing aid dispenser can work with that information and give the patient the best possible fit.

OK, so the second regulation is the conditions for sale regulation, and this one basically requires a medical evaluation by a licensed physician within the six months prior to dispensing. There is a provision for a waiver of the evaluation in adults, which we're considering for this purpose as 18 years and older. There are requirements surrounding that waiver, regarding signing a statement that they know that it's not in their best health interest. The dispenser cannot actively encourage the waiver, and they need to provide the consumer with an opportunity to review the instructional brochure. There are also some record-keeping requirements.

This, by far, has been the more controversial of the two additional regulations. The labeling regulation has not been terribly controversial, but this one has gone the gamut from in the late '90s, the Commissioner wanted to actually eliminate the waiver provision, so that everybody would get a medical evaluation. That did not come into

effect, but in 2003, we had several citizen petitions. We, since that time, have had additional ones seeking to either eliminate or decrease the scope of this regulation. So just to emphasize the rationale behind the original requirement for the medical evaluation, when you look at the preamble to the regulation back in 1977, it was that the Commissioner emphasizes that the evaluation is based on the fact that an unnecessary or partially effective hearing aid would be substituted for primary medical or surgical treatment; so basically, a delay in diagnosis of treatable condition. That was the major concern that led to that development of that regulation.

Most recently, we've had more scrutiny of this conditions for sale regulation. In October of 2015, the PCAST, or the President's Council of Advisors on Science and Technology, published a report and had some very specific recommendations for FDA. Number one, that we create a new class of hearing aids for over-the-counter sale for mild to moderate age-related hearing loss. That we exempt this class of hearing aids from the Quality Systems Regulation, so regulation in its present form, and substitute it with standards that are more appropriate for the consumer electronics industry. The hope there would be that you'd drive down costs and promote innovation by doing that. And they also recommended that we rescind the 2013 hearing aid PSAP guidance and allow PSAPs to make claims about their technological capabilities.

So following the publication of that report, we did follow up on the second item that I just discussed there. We held a public workshop on streamlining good manufacturing practices for hearing aids. This was in April of last year, and we received a lot of good comments and recommendations on the pros and cons of GMPs versus other performance standards. We got a lot of feedback on the FDA regulations, and whether or not they were creating a barrier to access to individuals. We got a lot of really good comments from the consumer perspective, as well as viewpoints on whether or not people can self-diagnose and treat mild to moderate hearing loss.

So in June of last year, following the workshop, the National Academy of Sciences published their study on priorities for improving access and affordability of hearing health care. FDA was a co-sponsor of that study, and we were very pleased with

the in-depth review by the very distinguished panel, and all the effort that went into that. They included also some very specific recommendations for FDA. Number one, that we remove the medical evaluation and waiver requirement, because they felt that it really was not adding any appreciable clinical benefit. They thought it could be really handled in the user instructional brochure, outlining things in a written form, rather than requiring the medical evaluation. They also, like the PCAST report, recommended establishment of a new category of OTC hearing devices that could assist adults with mild to moderate hearing loss. They also felt it was very important that we retain some sort of guidance document that would clarify the distinction between hearing aids and PSAPs. So that certainly has been an area that we have focused on in recent months.

We did, in December of last year, issue the guidance document on December 10th, which basically indicated that we will not be enforcing the medical evaluation and waiver requirements for individuals 18 years and older. That, of course, was based on the NAS report, on the PCAST recommendations, on the feedback that we got from our public workshop. So based on all of that information and input, we decided that we would not enforce it. We are in the process of considering how we're going to modify the regulations to actually make that formally changed in the regulations. However, for now at least, the labeling regulation is still being enforced.

I think this morning it was mentioned that Senators Warren and Grassley introduced the Over-the-Counter Hearing Aid Act of 2017. This would allow hearing aids to be used by adults to compensate for moderate hearing loss, and be sold over counter without the requirement for a credentialed dispenser.

OK, so in terms of future directions. We are continuing, based on the PCAST and the NAS recommendations, to consider creating a category of OTC hearing aids that could deliver new, innovative, low cost products to consumers without the requirement for a credentialed dispenser. We have been having a lot of internal meetings. We're continuing our co-sponsorship of the ongoing activities regarding the NAS study. I want to point out that there is an open public meeting on June 9th, and during that meeting, we will be soliciting input from all stakeholders on the NAS recommendations, including

those related to OTC hearing aids. And finally, as recommended by the NAS report, we are actively looking at the guidance document regarding the regulatory requirements for hearing aids versus PSAPs, and we hopefully will be issuing a revision to that in the future. That pretty much summarizes what I wanted to say about hearing aid regulation. I put my contact information, in case there are any questions related to the presentation. Thank you.

[APPLAUSE]

PANEL 3: THE COSTS AND BENEFITS OF HEARING HEALTH CARE REGULATIONS

Panelists:

- **Bill Belt, Senior Director, Technology & Standards, Consumer Technology Association**
- **Richard L. Cleland, Assistant Director, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission**
- **Rick Giles, President, International Hearing Society**
- **Frank Lin, Associate Professor of Otolaryngology, Geriatric Medicine, Mental Health and Epidemiology, Johns Hopkins University**
- **Ian Windmill, Clinical Director, Division of Audiology, Cincinnati Children's Hospital Medical Center, and President, American Academy of Audiology**

Moderators:

- **Ellen Connelly, Office of Policy Planning, Federal Trade Commission**
- **David Schmidt, Bureau of Economics, Federal Trade Commission**

ELLEN CONNELLY: The regulation panelists could come forward.

Good afternoon, everyone. I am Ellen Connelly, an attorney advisor in the Office of Policy Planning here at the FTC. My co-moderator today is David Schmidt, an assistant director in the FTC Bureau of Economics. We want to welcome you to our panel, which is entitled "The Costs and Benefits of Hearing Health Care Regulations." On this panel, we will explore how federal and state regulations affect the hearing industry. For instance, how might a modification of regulations, to create an over-the-counter category of hearing aids, affect the hearing marketplace? What role does state regulation play in hearing care? And is there a role for voluntary industry standards? We have an impressive panel here today to discuss these and other issues relating to the benefits and costs of regulations in the hearing health care space.

First, we have Bill Belt. Bill Belt is the senior director of technology and standards for the Consumer Technology Association. He can share with us the lessons learned from CTA's study of consumer attitudes towards PSAPs, in addition to discussing ANSI and CTA's standard for personal sound amplification products, which was released in January.

Then we have Richard Cleland, who serves as an assistant director of the FTC's division of advertising practices and has expertise in the advertising and marketing of health-related products. He will help us understand the regulations governing advertising of hearing care products.

Then we have Rick Giles. He is with us from the International Hearing Society. Mr. Giles serves as that organization's president, and also has on-the-ground experience, having worked as a hearing aid dispenser for over 35 years. He has extensive experience in policy developments, and we look forward to hearing his views on a variety of regulatory issues relating to hearing care.

We have Frank Lin next down the line, who is an associate professor of otolaryngology, geriatric medicine, mental health, and epidemiology at Johns Hopkins University. Dr. Lin has focused his research on studying questions at the interface of hearing loss, gerontology, and public health. He will help us understand how current regulations have shaped the model of care, as well as barriers to access.

And last, but definitely not least, we have Ian Windmill. Dr. Windmill currently serves as president of the American Academy of Audiology, and is also clinical director of audiology at Cincinnati Children's Hospital Medical Center. And he is an adjunct professor in the Department of Otolaryngology at the University of Cincinnati. He has extensive experience in the audiology field and will bring that perspective to our discussion. More detailed bios for all of our panelists can be found in today's materials.

I have a few procedural points before we get started with the discussion. We will run this panel a little differently. It will be a structured question and answer session, so we won't have any presentations. We'll direct each question to a particular panelist to start us off, and then we'll move to responses from other panelists. If a panelist has something to contribute regarding a particular question, please just turn your name card on its side to signal to us that you'd like to speak. We may limit discussion around some questions to ensure that we're able to move through the topics. And finally, we will be taking questions from the audience, as we have with the other panels. So if

anyone in the audience has a question, please just flag down one of the conference staff, and they will give you a comment card and collect those for us. Thank you very much.

DAVID SCHMIDT: So we wanted to start off this discussion of regulation by considering advertising. We heard this morning that one of the key differences between PSAPs and hearing aids was in how the companies were allowed to market the different devices. Certainly there can be other technological differences, but the marketing seems to be a very key difference. So since we are at the FTC, we thought we would start by asking Richard Cleland to talk to us a little bit about the FTC's regulations of health claims in medical devices. And so Richard?

RICHARD CLELAND: Well, thank you. It's a pleasure to be here. Good afternoon. Hearing aids are devices that are covered under the 1971 MOU with the FDA. Under that MOU, FDA has primary jurisdiction over the labeling of hearing aid devices. The FTC has primary jurisdiction over the advertising of those devices. So that's sort of the line between the FDA and the FTC on that.

Now it's very important—you just heard discussion about what FDA approves or doesn't approve in terms of hearing aids—it's extremely important to us that it's very clear what FDA has approved and in what form it has approved it for FTC advertising regulation, because while we have primary jurisdiction over the advertising, on some issues we're going to defer to FDA where they have already approved a product. So that provides—that's a critical link between FDA and FTC regulation.

With regard to PSAPs, I'm not sure—I mean since they are not medical devices—what kind of jurisdiction FDA currently has over the labeling of PSAPs. I think that that's probably an area where the FTC has primary jurisdiction over both the advertising and the labeling of those devices. Now I'm glad you set this up the way you did, in the context of, well there's a difference between the marketing of hearing aids and the marketing of PSAPs. That's not true for advertising. Ultimately, the advertising rules that apply to these, either PSAPs or hearing devices, are that objective performance claims

for hearing aids and PSAPs must be truthful and substantiated. There must be a reasonable basis for the claims that are made in the marketing of those products. Now, what constitutes substantiation or a reasonable basis for claims made for PSAPs or hearing aids? It's going to depend on what the claim is. In some cases, it might be competent reliable scientific evidence. For example, if the claim says "allows wearers to distinguish and understand speech sounds in noisy or group situations," that's the kind of claim that normally would require competent reliable scientific evidence to substantiate.

But other types of claims we've seen over the years, such as “the hearing aids are invisible,” or that they're a new invention that involves new models, features, or new mechanical engineering, or scientific concepts. there can be a reasonable basis for those that's other than a competent, reliable scientific basis. So in terms of determining where competent, reliable scientific evidence is required for a claim, how are we going to make that determination of what's required in that situation? And the primary factor that we would look to in that case is what experts in the field would generally require to substantiate that the claim is true.

Now in terms of actual enforcement actions, we've been sort of sporadic over the years. There were some cases brought in the 1950s. A few more in the 1970s. The last case that the FTC brought in this area was brought in 1996. The types of claims that we've challenged over the years, in addition to the ones I've already mentioned, are: superiority claims, claims that a product is beneficial to persons with hearing loss regardless of the type or extent of loss, helps persons to hear but don't understand, restores natural hearing to wearers and will able wearers use such devices to hear naturally, allows users to hear whispers as far as 100 feet away—that'd be useful—and allows users to hear a pin drop from 50 feet away. So we have a full gamut of types of claims that we've challenged over the years. Thank you.

ELLEN CONNELLY: Anyone else on this topic? OK we will move on to the next topic, which has to do with industry standards. And we'll start off with Bill for this one.

FRANK LIN: Can I clarify one question? Sorry.

ELLEN CONNELLY: Sure, of course

FRANK LIN: Richard, you mentioned before, I think you said from the FTC perspective of advertising for a PSAP versus a hearing aid, it doesn't really matter, per se. It's considered the same way?

RICHARD CLELAND: Yeah, exactly. It doesn't matter what's going to drive the level of substantiation that's required. It's what the claim is.

FRANK LIN: So I guess one issue that was raised this morning, was the issue of—from the FDA perspective of labeling, per se. So if it's—someone brought the comment that it could be the same device, but if you say it treats hearing loss, it's going to be classified as a medical device, a hearing aid, versus you say, same device, you don't say it's treating hearing loss, it's classified as a PSAP technically. So are you saying then, for example, let's say you had a PSAP device which was scientifically, in a study, proven to help hearing a noise, that you could then claim in advertisement that this PSAP, it improves hearing a noise based on such a study? Because it seems like that'll be crossing a line, so then that's actually a medical device.

