

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

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[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 conker 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]