PANEL 2: INNOVATIONS IN HEARING HEALTH DELIVERY

Panelists:

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

Moderators:

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

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

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

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

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

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

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

And Gary Swearingen, Corporate Counsel for Costco Wholesale.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

KIM CAVITT: Having the space to care.

SCOTT DAVIS: Yes

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[LUNCH BREAK]