RICHARD CLELAND: We run into—actually, by analogy, I'm going to turn to the regulation of dietary supplements. Dietary supplements are prohibited from making disease-related claims under the Food, Drug, and Cosmetic Act, but they're not prohibited to making those claims in advertising. The advertising requirement is that those claims be substantiated by whatever the appropriate level of substantiation is. Where there is some interplay is the hearing aids are usually going to have some type of FDA clearance, or some type of FDA approval. So when we're evaluating the claims and advertising that are made for hearing aids, we would look to FDA to see what FDA has approved, and FDA's view on the advertising claims that were being made.

RICK GILES: Yeah, right. So let me follow up on Dr. Lin's point. Let me ask you, if a personal sound amplification product is being advertised wherever—online, newspapers, magazines—and they claim to be a hearing aid? That's not something that

they should do, but it happens all the time. If you go on Amazon this morning, and looked at 2,500 devices that were advertising themselves as hearing aids, and at least 1/3 of them were clearly PSAP devices. They were not truly hearing aids.

RICHARD CLELAND: Well, stump the chump.

RICK GILES: Sorry.

RICHARD CLELAND: No, I think that that's a good point. I mean, I would have to give that actually a little more thought. I mean, I would want—the primary issue for us is whether the benefit that's being claimed for the product has a scientific basis in that situation. And if it does, then referring to it as a hearing aid versus something else might not be misleading, unless consumers are going to automatically assume—we don't know this, because we don't have the evidence for this—but if consumers are going to take an implied claim, that if you call something a hearing aid, it's going to be FDA approved. You know, the government's already approved this product. So there might be something in that that could be misleading to consumers.

RICK GILES: Thank you.

ELLEN CONNELLY: OK, we will now move on to Bill. And we will talk a bit about voluntary industry standards. And so the question is, can voluntary industry standards, such as CTA's PSAP quality standard, help consumers make more informed purchasing decisions? And how does that standard relate to what's applicable to hearing aids?

BILL BELT: So, thank you for inviting me, and thank you for the softball question, I appreciate it. I'm Bill Belt, I'm with the Consumer Technology Association. If you know of us at all, you know of our trade show, the Consumer Electronic Show, held every January in Las Vegas, which brings about 180 thousand people into Vegas for four days, to go see around 3000 companies.

There's been a sort of growing interest in all things related to medical care. And the line certainly between medical devices and consumer electronics devices is blurred, if not completely gone actually. So specifically the question was about standards, and

what can be done with industry standards. Besides our show, one of the other things we do is write standards on behalf of our industry. We've been writing standards since the late 1920s, with our first standards related to radios, which were the first device people had in their homes that were consumer electronics.

Our probably most famous standard is actually one that benefits the exact same community we're talking about here, and that's the closed captioning standards. The reason that closed captioning works on any TV, regardless who the manufacturer is, regardless of how the video is coming to the TV, it's not magic. It's a standard, an industry standard made that happen. Now I personally don't write any standards at all. What we do is facilitate the writing of standards. I make sure the coffee is hot, and the donuts are fresh, and I invite industry to come in and write the standard. And I try to referee the fights.

So we have a standard, fairly new, January of this year, ANSI/CTA-2051. These numbers are horrible. We don't make them up. We're accredited by ANSI, the American National Standards Institute, to write standards for consumer electronics products. That standard sets out minimum performance requirements. So if you build a device, and that device complied with the minimum performance requirements in that standard, we believe that you would be buying a very high quality device. In fact, there are hearing aids being sold today, that would never pass our own standard for PSAPs.

Now there are two ways that can be done. One way is to codify that in regulation at the FDA. Say if you want to sell an over-the-counter hearing aid, here are the minimum performance requirements. You could do that. But a better way is to say, we're the FDA. We know there's a standard out there. If you build to this standard you can sell your device as an over-the-counter hearing aid. The benefit to that is that we can mostly keep pace with our own industry. We can't really. Our industry is beyond lightning fast. But we're not bad at keeping pace with our own industry. And not that I'm saying something negative about the government, but honestly, regulators can't. It's just an impossible job for a regulator to stay ahead of the constant march of technology. So I

think that that's how a standard can help is it's a sort of prepackaged set of rules that the government could rely on if they wanted to. Or that consumers could rely on.

Second part of your question was about consumers. Consumers know nothing about standards, they don't care. They just want to go to the store and buy something cool. They want it to work. They want it to look cool. They want it to last. They don't care about the standard. They don't care at all. So given that, what our next project now is to create a standardized logo, some kind of seal of approval, that all of us in a couple of years will recognize. And we'll know when we go to buy a PSAP-type device, to look for this seal of approval. And what we'll do is, anybody who meets our standard and certifies that they meet our standard, will get a license to use our logo, either on their product, on their product packaging, on their website, wherever they want to market their device. And that would help a consumer tell the difference between a high quality device and something else. Something less.

ELLEN CONNELLY: Thank you. Do any of the other panelists have any comments on this topic? Yes, Ian.

IAN WINDMILL: I just wanted clarification, because I wasn't sure I heard this correct, and I apologize if I didn't—that the current hearing aids would not meet the standards for PSAPs. And so I'm just wondering if you could compare and contrast for us what kind of differences in standards those would be? And help us understand why or why not that might be the case?

BILL BELT: Sure, so I know very little about the standards that exist, if any, for the hearing aid industry. So I can't speak to the hearing aid industry's own standards. What I can say is that very well respected researchers have taken our standard, bought products, ran them against our standard, and found most hearing aids failing. And that information is publicly available. The standards are very strict. If you're going to write straight standards they have to be strict. You know, what's the point of a standard if it's not strict? And when we say we want these devices to be good, meaning helpful, we mean we want them to be really good. We don't—the worse scenario is a scenario

where a consumer goes to CVS, or to the last page of Parade Magazine, and orders a $19 device, thinks it's going to solve their problem. Of course they get the device, if it works at all, it doesn't help them. And then they wait another 10 years before they try again. And there they have gone 10 years with hearing loss that they didn't need to have. And that happens all the time to people.

ELLEN CONNELLY: Anyone? Frank?

FRANK LIN: I guess commenting on Bill and also Ian's question, I guess. Talking to some of the audiologists who have tested the standards now with the CTA/ANSI standards—I mean, there standards revolve around frequency response distortion, those characteristics. So my understanding from the white papers I've seen of that is that a lot of current hearing aids actually would not necessarily meet that standard. And almost the vast majority of PSAPs actually also wouldn't meet that standard. A few do from both categories, without a doubt. Obviously more hearing aids than PSAPs, but it does appear to be a very, very strict standard in terms of looking at electroacoustic characteristics, as well as the characteristics of the amplification that they've provided.

IAN WINDMILL: But are those characteristics specific ranges, or certain types of characteristics, that typically haven't been built into hearing aids? I guess that's what I was trying to understand. Are they characteristics that—we know—gain characteristics of hearing aids, and we know that all hearing aids are required to meet certain standards, whereas this one is voluntary? So I'm just trying understand that—what characteristics differentiate the two on paper that I would look at it and say I can tell that this is a standard that's not similar to what I typically see with hearing aids? That's all I was trying to discern.

ELLEN CONNELLY: Rick.

RICK GILES: So current hearing aid standards also include obtaining your hearing aid through a licensed provider, and all hearing aids have to be FDA approved. Are you saying then, that your standards would also include a licensed provider, and they would be FDA approved?

BILL BELT: Can you ask again? I think the answer is no, but I want to make sure I—

RICK GILES: The current industry standards require that a person receives their hearing aid through a licensed provider.

BILL BELT: OK, yeah. No. OK. Thank you. My standards are purely technical. They don't tell you what you can do with them. You can do whatever you want with them, but they focus exclusively on the technical characteristics of these devices. And they, again, don't give guidance, or whatever the right word would be, with what you do with that information.

FRANK LIN: So I guess following up on Rick's point, actually. I think one key thing there, and I think Eric mentioned as well, is FDA standards don't say hearing aids can't be sold over the counter, right? They just don't say they can be, right? So much of the restriction for hearing aid sales having to be provided through a licensed provider, is at the state level, right? So every single state licensing board says, this is a medical device, it's not supposedly intended for over-the-counter. It doesn't say it can be over-the-counter. Hence, at the state level, we restrict hearing aids can only be sold through a licensed provider.

And where that falls apart, a little bit though, as you know, is that you can buy a hearing aid online or mail order from another state. That is interstate commerce. So it's not subject to state laws necessarily, though.

RICK GILES: I understand that.

FRANK LIN: Yeah.

DAVID SCHMIDT: I think that's a great segue to our next topic, which is state licensing standards. We heard this morning that state licensing can have impact on the ability for providers to provide telepractice or teleaudiology services. And it also, obviously, impacts FDA regulations, and interacts with the medical examination requirement and the potential waiver. So I wanted to turn it over to Rick to ask you

what you saw, right now, as sort of the most important state regulatory issues in this industry?

RICK GILES: I think the most important state regulatory issues ensure that consumer protection is achieved via competency, through professional licensing, where the licensee, whether they're an audiologist or hearing aid specialist, has to pass a competency exam to prove that they are capable and have the knowledge in the field.

Back in the '80s, Colorado had a licensing law, and decided that because there were very, very few consumer complaints, and that the license division was costing the state of Colorado some money, that they would eliminate licensing in the state of Colorado. That then, over the preceding five or six years almost to a decade, allowed anyone who wanted to sell a hearing aid without being licensed to flock to Colorado. And a great number of people who had lost their licenses in other states, people who could not achieve competency through the licensing examinations, flocked to Colorado. And the consumer complaints went through the roof.

After about a decade, they decided that licensing and competency standards were a good thing to have, and they reinstituted that. And I'm happy to say now, since the mid-90s, that has pretty much solved a lot of the issues that they had by unlicensed people providing devices that, although they were hearing aids, maybe incompetently fit.

DAVID SCHMIDT: Ian.

IAN WINDMILL: Well, I think this is an issue that we haven't touched on much over the last 12 months, in terms of the licensing and regulation of the device and/or the dispenser. And that's part of the confusion, I think, that we have out in the field is do our state laws regulate the device or do they regulate the individual who sells the device? And that seems to be a confusion at the practitioner level, and understanding what it is. And depending on who you're talking to, protecting the consumer about the device or protecting it from the dispenser? So there's a confusion there that needs to be cleared up. But I think it speaks to a larger confusion and that is that we do have a

patchwork of licensing laws across the country for devices and for the dispensing of devices.

In 40 states we have licensing laws that an audiologist can dispense under their license. In 10 states you have to have a dual license. I live in Southwest Ohio, at the confluence of three states, Indiana, Kentucky, and Ohio. And we have locations in those three states, and I have different licensing laws that I have to abide by, both in terms of getting the license, but also in terms of maintaining license. And what we can and can't do. Practices within the license, how often you have to have any examination. Ohio, I don't have to have an examination, I can dispense. In Indiana, I have to take an examination on the state law. In Kentucky, I have to have a dual license. And just in terms of moving our staff around between sites, and paying for all those licenses, it becomes very difficult.

So I think portability of license, which was touched on earlier about telehealth, is also kind of an obstacle and barrier in the system that certainly doesn't allow ease for either consumers or for practitioners. That also, within the licensing laws, there are differences in the trial periods, the refunds amounts, those type of things that exist. They are also obstacles, and you have to know multiple sets of those. Different states, some say 10% refund, some say 5% plus $200, others say reasonable fee. So it varies from state to state, and that probably contributes to some of the responses that state licensing boards or the FDA or FTC get about the cost of hearing aids and devices, which can vary from state to state based on what's going on there. And then certainly the mail order issues are also issues in different states that are addressed differently in terms of the practitioner licensing laws—what we can and can't do. Or maybe the general practice laws that talk about telehealth or mail order standards.

So it's a little confusing out there. Some of it, the telehealth is understandably confusing, because that's still emerging. But a lot of the others have been around a long time, and are fought tooth and nail about what should be under licensing law or not. That certainly does contribute to the state regulatory milieu of problems that we have.

RICK GILES: Yeah, and I think if the OTC is to move forward, state licensing agencies will have to focus on how to draw the line between licensed providers and people who are selling OTC products—which is—and also how consumers can be educated on the difference.

ELLEN CONNELLY: That's actually a good segue into our next topic, which I suspect will generate a lot of discussion, which is the OTC category, or the possibility of an OTC category. So this idea of an over-the-counter category for hearing aids has received considerable attention recently: in reports, regulatory proposals, and proposed legislation. And so we're wondering what each of you would see as the likely impact of such a policy change for the accessibility, affordability, and efficacy of hearing health care? I'd like to start with Frank, and then move to Rick, and anyone else who might have a comment.

FRANK LIN: Thanks Ellen. So it's a doozy of a question. So I'll mention for my background, I basically come at, from very much a public health perspective. I'm trained as an otologist, but it really comes from my perspective as being a public health person who studies the field. So I think if we look broadly at the field of just hearing health care—and no matter what statistic you look at—there has been very, very generally low uptake of hearing technologies. Regardless of whether or not you're in a market like the United States, where it's self-funded, versus some Scandinavian countries. And there are differences to some degree, but we're not talking a home run, per se, in terms of everyone's adopting here in health care who could possibly use it in countries that are fully funded.

And I think what that gets at is there are many, many barriers to hearing health care. It's not just cost. But cost is a big one. The fundamental issues we've talked about this morning, of accessibility. The only way right now the United States you can access a technology to help your hearing is through a licensed provider. So issues of fund-related access. Broader awareness issues, obviously, of even understanding what hearing loss is, how it manifests, what's the difference between a PSAP versus a hearing aid? What's

the difference between the hearing aid specialist versus an audiologist? Fundamentals of awareness. And then innovation to some degree.

I think the hearing industry has done a phenomenal job over the last several decades, but clearly there's a lot more that can be done. And especially, what we talked about this morning, is the merger or convergence between a consumer electronic and a hearing aid, where it becomes really, really interesting in terms of innovation. So my personal take on this is very much my personal take from a public health perspective. I think the passage of legislation, basically the Warren Grassley legislation, is the biggest game changer. And the reason why I say that is I think it affects all four of those barriers simultaneously. So you can make hearing aids free, like you do in the UK or Scandinavia. It doesn't make much of a dent in terms of impact. But if you can lower all four barriers—you can lower issues of cost, awareness, accessibility, and innovation—then you make a big difference.

And I think what the Warren Grassley bill does is it allows for essentially a level playing field for new market entrants, from let's say Samsung and Apple's, as well as smaller startup companies. So I think it allows for tremendous innovation there. By definition, that will likely lower cost, quite simply, with economies of scale. I think in terms of accessibility—I think it clearly lowers that. Right now 2/3 of everyone over 70 has a meaningful hearing impairment. The only way to access technology that could help hearing is through a licensed provider, which sets up barriers automatically. We heard [INAUDIBLE] from Costco. How Costco is one model of reducing that accessibility barrier, but I think, clearly, a regulated market of over-the-counter devices, which you can ensure quality and safety, would clearly lower issues of barriers to accessibility.

And finally, even awareness. I mean think when you have a regulated marketplace that allows for over-the-counter devices, automatically there is going to be a much more consumer interest in what these devices are, and I think with interest comes awareness naturally. So I think—I'm a big fan of—I'm actually very left leaning overall, but I'm a big fan of market changes by themself. So I think if you have a regulated marketplace that allows for a fair playing field, I think it's when you let the

industry and you let the market determined what happens, and I think that's where you make a lot of changes very, very quickly.

RICK GILES: I'm certain we would expect the competition to be heightened if an OTC class were adopted. That being said, we are very concerned about the ability for a consumer to self-diagnose their own hearing. I think there's a big, distinct difference between identifying that you can't hear, and knowing why, and the type of degree of hearing loss you may have. People get hearing aids when they're not appropriately or medically indicated, or that they're not right for the loss, will lead to poor satisfaction, leading to poor adoption rates. Consumers go to hearing aid providers, licensed and unlicensed, based on the congressional bill model, seeking the system just as likely as they do now their hearing aids and PSAPs—which drives up the cost to that product, and perhaps necessitating the purchase of a second device that was appropriately set, or possibly even revert back to year one of the seven to nine year cycle, of abandoning hearing aids for a while.

And then I wanted to follow up a little bit of what Frank said. We have that model now. It's active in Asia. Japan has absolutely horrendous adoption rates—very, very poor satisfaction rates. There is a push now with the International Standards Organization to try to develop hearing aid fitting management standards—that this will be an international standard—that IHS has a seat on. In fact there's a meeting in Copenhagen next month where we'll actually kind of formalize some of that individual—those individual guidelines. And that is something that the rest of the world is trying to follow the United States and adopting standards like we have in the United States, because they are impressed on how good of a job we actually do here compared to what is available in areas where there is no profession involvement.

ELLEN CONNELLY: Ian?

IAN WINDMILL: I was going like Frank respond but, I'll go ahead. So I think one of the things that's come out of this over today, you can see that this is not a simple issue. There's a lot of complexity here that's going on. In one level we talk about how the

consumer is confused about the system, and how they get into the system. The multiple entry points et cetera. Now we're going to introduce OTC which is—doesn't make a complex system simple. It makes a complex system more complex, because now they have another entry point. So on the surface you could make that argument.

But I think it's—kind of leads to another concern, another direction. And we're focusing a lot on the technologies, the providers and the delivery system, and that's been most of what we talked about today, or for the past several years. I know the next panel coming up is going to talk about the consumer. But it strikes me that we talk a lot about changing a system that's confusing already, without changing the other side, which is the consumer side of the equation.

And I'm struck by the arguments that we've had over again, the number—last 18 months or so—about the issue of mild versus mild-to-moderate hearing loss, who is the target market for OTCs, et cetera? The fact is that, there is no way for a consumer to say I have a mild hearing loss without getting an evaluation. Mild hearing loss or moderate hearing loss this severe is an audio-metric deviation from normal. That's the definition. It's based on an audiogram. Unless you get an audiogram, you can't tell. And so by using these languages, we're designing a system that the consumer still can't understand instead of thinking about, how do we get that consumer to be able to self-direct what they want to do, or self-identify what they need to do—what their course of action is. So for example, we need to start talking about language such as, does the consumer have an occasional problem? Or a situational difficulty? Or a communication impairment that interferes with their work abilities, et cetera? Those are languages the consumer can then say, Ah! That's me. Then if we have the tools, they can kind of self-select into the right pathway. Just changing our system, on one level is just going to make it more complex. And I'd like to see part of the discussion focus on how that consumer, what tools, languages, processes we can give the consumer that allows them to be able to self-select correctly into the right categories.

ELLEN CONNELLY: Thank you. Frank?

FRANK LIN: So, I guess to comment on a few points from Rick and from Ian. I think the market is incredibly confusing right now, but I would say, Ian, I think, it's less so much that this will introduce another factor. I mean, I think the issue is we already know that over-the-counter devices—whether you call it a PSAPs, or whatever you want to call it—they already exist. And I think it's what makes it so confusing. So I think by creation of a regulatory classification, whether it is just purely through CTA/ANSI standards or through the FDA—that's what actually brings clarity to the marketplace. Right? So you know if you buy something over-the-counter, that's going to meet a certain level of criteria and standard for safety and performance. I think that's the key thing there. I think, also, along on the lines of mild to moderate, tricky question. I think a big thing with the way the National Academies recommendations came out, and also the Warren Grassley bill though, is that—and we talked a little bit about this this morning—it would allow for companies that produce these devices to also create corresponding algorithms programmed to allow you to self-diagnose, to some extent, in terms of overall severity of hearing loss. And yes it's not going to be as precise necessarily as a full-fledged [INAUDIBLE] audiogram, but it could give me a rough level of whether I'm in the mild, moderate, severe, or profound category. I think it probably fairly could.

With Rick's question about Japan, I think this comes up often, is we look to Asia and we say, well in unregulated marketplaces it's horrendous. And it is. But the issue here, though, is that we're not asking for less regulation here. We're asking for more regulation and that's the distinction, right? So the issue with Japan right now, the reason why the rates are so low, it's a misnomer. It's for several levels. One is culturally Japan, East Asia, is completely different when it comes to approaching issues with hearing and older age. It's a completely different cultural aspect that hands off changes the denominator, right there. On top of that, the problem with Japan in many ways is that there are actually—there's no really practical audiology in Japan. I mean, that's part of the problem, is that there are no providers right now who can even guide people to what the right technologies are. So that's another second big problem. The third big

problem in Japan too, right, is that the marketplace is completely unregulated. Much like it is in the states to some degree, but on a worse so level. So you can sell any product, anything. And if you buy—I've been to stores in Japan, and if anything I guarantee most of them are horrendous, much like the over-the-counter devices here.

So I think the clear misnomer of the over-the-counter regulations is that it's not de-regulating. We're asking actually for FDA and/or CTA and ANSI standards to allow for better regulatory classifications and performance standards so that there is clarity. I think that there are some key differences there in terms of the examples that are brought sometimes. It's not deregulation. It's actually – you could argue even increased regulation – is what maybe I think would improve the field.

ELLEN CONNELLY: Richard.

RICHARD CLELAND: Yeah, I want to step into the dark side for just a second here. Anytime you open a door, and particularly in an area where you already have a lot of consumer confusion, and the standards deviate—distinctions between types of products may not all be all that clear, particularly to consumers. I'm concerned that whether the system, as it's currently set up, has the capacity to regulate the bad guys here—the people who are making the deceptive claims. Now even if you have standards, even if you have an FDA approved product, even if you have a technical standard that a product complies with, that doesn't necessarily mean the advertising for that product isn't deceptive if the advertising goes beyond what's approved, or what can be accomplished within a standard. So essentially you're asking the regulators to either in some sense if they're going to do anything to divert resources from what they're already doing to a whole new area, and I just—that's something that should be taken into consideration whatever road you go down here.

BILL BELT: I just wanted to echo, I think, what Richard just said, which is that is exactly what we're asking. We're asking, among other things, that regulators do more than what they're doing now. What they're doing now, in effect, is writing rules and creating regulations for all of six companies. And I'd rather see them do it for 600, with

594 of them making PSAPs. So yeah, we're asking for more. We're asking for more, because technology has moved forward, the number of people with hearing health issues has increased, and will continue to increase, and there are government agencies that have a responsibility to make sure that the products and services that are out there are safe. So it's a little hard to be sympathetic to a complaint that says, well I only have to worry about six people and if the law changes I'm going to have to worry about 600. Well too bad. Time to catch up.

RICHARD CLELAND: Well you know, it may—I don't necessarily disagree with you. But having lived through this in different product areas, it's one thing to say, OK go, go market your product guys. It's another thing to get the resources to do the kind of job that has to be done. They don't—we don't control our resources.

DAVID SCHMIDT: We have a question from the audience that I'd like to address, which is on how we can ensure that children are not accessing PSAPs and OTC hearing aids? And as an economist I'd like to follow up on that by asking, what are the reasons why children would be treated differently than adults in the use of these devices? Is this primarily a medical concern that children's ears are still developing and devices that are suited for adults might not be best suited for children? And then getting back to the audience question how can we ensure that children won't be given these devices, if we can? Anyone?

IAN WINDMILL: Boy, I wish you bad wish you had somebody from a pediatric hospital on this panel. You know, that's a good question. I think it's one of those things you do you flip back at the FDA. I mean to me it's part of the FDA, is how do you regulate any other device or drug that you want to keep out of the hands of certain populations? And will no children ever use an OTC or a PSAP? I don't think that—you cannot answer in the affirmative that they would never use that. There will be people that will do it. There will be people that, for financial reasons, will do it. We know that there are children that don't have access to those kind of services in some way, and they might choose to do it.

Their parents—it's not the children—it's the parents, who might find that the difficulty in accessing service based on distance, or cost, or it's not covered by third parties, would opt to try something different. I think that's certainly a possibility that exists out there. I will say that in our facility we are looking at how OTC devices or hearing aids or PSAPs could be used when, so that we can develop some guidelines that would say for the child that has a hearing loss where they're going to go through several surgeries and it's a temporary six-month unilateral loss, they could use a simple device as opposed to a hearing aid. So, I think that we, the community, the hearing care community, have got to evolve some guidelines, as well, in order to inform parents, and to inform those that shouldn't be using the devices, how to use them. But I think it's going to be the enforcement of that is going to be very difficult.

On the other hand, typically, in the pediatric area most individuals are identified early and come in through the audiology, through the medical system, are being managed and often, as in many states, have insurance coverage for hearing aids. So I would guess that those would be self-limiting factors in terms of people who would get out and use them. So parents can access the systems easily and readily, state laws require coverage. And I think that's going to be part of the system that helps to limit access for some of those individuals.

FRANK LIN: I think just echoing Ian's point, especially I think pediatric hearing loss is completely different than the classic age-related hearing loss as Ian just mentioned briefly. There are different sorts of medical issues we need to evaluate in children, things like that. So it is completely different. So I think echoing Ian's point too, I mean, yeah—I mean there are medications that are meant for adults. Nicorette gum, nicotine gum, adults strength Tylenol. These are all things that are meant for adults, not children. How is it regulated now? It's much like you label it properly. Well sometimes kids take Nicorette gum they probably shouldn't? I'm sure it does happen actually, but it is probably—I imagine it's not unique to the situation.

In terms of children possibly, and parents buying over hearings for children though, so there's that issue. But you know what I would hope, actually, with an over-

the-counter regulated marketplace, though, is that actually I'm guessing many patients might actually buy this device, and then go to an audiologist, or hearing help professional, and ask for their help. Say I bought this device. Can you help me program it now, to adjust it to my needs, and what else needs to be done? So I think it's not an either/or phenomenon. You have either regulate—you have over-the-counter devices, or you have services. It can be very much the same thing a lot of times. And I think that's the importance—we heard this morning about the importance of unbundling policies to a different model is, I think, many audiologists I know who do unbundle, they're very not threatened by this model of over-the-counter devices. That's fine. I charge for my services, you can bring me any device you want, and I can help you with it. Right? So, I think a lot of times, all too often society nowadays, we equate audiologists with a hearing aid sales person, which is not the way it's meant to be. I mean, for an audiologist, their goal is to help someone communicate better, right? And whether that's with an over-the-counter device, an iPhone app, a hearing aid, or cochlear implant, it doesn't really matter actually, right? Any hearing help professional should be able to help anyone hear better regardless of the technology. So I think that's the key thing to keep in mind, it's not either/or, it's very much an and phenomena I think, a lot of times.

IAN WINDMILL: And I feel as we broached the topic here, I'd like to just kind of raise the issue of reimbursement for hearing aids. And we heard from our earlier panel that there's not a lot out there. There are some, particularly in those places that were strongly union in the past, et cetera. So there's—and there are some riders on some of the bills. There's a concern that an OTC-type device would cause individuals to lose that coverage in some way—that an insurance company might say, hey, if you can buy an OTC, we don't need to cover it anymore. And then examples would be new over-the-counter drugs, or a drug that is just made over-the-counter. Well you don't lose insurance coverage for those that are not over-the-counter. But I do think one of the things that's imperative in the OTC discussion, is to ensure that patients don't lose coverage in the event of an OTC device. That those that do have it, and those that are

emerging coverages, continue to happen for the traditional devices and services. And so I just think that's an imperative—that we kind of focus and make sure that—it's kind of "repeal and replace" for hearing aids. So we want to make sure that we do this cautiously so that people don't lose coverage in the future.

ELLEN CONNELLY: Bill, Rick, and then I think we'll have to move on to the next topic.

BILL BELT: OK great. I will try to be quick. I wanted to echo what Dr. Lin said. In 2014 CTA did a study, publicly available at our website, and probably many other places, that found that contrary to what most people might think, the type of consumer that would go out and shop for a PSAP is much more likely to go to an audiologist than a typical consumer. So I think there's a lot of evidence for what Dr. Lin was saying, it's not an either/or thing, it's an and thing. The second thing is just a very general observation, which is words matter. Actually, this whole event today is about words. Is it the word OTC, is the word PSAP, or is the word hearing aid? So words matter.

On this panel a few minutes ago, you heard somebody refer to when you might use a device for a child. Like for example, the surgery is scheduled six months away, and you want them using a simple device until they get a more complicated device. And as I said words matter, words matter. There's nothing simple about PSAPs. Nothing simple about them at all. And in fact, I would argue that the vast majority of them, of the good ones I should say, the kind that pass my standard, are better than traditional hearing aids. So saying there is this sort of simple device versus hearing aids, I don't know in what world that exists. What there is are high tech, wonderful, fantastic, almost miraculous devices. And there's stuff called hearing aids.

FRANK LIN: Wow. And how do you really feel about it?

RICK GILES: So I think it's important here, that we don't—that we understand that a hearing aid is not a commodity. A hearing aid and proper hearing health care involves a lot more than just that device. And regardless of where the person buys the device, whether they buy it over-the-counter, whether they buy it from one of the

major manufacturers, it's just a piece of plastic with electronics in it. It's the care, and the concern, and the experience, and the time that a licensed professional has in this field that allows them to take even the most basic hearing device and make it work well, or conversely take the most expensive whiz bang thing and make it fail. It really revolves around that licensed person, and that's critical. I just want to make sure that—I haven't heard this yet today, but it's not a commodity, it's the person.

DAVID SCHMIDT: One topic we haven't really discussed yet, relates to information that would allow consumers to shop for hearing aids that both satisfy their hearing needs as well as their financial constraints, and one analogy that people have drawn between hearing aids is with vision care. And the FTC, most of you know, regulates parts of eye care. We have the Eyeglass Rule and the Contact Lens Rule that require prescribers to give consumers a copy of their prescriptions. And people have drawn analogies to hearing aids. So I wanted to start by asking, Richard, if he could explain to us a little bit about what the FTC has done in the eye care, and then turn it over to the rest of the panel to talk about whether this analogy holds any water in the hearing aid industry.

RICHARD CLELAND: OK. I'm going to be quick about this, because we're a little bit short of time. As you already heard, both the Eyeglass Rule and the Contact Lens Rule require that the consumer receive—automatically receive—a copy of their prescription. In terms of eyeglasses, it's when the refraction is finished. In terms of contact lenses, it's when the fitting of the contact lens is finished. The prescriber is prohibited from a number of things—associated conducts like charging a fee for providing a copy of that prescription. They're also prohibited, well under most circumstances, and then also prohibited from requiring some things like waivers in exchange for providing a copy of the prescription. For contact lenses, and not for eyeglasses, because most consumers who have contact lenses already know what their prescription is, because it's on their contact lens box already. So there is a very strong online market for contact lenses. And so, the Contact Lens Rule has a system of verification where the consumer doesn't actually have a copy of their prescription, but they can, the seller of the contact lenses

can either through active or passive verification get an authorization to dispense the contacts from the prescriber.

I will tell you that in both rules, we are not satisfied—I am not satisfied with the—I hope somebody gave the general disclaimer for all FTC speakers today.

ELLEN CONNELLY: Give it now.

RICHARD CLELAND: Yeah. My views, my views are my own and not those of the Commission or any individual commissioner, but from my perspective. And if you'll see some of the comments that have been filed both for the Eyeglass Rule and the Contact Lens Rule, which are currently under review, there is a question about the—have we reached the appropriate level of compliance. Are the prescribers actually giving out the prescriptions when they're supposed to? With regard to whether or not, or the extent to which our experience with contacts or eyeglasses is generalizable, I will say that, and I have seen my audiology report, but I've never actually gotten a copy of it. But compared to my contact or my eyeglasses prescription, my eyeglass prescription is pretty simple. And you know, particularly for contact lens wearers, but also I think for eyeglass wearers is the issues of convenience and cost are very important to buyers here. You know, you're going to replace your contacts a lot. Even your eyeglasses, you're going to, usually every couple of years you'll get a new pair of eyeglasses depending on your insurance. So they're replaced more often than I'm going to replace my hearing aids. You know, I hope never to have to replace them, but once is enough. And there's also, and this is area both in eyeglasses and in contacts, we have a very strong competitive market that's willing to compete on prices and convenience.

IAN WINDMILL: So I'd like to respond to this, because I think you brought up a great point, is that there's a kind of a simple system for eyeglasses. In hearing care we don't have a simple system. We have an audiogram that's pretty common and universal, but it—an audiogram—is a measure of peripheral hearing loss, not of auditory impairment or functional limitations. We have a lot different tests that we have to do or utilize to kind of get at that. It doesn't take into account cognitive function, dexterity, all

the things that are necessary to deal with ear canal size, shape, all those types of things that we have to consider with amplification devices. And recently there's an emerging body of literature about changes in cognitive function as a result of hearing loss. It's been demonstrated in children with cochlear implants, and is being demonstrated now in adults.

And some work out of the University of Colorado in particular, that's demonstrating cortical reorganization, changes in brain function that directly result from peripheral hearing loss—even mild hearing loss that occurs as soon as three months after you lose your hearing, you start to see changes in brain function. That kind of changes the equation to a great degree moving forward, if that's in fact true. And I think some of the work that Frank's doing on long term effects of hearing loss and cognitive decline et cetera—those are game changers in terms of prescribing a device in lieu of understanding what's going on in the brain as well. That's really, really different. And so I guess my little catch phrase of the week is that, glasses are for eyes, but hearing aids are for brains. And that's different than just getting a prescription that says here's how much loss you have here's the device you need. You have to take into account what's going on cognitively and cortically, as part of our discussion evaluation about and fitting of devices.

RICK GILES: Can I give a real world example of that?

ELLEN CONNELLY: Sure.

RICK GILES: My wife who's had terrible vision since she was an infant, her eyeglass prescription is one page, and it's mostly white space. Her hearing aid prescription is six pages long. So it's just, comparing eyeglasses and hearing aids are again, doing, proverbially, the apple and orange thing.

ELLEN CONNELLY: Thank you. We are just about out of time. I'm wondering if any of the panelists have any just last minute really wrap-up comments. In particular, sort of how you see the future. If you think regulations need to change, or if they're able to accommodate. We've heard some differing viewpoints early today on that.

FRANK LIN: I'll say my one quick summary on that one is, I think, there's a gold standard model now which is great. It really is. But it's not meeting the needs of everyone, quite simply. That's all it comes down to. So you can use any figure you want, 70-80% of people who have a meaningful hear impairment don't have treatment. So clearly there are other models that are needed.

RICK GILES: One of the questions this morning regarded trends in what the industry is. If we look back at Market Track and go back to 2008, penetration rate was about 28%, now it's almost 36%. So in less than a decade, we've increased our market penetration by 10%, or near 10%. And that, I think, is due to the quality of products that are available today. And I think also due to some of the other distribution channels like Costco. And Costco has had a tremendous impact on the person going and buying their first hearing aid.

ELLEN CONNELLY: Anyone else? We are out of time. So thank you very much. This has been a very interesting discussion.

[APPLAUSE]

[MUSIC PLAYING]

[SHORT BREAK]

PANEL 4: INFORMING CONSUMER CHOICE IN HEARING HEALTH CARE

Panelists:

- **Stephanie Czuhajewski, Executive Director, Academy of Doctors of Audiology**
- **Barbara Kelley, Executive Director, Hearing Loss Association of America**
- **K.R. Liu, Director, Accessibility & Advocacy, Doppler Labs**
- **Lisa McGiffert, Director, Safe Patient Project, Consumers Union**
- **Carole Rogin, President, Hearing Industries Association & Better Hearing Institute**

Moderators:

- **Gerald Stein, Bureau of Competition, New York Regional Office, Federal Trade Commission**
- **Daniel H. Wood, Bureau of Economics, Federal Trade Commission**

DANIEL WOOD: Hello, I'm Daniel Wood, and I'm pleased to introduce my co-moderator Gerald Stein.

In this panel, we're going to focus on the consumer decision making in hearing health care. So, what the consumers know or learn as they engage in the process of purchasing a hearing aid and having it fit, what the consumers need to know in order to make appropriate decisions.

We're hoping there will be a lively discussion between our knowledgeable panelists about these issues. Gerald is going to introduce them.

GERALD STEIN: Since last panel was all men, we figured we would have all women. And I'm pleased to introduce our panel. Our panel is also going to be slightly different than the other ones. Like the prior panel, we're not doing the little intros, but we're also not directing questions. We're going to have just a free for all. We'll introduce topics, and our panelists will engage in conversation about them.

So I'd like to introduce our panelists.

Sitting next to Dan is Stephanie Czuhajewski. I knew I was going to screw that up. Stephanie Czuhajewski. Stephanie is the executive director of the Academy of Doctors of Audiology, ADA, a leading national association representing autonomous audiologists who are committed to best business and clinical practices. Ms. Czuhajewski has two

decades of nonprofit leadership experience, with a focus on outreach and stakeholder relations.

Next is Barbara Kelley. Barbara is the executive director of the Hearing Loss Association of America, otherwise known as HLAA, a consumer organization whose mission is to open the world of communication to people with hearing loss through information, education, advocacy, and support. Their national headquarters is in Bethesda, Maryland, and they have state organizations and local chapters across the country.

Next is Kristen "KR" Liu. She's the Director of Advocacy and Accessibility at Doppler Labs. KR leads the advocacy and accessibility at Doppler Labs. She has been a technology executive for over two decades. Diagnosed with severe hearing loss at the age of three, KR has made it her life's work to be a strong advocate and voice championing new products that enhance the way we hear the world.

Next is Lisa McGiffert. Lisa directs Consumer Reports' Safe Patient Project, which works on state and federal policies to end medical harm, including medical device safety. Consumer Reports recently updated its hearing and buying guide and included, for the first time, tests of several PSAPs available to consumers over the counter.

Last, but not least, is Carole Rogin. Carole is the president of the Hearing Industries Association and its consumer information and education arm, the Better Hearing Institute. The members of her association are the 17 hearing aid and components manufacturing companies that produce over 90% of the hearing aids dispensed in the United States on an annual basis and support MarkeTrak, the highly referenced longitudinal survey of people with hearing impairments in the United States.

And without further ado, I'll turn it back to Dan.

DANIEL WOOD: OK. Well, this morning in the delivery panel, Kim Cavitt said something like, the road to hearing evaluation is treacherous. Lisa, could you start us off by explaining some of the difficulties at sort of the beginning of this road?

LISA MCGIFFERT: Yes, thank you. So I feel like we need to talk about a few things related to how people pay. You know, it's all tied up with pay. So insurance often determines how people enter into this market, and a lot of people just go to their primary care doctor, which we've heard about. Some people have access to specialists.

But generally—we did a survey and I'm going to be talking a lot about a survey that Consumer Reports did of our subscribers. Our subscribers are generally higher income, higher educated. It's not a randomly selected group, representative group. But we did this survey of a significant number of people, I think 130,000 people, and about 20,000 of them had bought hearing aids. So I'm going to be talking about this.

About 60% of those that we surveyed that had hearing aids said nothing was covered. Their aids were not covered by the insurance coverage. I don't think we parsed that out separately, but I think that this is definitely an issue that has been raised over and over about how people access the diagnosis and where they go to get care.

And I might say that we looked at what reasons—there were a significant number of people who had hearing loss, reported hearing loss, who had not gotten a hearing aid, and we asked that group why they didn't. And we found that the highest reasons for those with hearing problems that didn't get an aid were, my hearing loss was not severe enough, that was 57%, and 34% said, I only have trouble hearing in certain situations. So cost was not at the top of the list.

So I think there is sort of an issue with people determining whether they do have significant hearing loss or not. Some others might want to weigh in on that.

GERALD STEIN: Carole?

CAROLE ROGIN: I'd like to just reinforce the information that Lisa just provided from her survey, and also put our survey, MarkeTrak, on the table.

I think most of you here know that we have been conducting a demographically balanced, highly projectable survey of the beliefs, attitudes, and behaviors of people with hearing loss in America, for over 35 years. We tend to do the survey every four to

five years. And one of the things that has not changed over that time is exactly what Lisa just said.

Where I don't mean to diminish cost as a consideration in people's acquisition of hearing health care, the two primary reasons that people with hearing loss tell us that they have not yet tried hearing aids are because they believe—for their lives, their hearing loss is not severe enough yet. And they don't have problems in a sufficient number of situations.

So I think this afternoon, if we can close our discussion today, which I think has been very, very valuable, with a consideration of the kinds of information and the delivery channels for that information that consumers need, we will do a real service to ourselves—all of us who are committed to what my organizations have been committed to, which is first and foremost, raising the importance of hearing in the hierarchy of health concerns in the United States, and secondly, increasing the numbers of people with hearing loss in America who benefit from hearing aid use.

GERALD STEIN: Steph? Did you want to—

STEPHANIE CZUHAJEWSKI: Sure. Thank you.

In addition to that statement, I know that there have also been significant studies done around stigma. And I think we have to recognize that stigma is really a formidable adversary.

Cost is certainly a factor. Stigma is also a huge factor. I believe Dr. Weinstein and Dr. Blustein conducted—They wrote an article in 2016 where they cited data that showed that half of people who would benefit from a hearing aid and don't have one, don't have one because of stigma.

GERALD STEIN: And Barbara, do you want to add to that?

BARBARA KELLEY: Yes, and thank you for inviting me, because I feel like I represent the boots on the ground consumer. We've heard some great speakers today, but I feel it's all come from a very paternalistic point of view, maybe.

So we have to hear what the consumers think. And it might be anecdotal evidence, but I've been with HLAA for 29 years, and since day one, we at least have two inquiries, phone calls, emails a day, and we've had up to eight, consistently of people saying, I can't afford hearing aids. I need some help.

It might be a little piece of plastic and it might be a device, but the majority of people can't afford it. And, you know, why can't we have a competitive marketplace for hearing aids? And I think we here in Washington DC, we forget that even the Costco price, which is lower and wonderful, it's a very non-threatening environment—$1600 is still not a line item in most people's budget.

Cost is a factor, and I just think there are no two ways around it. And people aren't getting help because of cost. And also when they think of buying a hearing aid, they might be thinking of a traditional type of hearing aid.

And I've talked with some people in a certain age group who are talking about, I don't need a hearing aid, but at a certain price point, I sure might like some hearing enhancement from time to time. So I think that plays into stigma. And I also addressed the cost.

[APPLAUSE]

LISA MCGIFFERT: I want to follow up on the cost issue, because 25% did say cost—of the big group—I can't afford it, afraid that I'm going to be pressured to pay a lot of money for a product. But when we looked at the people who did buy hearing aids, and we asked them some questions, 70% waited two years or more before they got a hearing aid, and half of those waited five years, and among that group, the most common reason for waiting was cost.

So I really didn't want to diminish the cost factor, because it is a great one when consumers get to the point where they really know they need something, they may not move forward if there's not an affordable product for them to choose.

GERALD STEIN: We have a question from the audience regarding insurance reimbursement and how that works, and whether or not—and we're going to get to OTC later—but whether if hearing aids are available over-the-counter, how that might change or how might that complicate, if at all, the situation?

LISA MCGIFFERT: Well, I don't think—I think that it might complicate it for a small minority, but most people don't have insurance coverage for the full array of services, whether it be to buy the hearing aid or to get an audiologist test or to even see a specialist, if they decide to do that. So, you know, those are real barriers without insurance coverage, and these are pretty costly. I have a really good insurance plan with my organization, and they paid a small amount of my hearing aid cost. So the rest of it is out of pocket, and I know most people don't have that kind of coverage.

STEPHANIE CZUHAJEWSKI: And if I could just jump in here. Cost is an absolutely irrefutable barrier to care, both in terms of insurance coverage and also just, with or without it, the cost of the device itself, but also the services to be provided. So what we're seeing is—you've seen at least seven federal agencies over the past couple of years taking steps to address this. We've also had significant numbers of legislation and bills in Congress trying to address this, both from the device standpoint, but also from the service side of the equation.

As we sit here today, Medicare Part B does not cover audiological rehabilitative services when they're provided by an audiologist. As we sit here today, for a patient to have Medicare Part B coverage, the audiologist and the patient has to get an order from a physician in order to go to the audiologist. In this day and age, where the FDA has now come out and said—and there's been a lot of agreement around the fact that there is no clinical benefit to the medical evaluation prior to seeking treatment directly from the audiologist, there is no reason why this should continue going forward.

So in as much as the cost of the device is an issue, so too are the costs of the services. We've done a fantastic job. The research areas—medicine, everybody's done a great job in early intervention in children, and we have seen the outcomes from that

based on how they've improved in their functionality. We must do the same thing for adults.

GERALD STEIN: And one of the other topics we wanted to talk about, and I think this provides a natural movement to that, is the role of audiologists and dispensers and what role they play, as well as other hearing care professionals, if you can comment on that.

STEPHANIE CZUHAJEWSKI: Sure. So audiologists and hearing aid dispensers are responsible for dispensing of about 90% of all hearing aids in the United States currently. They both play a very important role in those services, but their role is very different. So hearing aid dispensers are focused really around the device itself, evaluation of hearing for the purpose of fitting a device, device fitting, helping for the selection of the device, efficacy of the device, and so on.

The audiologist really has a longer role on that continuum, if you will, in that they are responsible for all of the diagnostic evaluations, communication needs assessment, all of the rehabilitative services that come after the device is fitted. So the best way that I can describe the differences, maybe, is that along that ideological continuum, the audiologist plays a role the entire way, where the hearing aid dispenser is on certain points in that continuum around the fitting of a hearing aid and that construct there.

What we have seen is that there are a lot of consumers who are extremely confused about the differences between audiologists and hearing aid dispensers. And some of that, frankly, is the industry's terminology around hearing health professional, which while it may be a convenient catchall for us to use, it really does sort of help form some of that confusion within the consumer community as they're attempting to try to select one provider or another.

What does that really mean? Is it a dispenser? Is it an audiologist? Is it an otolaryngologist? It really depends on the context when we use that term as to who we might be talking about. And then additionally there have been sort of some

unscrupulous practices for hearing dispensing that will sometimes use the word audiology in the name of their practice. And so the consumers become confused about, well, is that provider an audiologist or not? This has happened so frequently that there is now a term called "fraudiology" or "fraudiologists" that is sometimes used to describe people who will intentionally attempt to fool the public by tricking them into believing that they have an audiologist on staff when they don't.

GERALD STEIN: Barbara did you want to—

BARBARA KELLEY: Lucille Beck was talking about patient-centered care, and the whole trend today is a very well informed person coming to make choices on behalf of herself about her health care. There is so much confusion for the consumer about how to enter into the hearing health care system. Their primary doctors don't even know how to deal with it. They're often told, oh, you have hearing loss. It's part of aging. Learn to live with it. Because they really don't have an answer.

So there's no way for the person to even take control of their health care. They are very much at the mercy of the gatekeepers along the way. And it's incredibly confusing. The terminology is confusing. Dr. Windmill was talking about the words "mild-to-moderate" hearing loss. That means nothing to the consumer. All they know is I'm having trouble hearing around the dinner table, or something like that. So I don't know how we can have people take charge of their own hearing health care if we don't clear up this mess and offer some choices.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: I would just add that we also found a lot of confusion about the professionals, and most people were very satisfied with the audiologist or dispenser. And we had 87% of our surveyed people who went to seek care, said they visited an audiologist, but when we looked at who they visited, they were mostly vendors that don't hire audiologists, so that indicated a great deal of confusion.

We also, in 2009, we followed some people who bought hearing aids, and we had a separate audiologist check them for quality of fit. And there were 48 hearing aids

involved, and of those, two-thirds of them were a misfit, when looked at by a second audiologist expert. And they were either amplified too great or too little.

And so we did really find some concerns about the quality of the care, even though most people were very happy and satisfied with their audiologist, and the information from the audiologist was one of the highest influences on which hearing aid they selected.

DANIEL WOOD: Carole?

CAROLE ROGIN: Let me just comment on a few of the observations here. First of all, Stephanie's observation that we are confusing people by calling professionals "hearing care professionals." I want to share with everyone the fact that the users in MarkeTrak who talk about their satisfaction with their hearing aids, are above 80% of our users. In fact, 81% of the hearing aid users in MarkeTrak say that they are satisfied or highly satisfied with their hearing aids.

And, in fact, for those users who had hearing aids that were one-year-old or newer, that satisfaction rate jumps up above 90%, which I think, sitting here at the FTC, we have to agree even if we aren't reaching enough people with hearing loss, those that we are reaching, we are reaching very well. And there are other factors in satisfaction and the way that we're delivering hearing health care right now, that work for people who can get into the system.

So I just want to make sure that as we solve the problem, the very real problem, of not reaching enough people, we don't damage what's working really well for consumers. Our research indicates that people search for their hearing care professional in exactly the same way that they search for other hearing—or other health care professionals. They ask friends. They ask family. They do ask their family physician, because they know that their ears are attached to their bodies, and they view it as a medical condition.

And in a lot of qualitative work with physicians in the '90s, we learned that unfortunately general practice physicians know the same thing that most consumers

know about hearing health care. They know it from the same sources, and it is unfortunately very little.

So I think that when we're looking at this, we really need to make sure that the information that we want to change is the information that consumers need us to change and that we do it in a way that provides greater simplicity and clarity, rather than more and different terms that people need to learn.

GERALD STEIN: So you referenced MarkeTrak a couple times, and I've gotten a couple of questions. Is that study available?

CAROLE ROGIN: Yes.

GERALD STEIN: I've gotten a couple questions as to whether it's publicly available and people can access it.

CAROLE ROGIN: It absolutely is. All of the historical MarkeTraks dating back to an initial survey in 1981 are available at betterhearing.org, BHI's website. And the review of the MarkeTrak IX findings—they are the most extensive review of those findings, is also available.

GERALD STEIN: OK. Thank you.

DANIEL WOOD: Carole, you said that people tend to find their health care professional by word of mouth. Are there other sources people use? Is the web now used extensively?

CAROLE ROGIN: It's interesting. We looked in MarkeTrak IX at what people do before they make that first visit to a hearing care professional. And we found that, interestingly enough, although people go to that first visit to learn—they go to learn and get tested—is what MarkeTrak tells us—they don't do a lot of investigation before that first visit. Only 35% of our survey respondents with hearing loss who don't own hearing aids say that they did any investigation before they had their first appointment. But of those 35%, 66% of them told us that they went first to the Internet.

So just for fun the other day, I've been kind of tracking it, and about two days ago, if you Google "hearing aids," there were close to 12 million entries on the Internet. I think that anyone who is looking for information uses that as a sign to be a little more discrete in what they're looking for. But I think that there is a lot of information out there for people to at least get started learning. And consumers, as Barbara said, are taking a wonderful, an increased responsibility for all of their health care. People know how to evaluate information. And I think that the more we can put out there, the more people are going to be looking.

If I can just provide a little bit of insight into consumer behavior from our statistics at betterhearing.org. We had in just this past year a 50% increase in the visitors to our site. Additionally, the time that they spent on this site increased almost 50%, and very importantly, the numbers of those visitors who used the BHI hearing check to see if they perhaps ought to get a professional evaluation also increased 50%, and what I would say is that the efforts of the National Academy of Sciences, NIDCD, FDA, today FTC, over the past three years, and all of the organizations who are in this room, have shed a very bright light on hearing health care that I think has been very beneficial to consumers.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: Yeah I would just add that when people go on the Internet, we need to look at the kind of information that's available. And there really isn't much out there that compares products, that gives them information about what kind of situation this product would be better than another, or quality of the products.

And when we know that most people are choosing that product based on their audiologist's recommendation—and audiologists, like Carole said, you know, they get information, just like the rest of the health care system—they get it from the manufacturers, you know, just like drug companies give doctors information about drugs. The manufacturers of hearing aids are probably the major source for providers in getting their information.

So it's not exactly unbiased, and we really need a more unbiased evaluation system of these products that people can use when they make their choices.

GERALD STEIN: Stephanie?

STEPHANIE CZUHAJEWSKI: I agree with that wholeheartedly. When looking for comparative analysis on the Internet for products and services, it's very difficult to find information that is not manufacturer driven or in some way biased. Hearing Tracker is a site that I know a lot of consumers do use, and we have found it to be reputable. It's managed by an audiologist.

I believe that he's got a policy where the provider and the manufacturer cannot basically buy their way into ratings on that particular list. I know there are probably others out there, but they are very difficult to find. And a lot of times the names of the sites are a little bit tricky. There are some that look a lot like Consumer Reports, that in fact are being—driving people to a particular segment of either the provider community or a particular type of hearing aid.

BARBARA KELLEY: We get that question all the time. They need help finding an audiologist. We often point them to Hearing Tracker, or we point them to one of our local chapters so they can talk to people in the chapter to find out who they've used. Some audiologists are listed on Yelp. But there really is no clear information on comparing features. We also get the question, what's the best hearing aid? And years ago, I tried to dig into that and do a real comparison of different hearing aids, and at the end I was really still confused with no clear answer, as well as created more consumer confusion.

GERALD STEIN: Well, I'm glad you said that because I'm an antitrust guy, and when I started looking at this industry, the one thing that piqued my curiosity is how do consumers compare for quality, and how do consumers compare based on price. It seems to me, from the outside—I mean, two months ago I knew nothing about this industry. But when I started looking at it, it seemed the only way that people or consumers could do this is to actually go to the audiologist, sit through an exam, be

given the choices, and either take those choices, or go through an entire new exam with someone else.

I was wondering if you guys can talk about that process? How do consumers choose? How do they make informed decisions? What do they do? Anyone? Carole ?

CAROLE ROGIN: They do exactly what they do, as I said before, with other medical conditions. I mean, if you need a hip replacement, how do you compare and contrast? You visit a couple of orthopedic surgeons. Our data indicates that people who purchase hearing aids visit at least two hearing care professionals before they make that purchase. You listen to the professionals that you go to. You ask them what brand of hip replacement they use. You look that up on the Internet. And I think that people with hearing loss who are looking for a comparative experience, have the opportunity, and in fact, do the same thing.

GERALD STEIN: But I guess a big difference in my mind would be the hip replacement might be covered under some insurance. And so if you're going in-network versus out-of-network, you can make that choice as a consumer, whereas you don't have that option for hearing aids.

CAROLE ROGIN: Absolutely. You know the cost issue is different, although influenced by—or influences the decision making. But I think when we're talking about the decision making, how do you decide which professional to visit, what kind of technology to explore, we have to recognize that, at least at the current time, this is a medical device addressing a medical condition.

And in fact, I think Stephanie mentioned this before, maybe Barbara as well, when we look at satisfaction rates for hearing aid owners and ask them what feeds into that, the single most important element of their satisfaction is their hearing care professional.

GERALD STEIN: KR, Did you want to jump in?

KR LIU: Yeah, I think recommendations also come from consumers talking to each other who are experiencing a similar issue, and their satisfaction with the product that they would recommend. Then they usually ask for a recommendation of their audiologist, and then get an opinion.

But I actually think more feedback comes from consumers themselves in talking to one another about what their experience has been with certain hearing aids, and if they're happy with it. And if it's providing them what their needs are.

So I think that's really important, that it is word of mouth network. We do all talk to each other, as far as what product we think might be beneficial when compared to the other.

GERALD STEIN: Steph?

STEPHANIE CZUHAJEWSKI: I think I would just add that finding good pricing comparisons is very difficult for consumers, and it's also very difficult for independent audiologists. So they struggle a great deal in trying to determine if they can negotiate basically a fair price from the manufacturing community.

And that has resulted actually in a lot of them joining various buying groups. And through the buying groups, some have had more success than others in being able to at least negotiate or look across some of the various brands in a more holistic way.

But it is very much a challenge. And it's something that I think will continue to be, unless or until we're able to sort of, maybe bring more competition in a marketplace that's transparent.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: I would just say that when we looked, when we asked for consumer satisfaction in our survey, we didn't find any significant difference between the brands, the makers of the hearing aids. But we did find some differences in the retailers.

And most of that difference was connected to the evaluations that the retailers provided, the discussions and options, the staff. And very much the service. That service part was what set a couple of the higher rated retailers apart from the rest of them.

DANIEL WOOD: Barbara?

BARBARA KELLEY: The service is critical, because you don't necessarily get information from the manufacturers about some very practical things, like telecoil use in large area systems. Everything is to Bluetooth, which is great, but there is some latency if you use that with speech reading and your residual hearing at the same time.

The other thing is you might not get a hearing aid compatible rating, because cell phones have to be hearing aid compatible. If I buy a hearing aid, I want to know if it's going to work with my cell phone.

But I do agree, I think that people who have the good care of a hearing health care professional, whether it's an audiologist, or a dispenser, or a hearing instrument specialist, and they get really good needs assessment, they are satisfied.

But they have to be able to afford that hearing aid in the first place. And there are so many more people who can't afford that good care. And they deserve it.

DANIEL WOOD: We've heard about high prices. Just to turn it around a little bit, in certain markets, if you pay more for something, it actually provides better quality. If I pay $50,000 for a car, I know I'm getting a different experience than if I paid $10,000. To what extent is price a useful signal of quality in hearing aid hardware?

STEPHANIE CZUHAJEWSKI: I would say that Dr. Johnson's presentation this morning did a really good job in covering some of that. So what we have found is that there is not necessarily a correlation in terms of high price and outcomes. And there is more and more data that's being made available at this point that does allow researchers at least to compare across, although that data is still limited.

DANIEL WOOD: How about pricing for audiological services?

STEPHANIE CZUHAJEWSKI: I think, again, there's a limited amount of data, but one can expect that in going to an audiologist that they—actually HLAA has a fantastic resource that consumers can download that gives them the information, minimally, that they should expect through that process. And it has some really good prompts about questions that they can ask along the way to ensure that they're sort of—that that service is meeting the expectations of the consumer community.

But there should be the expectation by the consumer that the more intense the services are, and the more complex the needs are, that those prices would be higher. I know there has been some recent work done by Dr. Brian Taylor, and I think Dr. Windmill did some work as well, in looking at how to segment consumer needs by complex cases versus simple cases and being able to price those accordingly.

I think as we look at the future and the potential of over-the-counter devices—and really, we're kind of late to the table even talking about over-the-counter, because probably you're going to be able to bring your own hardware potentially, and you're going to have some sort of a subscription. Or your hearing aid may just be ubiquitous basically. So at that point it's going to come all down to the provision of the high quality services. And I think we'll have to look at different mechanisms and different models than what we're using today to sort of put people into the appropriate categories for care.

DANIEL WOOD: Barbara?

BARBARA KELLEY: The higher end, more expensive hearing aids, probably do provide more features, but it comes down to then the care. Does a person really need all those features? And are they going to use them? And I think Dr. Lin wrote an article that talked about those premium features have been around for a long time in hearing aids, yet the cost hasn't come down. And I'm sorry if I misattributed him, but I think that's who wrote it.

So there hasn't been any price decrease like there has been in cell phones and other technologies that have disrupted the market. And really there's no way for a

consumer to really compare prices, because the manufacturer's customer is the audiologist and the hearing aid specialists, and then that person has bundled prices within there. So it's just really confusing to compare apples to apples.

DANIEL WOOD: OK. Well, shall we turn to bundling?

GERALD STEIN: Well, I just want to address a question that we got from the audience. And we touched earlier on the notion that basically the only way a consumer can comparison shop based on price is to go to an exam, get fitted, get a quote. And then go to another exam, get fitted, and get a quote.

The question here is, does the restocking fee, for those instances where a consumer might have to pay a restocking fee, is that going to inhibit the ability for consumers to comparison shop? So, in other words, it's going to cost now, in addition to time, it's going to cost out of pocket money for a consumer to go from one to another. Do you guys have any views on that?

STEPHANIE CZUHAJEWSKI: I think that that is potentially an issue. Certainly that varies by state. And not to throw HLAA out there too much again, but they have another fantastic resource that consumers can download that actually outlines state by state what those basically return fees are, if that should happen, and how much money the consumer can expect to get back in different states. So at least they have that going in.

But it can be a challenge if you have to go from provider to provider. There are some mechanisms online to get a ballpark. I think most audiologists, if you went in and could start talking about the range before you're ever fitted with a hearing aid, they're going to be able to provide you with some of that information so that you have a decent understanding of where you are before you would be in a position to have to pay that fitting fee or restocking fee.

DANIEL WOOD: So we've heard about this issue of bundling and al a carte prices, itemized prices versus bundled prices, in the delivery panel and other panels this morning. To what extent do you think consumers understand the pricing model and know what they're paying for when they purchase a hearing aid?

BARBARA KELLEY: I think very few consumers understand it. I think if you're really astute and know what questions to ask—but I think it's very confusing.

Some people like a bundled model. That's great. They don't want to ever think about paying another dime, and they want to go back as many times as they can for adjustments. But I think other people would like a situation for pay-as-you-go and have a choice in how they want to deal with their own hearing loss. But I think it's confusing.

LISA MCGIFFERT: Our survey showed that most people didn't go back for more than two visits. So it wasn't like they kept going back and going back. I think in the bundling situation, it probably does help the person who is really needy and needs to have a lot of adjustments and has problems adjusting.

But for most people, it's probably not. They probably don't get the full value of the bundle.

GERALD STEIN: Related to that question from the audience, is there a correlation between lower-cost hearing aids and an increased amount of having to go back for service? In other words, is the—lower end hearing aid, does it require more visits to get tuned? Is there any correlation between visits and the quality of the hearing aid?

CAROLE ROGIN: There is no correlation.

GERALD STEIN: We all agree on that? Wow, we have agreement.

LISA MCGIFFERT: So one of the issues that we're not really talking about is value. And you can't really get to value, unless you have price and quality. And the fact is that this market doesn't have much out there for quality.

And also there's not much diversity in the market in terms of quality and consumer satisfaction. So we really do need to have more competition to get to determining different values of these products.

DANIEL WOOD: So pricing is often, sometimes problematic. What other business practices are consumers confused by in this industry?

STEPHANIE CZUHAJEWSKI: I can speak from ADA's perspective, from the audiology perspective. To us it's all about transparency. So if the consumer is not aware that the practice is owned by a manufacturer and the employees there are employed by the manufacturer. If there are manufacturer loans perhaps, or agreements where the dispenser is going to buy a certain number of units from a manufacturer, and the consumer is not aware of that, and it may somehow lead to bias in terms of what products are recommended for a patient, that's problematic.

We've looked at things like commissions for audiologists. I mean, we're dispensing medical devices here. And so is it ethical to pay on commission for somebody who is dispensing a medical device like that? So things around sort of the incentivization, if you will, that might lead somebody to choose one product over a different product based on money that they may be getting.

DANIEL WOOD: Barbara?

BARBARA KELLEY: I think there are also some issues, I think, sometimes you might get a copy of your audiogram and sometimes you might not. Or if you buy your hearing aid in one state and you move to Florida, that program for adjusting your hearing aid might be locked with that certain manufacturer. So you'll either go to a new person to get it adjusted and they can't do it, or it's going to cost a lot, or you have to start with new hearing aids. That's a problem.

DANIEL WOOD: And consumers are not informed of this, this locking before, when they buy this device originally?

BARBARA KELLEY: I don't know. Stephanie?

STEPHANIE CZUHAJEWSKI: Very seldom does that happen. A lot of times it may be a franchise or a particular brand. At the point where they're dispensed the consumer is not notified that the device is locked in some way and then if they try to seek another provider, they can have some significant challenges.

GERALD STEIN: Even a provider that services this same brand hearing aid?

STEPHANIE CZUHAJEWSKI: Not typically, no. It really depends a lot of times, as I said, if it's a franchise type arrangement, they can go from provider to provider within a franchise, and they'd be able to do that. But oftentimes they are not informed at the point of purchase.

So again, it's about transparency. If the consumer knows going in that that's the expectation, and that's the way it will be, great. If they're not informed, that's really where the problems come in.

GERALD STEIN: So, is it a best practice of an audiologist when they're getting to know the patient and saying, well, how are you going to live in your daily life? Is it to ask an elderly person, well, do you spend six months in Florida and six months in New York? Is that a question they should ask?

STEPHANIE CZUHAJEWSKI: Audiologists conduct a comprehensive needs assessment most of the time. You know, if they're doing it the right way, they're doing this for every single patient. And yes, as part of that they are talking to them extensively about their lifestyle, their family support, things like their dexterity, cognitive abilities. What settings are they going to be using the hearing aid in? I mean, it's a very lengthy process actually, and yes, as part of that, the expectation would be that they would ask.

Oftentimes we get on our Listserv requests from audiologists for other audiologists in another state. So I have a patient that's in Florida six months out of a year, can you recommend an audiologist so that we can have a cohesive care plan for this patient.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: I'd like to interject some age issues here. Because I think—my experience getting a hearing aid before I was 50, was that everything was kind of targeted towards older people who were much older than I was. And I think a lot of the advertising, a lot of the drawing in of patients, a lot of paying attention to what people are experiencing, there is this layer of, oh, this is a product for elders.

And I think that one of the things that we found that I thought was pretty interesting, and I'm trying to find the stat—well, I'll find it—but a good number of the people we surveyed who said they had hearing loss were under the age of 39, so there are—And we all know, this is our environment, our world. there are a lot of young people who have lost hearing. This market—what I hear all the time is it's a small market, and the market's not very big. Well, that's because the market doesn't fit the needs of the people. And I think that that is a real problem that we're facing here and that needs to be addressed. I'll let KR talk about that.

KR LIU: Yes I would love to talk about that, Lisa. I agree with her. A lot of advertising that you see out there shows people who are older or retired, right? It doesn't resonate with the younger demographic. The younger demographic in their 20s and 30s now are experiencing hearing loss and are being more vocal about it.

They're also the ones that are helping their parents and their grandparents make the decision as to what hearing aids they should get, because they're the ones telling them, you can't hear me as well as you used to. You should do something about that. So we have a lot of influence in that decision making process.

We also are looking for products that speak to our generation, that fit our lifestyle. And we're a very large demographic. I consider our generation the iPod generation, where we're wearing earbuds in our ears that are 144Db for six hours a day, every day.

We're losing our hearing even sooner than we used to. And that's a large, large demographic. And the World Health Organization released a report that said 1.1 billion young adults are at risk of hearing loss. And I believe this generation wants to do something about it. But there's no marketing, no petitioning, and no part of that speaking to us, to have us address that issue, so we're just not. And I think that's a big issue and that's something that needs to change.

LISA MCGIFFERT: So 39% of our surveyed population were between the ages of 18 and 29 that reported having hearing loss. A lot.

DANIEL WOOD: I don't think we would be the FTC if we didn't ask at least a little bit about advertising. So in many markets, advertising does provide information. What sort of advertising goes on in this, in hearing health care, and who are the ads targeted to, and are they useful? Entertaining? Barbara?

BARBARA KELLEY: Well, we've seen ads that use scare tactics, especially where there are concentrations of older people. Because they'll take the link with cognitive and dementia with untreated hearing loss and they'll put it together. And they'll say things like, prevent dementia. Get a hearing aid. And using scare tactics like that. A tactic that I recently was very surprised at, is—I personally like WebMD. I use it as my medical go-to very often, before I go to the doctor.

And they had something on hearing loss and they made you go through a hearing test. Of course, I took it because I wanted to see what happened. And then at the end of the hearing test—I purposely failed it—I wanted to see what they would tell me to do. And it immediately went to a manufacturer of hearing aids. No choice, no nothing. It was one of the big six manufacturers.

DANIEL WOOD: KR?

KR LIU: Yes, I'd also like to say that the advertising and positioning is not very diverse either. It doesn't speak to many different cultural demographics. It seems to speak to an older, white demographic, which I think is really alarming, right? You have people in many different backgrounds that are looking for hearing assistance and there's no marketing or advertising or information speaking to that group. So that's something that we really need to change.

GERALD STEIN: There was an audience question related somewhat to that, that I wanted to address. And the question is, has anyone surveyed reasons why people in lower income brackets don't use hearing aids? I imagine one reason might be cost.

KR LIU: Cost, and also again, back to the diversity issue. I don't think it speaks to many different cultural backgrounds or lifestyle backgrounds and their positioning. So, it doesn't speak to them.

DANIEL WOOD: Barbara? And then I think will move on to—

BARBARA KELLEY: And I think the system is intimidating, to get into the health care system. And we saw a panel at the American Academy of Audiology that talked about taking PSAPs and pocket talkers into inner city Baltimore, into the poor African-American neighborhoods, and taking those devices in there, and the responses that they got from that. Very interesting.

GERALD STEIN: So let's switch gears a little bit, and there's been talk on several panels today regarding over-the-counter, OTC, hearing aids. Putting aside the merits of whether we think that's a good idea or a bad idea, let's just assume it's here, what we want to ask you guys is, what information do you feel should be available to consumers who purchase hearing devices over-the-counter? Carole, do you want to start?

CAROLE ROGIN: Sure. I think we had a good introduction to that from Dr. Mann earlier, who went through the two aspects of current regulation. I think everyone here knows that FDA regulation is about two things, safety and efficacy.

I think that the regulatory scheme has worked extremely well for people with hearing loss, for manufacturers who make the product, and for professionals who serve people with hearing loss, because compliance with those regulations that Dr. Mann outlined earlier, have led to virtually no reportable incidents of injury or damage to people from hearing aids. If Dr. Mann is still here, I'd ask him to confirm that.

But there are not problems. And I think that as we talk about a new category of hearing aids, over-the-counter hearing aids, we will best serve consumers if we regulate those products in the same way for safety and effectiveness that current hearing aids are regulated. I think, again, going back to my guidance to us that we simplify, not make more complex, any decision making that has to be had.

FDA regulation, even if consumers don't know what it is, provides a level of assurance of safety to people. And I think that any consumer communications that we start about over-the-counter hearing aids need to give people the assurance that

regulations are in place for both the safety and the effectiveness of any hearing aids that they buy.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: Consumer Reports tested some PSAPs, and we looked at five different products. Unfortunately, two of them were off the market by the time we went to print. And that's another story probably. But we did see some differences demonstrated in this market.

We looked at two very cheap products that over amplified sharp noises like sirens, and we didn't really recommend them. These were typically worse—these were less than $50. When we looked at them, we said, this can cause more harm.

We also looked at two others that we felt were worth trying, and they were each very different. One was able to—it was pretty good at watching TV and came right out of the box without adjustments.

And the other one had a more sophisticated model, with tweaking the settings and customizing with a smartphone.

I think the thing that we really learned was that there needs to be more comparative information when these products go on the market, and that information needs to come from unbiased sources. And I think that having that will be important in the future if this moves forward.

We also support having some standards for these products, so that people can see some distinguishing issues among the ones that may meet certain standards and those that don't.

DANIEL WOOD: Barbara?

BARBARA KELLEY: I echo the standards like Bill Belt was talking about, with the voluntary standards for PSAPs. Also we need very clear language at health literacy levels that—where everybody can understand. I mean, not written to the level that people in

this room can understand, but everybody can understand, and clear expectations and ways to compare products. And choice, ways to compare your choices.

GERALD STEIN: Steph?

STEPHANIE CZUHAJEWSKI: I will just disclose the ADA has been very supportive of the efforts to go forward with an OTC product. We do have a caveat with that. One of our caveats is that they be very specifically labeled. We'd like to see that label include a strong recommendation that the consumer seek an audiologic evaluation. We also want to make sure that the consumer has information about the technical aspects of the device and the amount of gain, the expectations for how it will function, things of that nature.

DANIEL WOOD: Before we move on from over-the-counter, just to refocus the question a little bit, does anybody else want to tell us what consumers might need to know to purchase over-the-counter devices that will suit them well? Stephanie?

STEPHANIE CZUHAJEWSKI: I do have one additional comment. State by state laws vary widely about return policies as it relates to hearing aids today. This is going to be something that could be particularly problematic in the delivery process for these types of devices going forward. So it's going to be important that consumers have a good understanding on the front end of what their rights and responsibilities are as they take these products and in terms of returns. And it may be something down the line that we look at standardizing.

GERALD STEIN: So we touched a little bit during this panel and others about technology and stigma. And we wanted to just explore that a little more. And what we want to understand from your guys' perspective is, what are the views towards hearing aids? Have they changed over time? KR mentioned the iPod generation. And it's funny because I was walking around—I got turned around. I got lost and I wanted to ask people direction. I had to wait till like four people passed, because everyone had the earbuds in. It's amazing how many people walk around with things in their ears.

So has this stigma changed? Or do you see anything that can be done to destigmatize hearing aids?

KR LIU: Great question. As someone whose worn hearing aids for over 35 years, no. I would say the stigma has not changed. I can tell you from experience, in talking to many people who don't really identify with having hearing loss, but know they have hearing issues—just the stigma is still a really big barrier to entry and addressing their hearing issues. And I think that's partially because the technology perpetuates that. Invisibility is not the answer to solving stigma issues, whatsoever. People should be—

GERALD STEIN: So in other words, making a cooler looking hearing aid is not—

KR LIU: Making something that's more visible, more socially acceptable, more affordable—and with technology companies wanting to explore this area, companies like Apple and Panasonic and Bose, and others, there is a brand affinity and social acceptance with those brands. So I really believe that hearing technology and the hearing industry and consumer electronics companies can live hand-in-hand.

And they've already started doing that over the last few years, especially when you look at made for iPhone hearing aids. Apple partnering with other hearing aid manufacturers. People see Apple, and they trust that brand and they think that's cool, and it gets them looking into that type of technology.

But I think this whole issue is as much a social innovation issue as it is a technology and innovation issue. We have to change the conversation and what it means to have hearing issues. And I think more options to the consumer, more awareness on the issue, is going to change that conversation, which gets more people addressing the issue sooner. And I think that's really important here.

Not many people talk about stigma today, but that is one of the biggest reasons people don't get help, that they don't want to admit that they have an issue—makes them think they're getting older, makes them think they're not fitting in in certain social situations, so they isolate themselves and they just don't address it until it becomes a really big problem. And that's not just older people, that's younger people as well.

And cost also is a barrier to entry. So I think that's something that we really need to think about here, is that we have to give more options to consumers that not only are affordable, but are socially accepted, so that we start changing the conversation around hearing loss.

GERALD STEIN: Steph?

STEPHANIE CZUHAJEWSKI: I think, with that, as well, we have to give the consumer more ownership of hearing, not hearing loss, but prevention of hearing loss. I think we've done a fantastic job with optometry and dentistry and a lot of other health care fields, but not a very good job in audiology, in giving the patient ownership from the beginning, of optimizing their hearing over a lifetime.

And with that comes regular visits to your audiologist. With that comes the notion that you're going to pay for the services that the audiologist provides to you and that those are going to be decoupled from the device. So that there isn't this perception that it's this one-size-fits-all model. The one-size-fits-all model has been fitting exactly 25% of the population, leaving 75% out.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: Yeah, I totally agree with that. And I think that we need more public service type advertising or announcements about how hearing is degraded, and the things that people do that cause a problem, to sort of promote good hearing practices.

And it needs to be targeted at a younger population and not an older population. And it needs to be worked into our culture. I live in Austin, Texas, so I go to listen to a lot of music. And sometimes it's so loud that I have to leave. It's physically affecting me. And there are lots of young people up front, and a lot of them aren't protecting their ears.

And I think that there needs to be—we need to create a stigma for that. You know, we need to create that as unnecessary. And really help people understand what it is, how this is going to play out in the not too distant future for those consumers.

GERALD STEIN: Barbara?

BARBARA KELLEY: There are also times when people might not always need a hearing aid, but they have a hearing loss. And they might want—I talked about this earlier—some enhanced hearing. And you walk around that consumer electronics show, and you're faced with intelligent earbuds buds, where you have an app and you decrease the background noise and raise the volume.

And I know people who have a hearing loss, but they don't necessarily want to be treated with the traditional hearing aid, but they would go for this type of product when they need it. So I think there are all those kind of people that could be reached as well, and then probably would end up at the audiologist eventually with a traditional high tech hearing aid with telecoils and Bluetooth, and all of that.

GERALD STEIN: KR?

KR LIU: Yeah, I agree with what Barbara said. There are a lot of people who have trouble hearing in restaurants, or they work in an open office. It's very situational based. Where if they had technology that was available over the counter for those situations, to see if they helped them, that also might make them realize that they need to take that next step as to, wow, this is helping me in this situation, maybe I need to address it even more so and go see an audiologist. It's actually a tool to get them to address the issue.

Because not everyone needs it in every situation. Sometimes it's just in certain loud situations where they're trying to have a conversation. There is technology that could really benefit them.

STEPHANIE CZUHAJEWSKI: And the audiologist should be at the forefront of delivering this technology to the consumer. The audiologist, by and large, advances as

the technology advances, so changing that paradigm of what the services and products that you deliver to your patients are, so, in such a way, that you would have OTC devices. You would have all of these assisted listening devices in your practice that the consumer can come in, sample, and then when it's time for that care to be advanced to a different level, they know exactly where to go.

GERALD STEIN: Is there a relationship between—In selecting a hearing device, will a patient forego a better device for a less visible device? How does it work as far as when it comes time for the patient to select the device? Are they looking for something that they can't be seen or something that works best, if those things are mutually exclusive? KR?

KR LIU: I think it depends on who's making it, to be very honest. The consumers, everyone has an emotional attachment to brands and how things reflect who they are. I think it's really important on thinking about who is that product for and does it fit them? I think it's the consumer that will drive that decision.

So the more options that are out there and available, more mainstream brands that consumers resonate with, absolutely they would wear something more visible as opposed to hidden.

DANIEL WOOD: Carole?

CAROLE ROGIN: It's interesting to note that in about the past 10 years the style of hearing aids that consumers select has absolutely reversed itself. When in the late 1970s we were first able to make comfortable, attractive, in-the-ear hearing aids, it was a time at which visibility was an issue. And people flocked to in-the-ear hearing aids. They, at that point in time, although it's different now, did not have the same power as behind-the-ear hearing aids, but there was a desire to have what was viewed as a cosmetically desirable hearing aid.

Then President Reagan actually made that point to America. And if we could bring somebody back who encouraged people to get hearing aids to the degree that he did, we'd be having a very different conversation today.

But with the creation of what we call receiver in the canal instruments, which are behind-the-ear instruments where the microphone and receiver are down in the ear canal and provide a whole array of benefits, starting with technological benefits and reduction of things like wind noise and a whole host of things to comfort factors. We have seen a complete reversal from in the late '80s, early '90s, 80% of the hearing aids that people purchased in the United States being in-the-ear hearing aids, to today where 80% of the hearing aids that people purchase are behind-the-ear hearing aids. So I think people—consumers are smart. They're thoughtful. I think they are getting excellent professional services today that enable them to try out technology, to learn about it from their hearing care professionals. And I think that they are making the decision obviously more on the basis of performance than style.

DANIEL WOOD: KR?

KR LIU: As someone who has worn hearing aids for 35 years and wore hearing aids in the '80s and was bullied and picked on for many years, of course hearing aids will get more and more visible to hopefully help that problem. And technology has come so far and is so innovative that it's something that people are OK with wearing visibly, like Apple AirPods for example, who don't mind that because it's socially acceptable. And invisibility is not socially acceptable, it's just hiding the problem, right?

So over the years, "hearing aid", unfortunately has a very high stigma to the word, even. So to fix that problem they went to making invisible, instead of changing the aesthetic or partnering with brands that have more social acceptance and innovating that way. We're now seeing that now.

So I think that that's a little misleading. Yes, it's gotten more invisible and more technology savvy, but that's not the answer.

DANIEL WOOD: Should we go to the CTAs then?

GERALD STEIN: Sure. So with the remaining time, the prior panel had discussed the CTA standards for PSAPs, and we thought we would just ask from the consumer's

perspective, do the CTA standards provide information about PSAP quality that may help consumers obtain useful information?

KR LIU: So the Consumer Technology Association formed the PSAP quality standards committee to provide consumers with what would be called like a Good Housekeeping Seal of Approval for personal sound amplifiers that would meet the requirements of the standards. So it would give consumers trust in what they're buying is a good high quality product, much like when you go and buy a product that has a made for iPhone or a made for iPod logo on it, you're trusting that Apple has put their seal of approval on that product, and they think it's a good product.

So I think that standard would enable consumers to trust the seal of what they're buying and identify good products.

GERALD STEIN: OK. Steph?

STEPHANIE CZUHAJEWSKI: ADA has not had the opportunity to review the standards, so we don't have a comment. I just wanted to make it clear why we were not commenting.

GERALD STEIN: Lisa?

LISA MCGIFFERT: I have not reviewed the standards either but agree that standards do provide something for consumers to connect with. And I've followed the FDA for a long time, and it often takes a long time for the FDA to come up with standards. So I think what I've heard today is that this market is moving forward pretty quickly, and it might take a while for the regulators to catch up. So having some kind of standard out there to look at is probably a good idea, at least to get started.

CAROLE ROGIN: I would just observe that the FDA does have an excellent set of standards out there, and rather than, as CTA has done, relying on the manufacturers to regulate themselves, I think that we would be serving people with hearing loss well if we relied on the standards that the FDA has developed with scientists and engineers and

that have been proven over the years to provide safe and effective hearing aids to people with hearing loss.

GERALD STEIN: Barbara, you get the final word.

BARBARA KELLEY: Oh, thank you. I'd just like to go back to the National Academy of Sciences' engineering and medicine report, that says hearing loss is a primary health concern. And 85% of people who could benefit from hearing aids don't wear them. And hearing loss has been linked with co-morbidities, and that's the group that we have to worry about.

Those people need treatment. And I know that Mr. Cleland from the FTC said that it's really a nightmare regulating 500 devices and whatever, but from the consumer, I really don't care. I just want more. I want more choice for people, affordable choice. And people have to get treated for hearing loss.

Getting hearing aids just should not be for wealthy people. It should be for everybody. We all deserve to hear well.

GERALD STEIN: OK. Thank you very much.

[APPLAUSE]

CLOSING REMARKS

- **Daniel J. Gilman, Attorney Advisor, Office of Policy Planning, Federal Trade Commission**

DANIEL GILMAN: I want to thank the panel and all the panelists throughout the day, and the speakers, and participants. I have a couple of brief remarks—I promise they'll be brief—at the end of the day.

First, I'm asked to cover some administrative details. Number one, those of you who have telecoil headsets, please be sure to drop them back on the table where you got them.

Number two, those visiting the Commission, if you received a lanyard with a plastic FTC event security badge, please drop your lanyards with the guards at the front.

And, number three, if you could please take all the trash that you might have with you and throw it in the bins outside the auditorium, that would be great.

Also, a couple of thanks—I want to start with just three. We say there are too many people to name, but the three people I want to single out who have not been up here at the lectern or at the table who've been key—Liz Callison, from our Bureau of Economics has been part of the team planning this event, doing the research behind the scenes—very valuable; Chris Bryan, also from OPP, has been a terrific asset; and Jonathan Aid, a paralegal assisting us from the Bureau of Consumer Protection, has been very helpful. I did at least want to mention them.

Also—just all the staff who have been involved here. This has been a great collaboration between our Office, OPP, and the Bureau of Economics, and then, of course, having Gerald here come help us from our Northeast Regional office in New York has been terrific on a Bureau of Competition perspective.

I want to return to, very briefly, to a point Tara made at the beginning. This is an ongoing inquiry. And, in particular, we are receiving public comments through the website, through May 18th—a month from now.

So, we're going to review the transcript, input from participants, input from the public, and we hope that you'll share more information with us as we continue to think about these issues.

Thanks very much to all of you for sticking with us throughout the day, and again to our participants for their input. Thank you.

[APPLAUSE]

[END OF WORKSHOP]